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114TH CONGRESS
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HOUSE OF REPRESENTATIVES

REPT. 114–190
Part 1

21ST CENTURY CURES ACT

R E P O R T

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

[TO ACCOMPANY H.R. 6]

JULY 7, 2015.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. UPTON, from the Committee on Energy and Commerce, submitted the following

REPORT

[To accompany H.R. 6]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 6) to accelerate the discovery, development, and delivery of 21st century cures, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

95–371

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "21st Century Cures Act".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—DISCOVERY

Subtitle A—National Institutes of Health Funding

Sec. 1001. National Institutes of Health reauthorization.
Sec. 1002. NIH Innovation Fund.

Subtitle B—National Institutes of Health Planning and Administration

Sec. 1021. NIH research strategic plan.
Sec. 1022. Increasing accountability at the National Institutes of Health.
Sec. 1023. Reducing administrative burdens of researchers.
Sec. 1024. Exemption for the National Institutes of Health from the Paperwork Reduction Act requirements.
Sec. 1025. NIH travel.
Sec. 1026. Other transactions authority.
Sec. 1027. NCATS phase IIB restriction.
Sec. 1028. High-risk, high-reward research.
Sec. 1029. Sense of Congress on increased inclusion of underrepresented communities in clinical trials.

Subtitle C—Supporting Young Emerging Scientists

Sec. 1041. Improvement of loan repayment programs of the National Institutes of Health.
Sec. 1042. Report.

Subtitle D—Capstone Grant Program

Sec. 1061. Capstone award.

Subtitle E—Promoting Pediatric Research Through the National Institutes of Health

Sec. 1081. National pediatric research network.
Sec. 1082. Global pediatric clinical study network sense of Congress.
Sec. 1083. Appropriate age groupings in clinical research.

Subtitle F—Advancement of the National Institutes of Health Research and Data Access

Sec. 1101. Sharing of data generated through NIH-funded research.
Sec. 1102. Standardization of data in Clinical Trial Registry Data Bank on eligibility for clinical trials.

Subtitle G—Facilitating Collaborative Research

Sec. 1121. Clinical trial data system.
Sec. 1122. National neurological diseases surveillance system.
Sec. 1123. Data on natural history of diseases.
Sec. 1124. Accessing, sharing, and using health data for research purposes.

Subtitle H—Council for 21st Century Cures

Sec. 1141. Council for 21st Century Cures.

TITLE II—DEVELOPMENT

Subtitle A—Patient-Focused Drug Development

Sec. 2001. Development and use of patient experience data to enhance structured risk-benefit assessment framework.

Subtitle B—Qualification and Use of Drug Development Tools

Sec. 2021. Qualification of drug development tools.
Sec. 2022. Accelerated approval development plan.

Subtitle C—FDA Advancement of Precision Medicine

Sec. 2041. Precision medicine guidance and other programs of Food and Drug Administration.

Subtitle D—Modern Trial Design and Evidence Development

Sec. 2061. Broader application of Bayesian statistics and adaptive trial designs.
Sec. 2062. Utilizing evidence from clinical experience.
Sec. 2063. Streamlined data review program.

Subtitle E—Expediting Patient Access

Sec. 2081. Sense of Congress.
Sec. 2082. Expanded access policy.
Sec. 2083. Finalizing draft guidance on expanded access.

Subtitle F—Facilitating Responsible Manufacturer Communications

Sec. 2101. Facilitating dissemination of health care economic information.
Sec. 2102. Facilitating responsible communication of scientific and medical developments.

Subtitle G—Antibiotic Drug Development

Sec. 2121. Approval of certain drugs for use in a limited population of patients.
Sec. 2122. Susceptibility test interpretive criteria for microorganisms.
Sec. 2123. Encouraging the development and use of new antimicrobial drugs.

Subtitle H—Vaccine Access, Certainty, and Innovation

Sec. 2141. Timely review of vaccines by the Advisory Committee on Immunization Practices.

Sec. 2142. Review of processes and consistency of ACIP recommendations.
Sec. 2143. Meetings between CDC and vaccine developers.

Subtitle I—Orphan Product Extensions Now; Incentives for Certain Products for Limited Populations

Sec. 2151. Extension of exclusivity periods for a drug approved for a new indication for a rare disease or condition.
Sec. 2152. Reauthorization of rare pediatric disease priority review voucher incentive program.

Subtitle J—Domestic Manufacturing and Export Efficiencies

Sec. 2161. Grants for studying the process of continuous drug manufacturing.
Sec. 2162. Re-exportation among members of the European Economic Area.

Subtitle K—Enhancing Combination Products Review

Sec. 2181. Enhancing combination products review.

Subtitle L—Priority Review for Breakthrough Devices

Sec. 2201. Priority review for breakthrough devices.

Subtitle M—Medical Device Regulatory Process Improvements

Sec. 2221. Third-party quality system assessment.
Sec. 2222. Valid scientific evidence.
Sec. 2223. Training and oversight in least burdensome appropriate means concept.
Sec. 2224. Recognition of standards.
Sec. 2225. Easing regulatory burden with respect to certain class I and class II devices.
Sec. 2226. Advisory committee process.
Sec. 2227. Humanitarian device exemption application.
Sec. 2228. CLIA waiver study design guidance for in vitro diagnostics.

Subtitle N—Sensible Oversight for Technology Which Advances Regulatory Efficiency

Sec. 2241. Health software.
Sec. 2242. Applicability and inapplicability of regulation.
Sec. 2243. Exclusion from definition of device.

Subtitle O—Streamlining Clinical Trials

Sec. 2261. Protection of human subjects in research; applicability of rules.
Sec. 2262. Use of non-local institutional review boards for review of investigational device exemptions and human device exemptions.
Sec. 2263. Alteration or waiver of informed consent for clinical investigations.

Subtitle P—Improving Scientific Expertise and Outreach at FDA

Sec. 2281. Silvio O. Conte Senior Biomedical Research Service.
Sec. 2282. Enabling FDA scientific engagement.
Sec. 2283. Reagan-Udall Foundation for the Food and Drug Administration.
Sec. 2284. Collection of certain voluntary information exempted from Paperwork Reduction Act.
Sec. 2285. Hiring authority for scientific, technical, and professional personnel.

Subtitle Q—Exempting From Sequestration Certain User Fees

Sec. 2301. Exempting from sequestration certain user fees of Food and Drug Administration.

TITLE III—DELIVERY

Subtitle A—Interoperability

Sec. 3001. Ensuring interoperability of health information technology.

Subtitle B—Telehealth

Sec. 3021. Telehealth services under the Medicare program.

Subtitle C—Encouraging Continuing Medical Education for Physicians

Sec. 3041. Exempting from manufacturer transparency reporting certain transfers used for educational purposes.

Subtitle D—Disposable Medical Technologies

Sec. 3061. Treatment of certain items and devices.

Subtitle E—Local Coverage Decision Reforms

Sec. 3081. Improvements in the Medicare local coverage determination (LCD) process.

Subtitle F—Medicare Pharmaceutical and Technology Ombudsman

Sec. 3101. Medicare pharmaceutical and technology ombudsman.

Subtitle G—Medicare Site-of-Service Price Transparency

Sec. 3121. Medicare site-of-Service price transparency.

Subtitle H—Medicare Part D Patient Safety and Drug Abuse Prevention

Sec. 3141. Programs to prevent prescription drug abuse under Medicare parts C and D.

TITLE IV—MEDICAID, MEDICARE, AND OTHER REFORMS

Subtitle A—Medicaid and Medicare Reforms

Sec. 4001. Limiting Federal Medicaid reimbursement to States for durable medical equipment (DME) to Medicare payment rates.

Sec. 4002. Medicare payment incentive for the transition from traditional x-ray imaging to digital radiography and other Medicare imaging payment provision.
Sec. 4003. Implementation of Office of Inspector General recommendation to delay certain Medicare prescription drug plan prepayments.

Subtitle B—Cures Innovation Fund

Sec. 4041. Cures Innovation Fund.

Subtitle C—Other Reforms

Sec. 4061. SPR drawdown.

Subtitle D—Miscellaneous

Sec. 4081. Lyme disease and other tick-borne diseases.

TITLE I—DISCOVERY

Subtitle A—National Institutes of Health Funding

SEC. 1001. NATIONAL INSTITUTES OF HEALTH REAUTHORIZATION.

Section 402A(a)(1) of the Public Health Service Act (42 U.S.C. 282a(a)(1)) is amended—

(1) in subparagraph (B), by striking at the end "and";

(2) in subparagraph (C), by striking at the end the period and inserting a semicolon; and

(3) by adding at the end the following new subparagraphs:

"(D) $31,811,000,000 for fiscal year 2016;

"(E) $33,331,000,000 for fiscal year 2017; and

"(F) $34,851,000,000 for fiscal year 2018.".

SEC. 1002. NIH INNOVATION FUND.

(a) USE OF INNOVATION FUND.—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) in paragraph (23), by striking at the end "and";

(2) in paragraph (24), by striking at the end the period and inserting "; and"; and

(3) by inserting after paragraph (24), the following new paragraph:

"(25) shall, with respect to funds appropriated under section 402A(e) to the NIH Innovation Fund, allocate such funds to the national research institutes and national centers for conducting and supporting innovation fund initiatives identified under paragraph (3) of such section.".

(b) ESTABLISHMENT OF INNOVATION FUND.—Section 402A of the Public Health Service Act (42 U.S.C. 282a)is amended—

(1) by redesignating subsection (e) as subsection (f); and

(2) by inserting after subsection (d) the following new subsection:

"(e) NIH INNOVATION FUND.—

"(1) ESTABLISHMENT.—For the purpose of allocations under section 402(b)(25), there is established a fund to be known as the NIH Innovation Fund. The Director of NIH shall, with respect to funds appropriated to the NIH Innovation Fund, allocate such funds to support biomedical research through the funding of basic, translational, and clinical research.

"(2) AMOUNTS MADE AVAILABLE TO FUND.—

"(A) IN GENERAL.—Subject to subparagraph (B), there is authorized to be appropriated, and appropriated, to the NIH Innovation Fund out of any funds in the Treasury not otherwise appropriated, $2,000,000,000 for each of fiscal years 2016 through 2020. The amounts appropriated to the Fund by the preceding sentence shall be in addition to any amounts otherwise made available to the National Institutes of Health.

"(B) AVAILABILITY SUBJECT TO APPROPRIATIONS.—Amounts in the Fund shall not be available except to the extent and in such amounts as are provided in advance in appropriation Acts.

"(C) ALLOCATION OF AMOUNTS.—Of the amounts made available from the NIH Innovation Fund for allocations under section 402(b)(25) for a fiscal year—

"(i) not less than $500,000,000 shall be for the Accelerating Advancement Program under paragraph (5);

"(ii) not less than 35 percent of such amounts remaining after subtracting the allocation for the Accelerating Advancement Program shall be for early stage investigators (as defined in paragraph (7));

"(iii) not less than 20 percent of such amounts remaining after subtracting the allocation for the Accelerating Advancement Program shall be for high-risk, high-reward research under section 409K; and

"(iv) not more than 10 percent of such amounts (without subtracting the allocation for the Accelerating Advancement Program) shall be for intramural research.

"(D) INAPPLICABILITY OF CERTAIN PROVISIONS.—Amounts in the NIH Innovation Fund shall not be subject to—

"(i) any transfer authority of the Secretary or the Director of NIH under section 241, subsection (c), subsection (d), or any other provision of law (other than section 402(b)(25) and this subsection); or

"(ii) the Nonrecurring expenses fund under section 223 of division G of the Consolidated Appropriations Act, 2008 (42 U.S.C. 3514a).

"(3) AUTHORIZED USES.—Amounts in the NIH Innovation Fund established under paragraph (1) may be used only to conduct or support innovative biomedical research through the following:

"(A) Research in which—

"(i) a principal investigator has a specific project or specific objectives; and

"(ii) funding is tied to pursuit of such project or objectives.

"(B) Research in which—

"(i) a principal investigator has shown promise in biomedical research; and

"(ii) funding is not tied to a specific project or specific objectives.

"(C) Research to be carried out by an early stage investigator (as defined in paragraph (7)).

"(D) Research to be carried out by a small business concern (as defined in section 3 of the Small Business Act).

"(E) The Accelerating Advancement Program under paragraph (5).

"(F) Development and implementation of the strategic plan under paragraph (6).

"(4) COORDINATION.—In funding programs and activities through the NIH Innovation Fund, the Secretary, acting through the Director of NIH, shall—

"(A) ensure coordination among the national research institutes, the national centers, and other departments, agencies, and offices of the Federal Government; and

"(B) minimize unnecessary duplication.

"(5) ACCELERATING ADVANCEMENT PROGRAM.—The Director of NIH shall establish a program, to be known as the Accelerating Advancement Program, under which—

"(A) the Director of NIH partners with national research institutes and national centers to accomplish important biomedical research objectives; and

"(B) for every $1 made available by the Director of NIH to a national research institute or national center for a research project, the institute or center makes $1 available for such project from funds that are not derived from the NIH Innovation Fund.

"(6) STRATEGIC PLAN.—

"(A) IN GENERAL.—The Director of NIH shall ensure that scientifically based strategic planning is implemented in support of research priorities, including through development, use, and updating of a research strategic plan that—

"(i) is designed to increase the efficient and effective focus of biomedical research in a manner that leverages the best scientific opportunities through a deliberative planning process;

"(ii) identifies areas, to be known as strategic focus areas, in which the resources of the NIH Innovation Fund can contribute to the goals of expanding knowledge to address, and find more effective treatments for, unmet medical needs in the United States, including the areas of—

"(I) biomarkers;

"(II) precision medicine;

"(III) infectious diseases, including pathogens listed as a qualifying pathogen under section 505E(f) of the Federal Food, Drug, and Cosmetic Act or listed or designated as a tropical disease under section 524 of such Act; and

"(IV) antibiotics;

"(iii) includes objectives for each such strategic focus area; and

"(iv) ensures that basic research remains a priority.

"(B) UPDATES AND REVIEWS.—The Director shall review and, as appropriate, update the research strategic plan under subparagraph (A) not less than every 18 months.

"(7) DEFINITION.—In this subsection, the term 'early stage investigator' means an investigator who—

"(A) will be the principal investigator or the program director of the proposed research;

"(B) has never been awarded, or has been awarded only once, a substantial, competing grant by the National Institutes of Health for independent research; and

"(C) is within 10 years of having completed—

"(i) the investigator's terminal degree; or

"(ii) a medical residency (or the equivalent).".

(c) SUPPLEMENT, NOT SUPPLANT; PROHIBITION AGAINST TRANSFER.—Funds appropriated pursuant to section 402A(e) of the Public Health Service Act, as inserted by subsection (b)—

(1) shall be used to supplement, not supplant, the funds otherwise allocated by the National Institutes of Health for biomedical research; and

(2) notwithstanding any transfer authority in any appropriation Act, shall not be used for any purpose other than allocating funds for conducting and supporting innovation fund initiatives as described in section 402(b)(25) of the Public Health Service Act, as added by subsection (a).

Subtitle B—National Institutes of Health Planning and Administration

SEC. 1021. NIH RESEARCH STRATEGIC PLAN.

Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) in subsection (b), by amending paragraph (5) to read as follows:

"(5) shall ensure that scientifically based strategic planning is implemented in support of research priorities as determined by the agencies of the National Institutes of Health, including through development, use, and updating of the research strategic plan under subsection (m);"; and

(2) by adding at the end the following:

"(m) RESEARCH STRATEGIC PLAN.—

"(1) FIVE-YEAR PLANS FOR BIOMEDICAL RESEARCH STRATEGY.—

"(A) IN GENERAL.—For each successive five-year period beginning with the period of fiscal years 2016 through 2020, the Director of NIH, in consultation with the entities described in subparagraph (B), shall develop and maintain a biomedical research strategic plan that—

"(i) is designed to increase the efficient and effective focus of biomedical research in a manner that leverages the best scientific opportunities through a deliberative planning process;

"(ii) identifies areas, to be known as strategic focus areas, in which the resources of the National Institutes of Health can best contribute to the goal of expanding knowledge on human health in the United States through biomedical research; and

"(iii) includes objectives for each such strategic focus area.

"(B) ENTITIES DESCRIBED.—The entities described in this subparagraph are the directors of the national research institutes and national centers, researchers, patient advocacy groups, and industry leaders.

"(2) USE OF PLAN.—The Director of NIH and the directors of the national research institutes and national centers shall use the strategic plan—

"(A) to identify research opportunities; and

"(B) to develop individual strategic plans for the research activities of each of the national research institutes and national centers that—

"(i) have a common template; and

"(ii) identify strategic focus areas in which the resources of the national research institutes and national centers can best contribute to the goal of expanding knowledge on human health in the United States through biomedical research.

"(3) CONTENTS OF PLANS.—

"(A) STRATEGIC FOCUS AREAS.—The strategic focus areas identified pursuant to paragraph (1)(A)(ii) shall—

"(i) be identified in a manner that—

"(I) considers the return on investment to the United States public through the investments of the National Institutes of Health in biomedical research; and

"(II) contributes to expanding knowledge to improve the United States public's health through biomedical research; and

"(ii) include overarching and trans-National Institutes of Health strategic focus areas, to be known as Mission Priority Focus Areas, which best serve the goals of preventing or eliminating the burden of a disease or condition and scientifically merit enhanced and focused research over the next 5 years.

"(B) RARE AND PEDIATRIC DISEASES AND CONDITIONS.—In developing and maintaining a strategic plan under this subsection, the Director of NIH shall ensure that rare and pediatric diseases and conditions remain a priority.

"(C) WORKFORCE.—In developing and maintaining a strategic plan under this subsection, the Director of NIH shall ensure that maintaining the biomedical workforce of the future, including the participation by scientists from groups traditionally underrepresented in the scientific workforce, remains a priority.

"(4) INITIAL PLAN.—Not later than 270 days after the date of enactment of this subsection, the Director of NIH and the directors of the national research institutes and national centers shall—

"(A) complete the initial strategic plan required by paragraphs (1) and (2); and

"(B) make such initial strategic plan publicly available on the website of the National Institutes of Health.

"(5) REVIEW; UPDATES.—

"(A) PROGRESS REVIEWS.—Not less than annually, the Director of NIH, in consultation with the directors of the national research institutes and national centers, shall conduct progress reviews for each strategic focus area identified under paragraph (1)(A)(ii).

"(B) UPDATES.—Not later than the end of the 5-year period covered by the initial strategic plan under this subsection, and every 5 years thereafter, the Director of NIH, in consultation with the directors of the national research institutes and national centers, stakeholders in the scientific field, advocates, and the public at large, shall—

"(i) conduct a review of the plan, including each strategic focus area identified under paragraph (2)(B); and

"(ii) update such plan in accordance with this section.".

SEC. 1022. INCREASING ACCOUNTABILITY AT THE NATIONAL INSTITUTES OF HEALTH.

(a) APPOINTMENT AND TERMS OF DIRECTORS OF NATIONAL RESEARCH INSTITUTES AND NATIONAL CENTERS.—Subsection (a) of section 405 of the Public Health Service Act (42 U.S.C. 284) is amended to read as follows: "(a) APPOINTMENT; TERMS.—

"(1) APPOINTMENT.—The Director of the National Cancer Institute shall be appointed by the President and the directors of the other national research institutes, as well as the directors of the national centers, shall be appointed by the Director of NIH. The directors of the national research institutes, as well as national centers, shall report directly to the Director of NIH.

"(2) TERMS.—

"(A) IN GENERAL.—The term of office of a director of a national research institute or national center shall be 5 years.

"(B) REMOVAL.—The director of a national research institute or national center may be removed from office by the Director of NIH prior to the expiration of such director's 5-year term.

"(C) REAPPOINTMENT.—At the end of the term of a director of a national research institute or national center, the director may be reappointed. There is no limit on the number of terms a director may serve.

"(D) VACANCIES.—If the office of a director of a national research institute or national center becomes vacant before the end of such director's term, the director appointed to fill the vacancy shall be appointed for a 5-year term starting on the date of such appointment.

"(E) TRANSITIONAL PROVISION.—Each director of a national research institute or national center serving on the date of enactment of the 21st Century Cures Act is deemed to be appointed for a 5-year term under this subsection starting on such date of enactment.".

(b) COMPENSATION TO CONSULTANTS OR INDIVIDUAL SCIENTISTS.—Section 202 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1993 (Public Law 102–394; 42 U.S.C. 238f note) is

amended by striking "portable structures;" and all that follows and inserting "portable structures.".

(c) REVIEW OF CERTAIN AWARDS BY DIRECTORS.—Section 405(b) of the Public Health Service Act (42 U.S.C. 284(b)) is amended by adding at the end the following:

"(3) Before an award is made by a national research institute or by a national center for a grant for a research program or project (commonly referred to as an 'R-series grant'), other than an award constituting a noncompeting renewal of such grant, or a noncompeting administrative supplement to such grant, the director of such national research institute or national center—

"(A) shall review and approve the award; and

"(B) shall take into consideration—

"(i) the mission of the national research institute or national center and the scientific priorities identified in the strategic plan under section 402(m); and

"(ii) whether other agencies are funding programs or projects to accomplish the same goal.".

(d) IOM STUDY ON DUPLICATION IN FEDERAL BIOMEDICAL RESEARCH.—The Secretary of Health and Human Services shall enter into an arrangement with the Institute of Medicine of the National Academies (or, if the Institute declines, another appropriate entity) under which the Institute (or other appropriate entity) not later than 2 years after the date of enactment of this Act will—

(1) complete a study on the extent to which biomedical research conducted or supported by Federal agencies is duplicative; and

(2) submit a report to the Congress on the results of such study, including recommendations on how to prevent such duplication.

SEC. 1023. REDUCING ADMINISTRATIVE BURDENS OF RESEARCHERS.

(a) PLAN PREPARATION AND IMPLEMENTATION OF MEASURES TO REDUCE ADMINISTRATIVE BURDENS.—The Director of the National Institutes of Health shall prepare a plan, including time frames, and implement measures to reduce the administrative burdens of researchers funded by the National Institutes of Health, taking into account the recommendations, evaluations, and plans researched by the following entities:

(1) The Scientific Management Review Board.

(2) The National Academy of Sciences.

(3) The 2007 and 2012 Faculty Burden Survey conducted by The Federal Demonstration Partnership.

(4) Relevant recommendations from the Research Business Models Working Group.

(b) REPORT.—Not later than two years after the date of enactment of this Act, the Director of the National Institutes of Health shall submit to Congress a report on the extent to which the Director has implemented measures pursuant to subsection (a).

SEC. 1024. EXEMPTION FOR THE NATIONAL INSTITUTES OF HEALTH FROM THE PAPERWORK REDUCTION ACT REQUIREMENTS.

Section 3518(c)(1) of title 44, United States Code, is amended—

(1) in subparagraph (C), by striking "; or" and inserting a semicolon;

(2) in subparagraph (D), by striking the period at the end and inserting "; or"; and

(3) by inserting at the end the following new subparagraph:

"(E) during the conduct of research by the National Institutes of Health.".

SEC. 1025. NIH TRAVEL.

It is the sense of Congress that participation in or sponsorship of scientific conferences and meetings is essential to the mission of the National Institutes of Health.

SEC. 1026. OTHER TRANSACTIONS AUTHORITY.

Section 480 of the Public Health Service Act (42 U.S.C. 287a) is amended—

(1) in subsection (b), by striking "the appropriation of funds as described in subsection (g)" and inserting "the availability of funds as described in subsection (f)";

(2) in subsection (e)(3), by amending subparagraph (C) to read as follows:

"(C) OTHER TRANSACTIONS AUTHORITY.—The Director of the Center shall have other transactions authority in entering into transactions to fund projects in accordance with the terms and conditions of this section.";

(3) by striking subsection (f); and

(4) by redesignating subsection (g) as subsection (f).

SEC. 1027. NCATS PHASE IIB RESTRICTION.

Section 479 of the Public Health Service Act (42 U.S.C. 287) is amended—

(1) prior to making the amendments under paragraph (2), by striking "IIB" each place it appears and inserting "III"; and

(2) by striking "IIA" each place it appears and inserting "IIB".

SEC. 1028. HIGH-RISK, HIGH-REWARD RESEARCH.

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended by adding at the end the following:

"SEC. 409K. HIGH-RISK, HIGH-REWARD RESEARCH PROGRAM.

"The director of each national research institute shall, as appropriate—

"(1) establish programs to conduct or support research projects that pursue innovative approaches to major contemporary challenges in biomedical research that involve inherent high risk, but have the potential to lead to breakthroughs; and

"(2) set aside a specific percentage of funding, to be determined by the Director of NIH for each national research institute, for such projects.".

SEC. 1029. SENSE OF CONGRESS ON INCREASED INCLUSION OF UNDERREPRESENTED COMMUNITIES IN CLINICAL TRIALS.

It is the sense of Congress that the National Institute on Minority Health and Health Disparities (NIMHD) should include within its strategic plan ways to increase representation of underrepresented communities in clinical trials.

Subtitle C—Supporting Young Emerging Scientists

SEC. 1041. IMPROVEMENT OF LOAN REPAYMENT PROGRAMS OF THE NATIONAL INSTITUTES OF HEALTH.

(a) IN GENERAL.—Part G of title IV of the Public Health Service (42 U.S.C. 288 et seq.) is amended—

(1) by redesignating the second section 487F (42 U.S.C. 288–6; relating to pediatric research loan repayment program) as section 487G; and

(2) by inserting after section 487G, as so redesignated, the following:

"SEC. 487H. LOAN REPAYMENT PROGRAM.

"(a) IN GENERAL.—The Secretary shall establish a program, based on workforce and scientific needs, of entering into contracts with qualified health professionals under which such health professionals agree to engage in research in consideration of the Federal Government agreeing to pay, for each year of engaging in such research, not more than $50,000 of the principal and interest of the educational loans of such health professionals.

"(b) ADJUSTMENT FOR INFLATION.—Beginning with respect to fiscal year 2017, the Secretary may increase the maximum amount specified in subsection (a) by an amount that is determined by the Secretary, on an annual basis, to reflect inflation.

"(c) LIMITATION.—The Secretary may not enter into a contract with a health professional pursuant to subsection (a) unless such professional has a substantial amount of educational loans relative to income.

"(d) APPLICABILITY OF CERTAIN PROVISIONS REGARDING OBLIGATED SERVICE.—Except to the extent inconsistent with this section, the provisions of sections 338B, 338C, and 338E shall apply to the program established under this section to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established under section 338B.

"(e) AVAILABILITY OF APPROPRIATIONS.—Amounts appropriated for a fiscal year for contracts under subsection (a) are authorized to remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.".

(b) UPDATE OF OTHER LOAN REPAYMENT PROGRAMS.—

(1) Section 464z–5(a) of the Public Health Service Act (42 U.S.C.285t–2(a)) is amended—

(A) by striking "$35,000" and inserting "$50,000"; and

(B) by adding at the end the following new sentence: "Subsection (b) of section 487H shall apply with respect to the maximum amount specified in this subsection in the same manner as it applies to the maximum amount specified in subsection (a) of such section.".

(2) Section 487A(a) of such Act (42 U.S.C. 288–1(a)) is amended—

(A) by striking "$35,000" and inserting "$50,000"; and

(B) by adding at the end the following new sentence: "Subsection (b) of section 487H shall apply with respect to the maximum amount specified in this subsection in the same manner as it applies to the maximum amount specified in subsection (a) of such section.".

(3) Section 487B(a) of such Act (42 U.S.C. 288–2(a)) is amended—

(A) by striking "$35,000" and inserting "$50,000"; and

(B) by adding at the end the following new sentence: "Subsection (b) of section 487H shall apply with respect to the maximum amount specified in this subsection in the same manner as it applies to the maximum amount specified in such subsection (a) of such section.".

(4) Section 487C(a)(1) of such Act (42 U.S.C. 288–3(a)(1)) is amended—

(A) by striking "$35,000" and inserting "$50,000"; and

(B) by adding at the end the following new sentence: "Subsection (b) of section 487H shall apply with respect to the maximum amount specified in this paragraph in the same manner as it applies to the maximum amount specified in such subsection (a) of such section.".

(5) Section 487E(a)(1) of such Act (42 U.S.C. 288–5(a)(1)) is amended—

(A) by striking "$35,000" and inserting "$50,000"; and

(B) by adding at the end the following new sentence: "Subsection (b) of section 487H shall apply with respect to the maximum amount specified in this paragraph in the same manner as it applies to the maximum amount specified in such subsection (a) of such section.".

(6) Section 487F(a) of such Act (42 U.S.C. 288–5a(a)), as added by section 205 of Public Law 106–505, is amended—

(A) by striking "$35,000" and inserting "$50,000"; and

(B) by adding at the end the following new sentence: "Subsection (b) of section 487H shall apply with respect to the maximum amount specified in this subsection in the same manner as it applies to the maximum amount specified in such subsection (a) of such section.".

(7) Section 487G of such Act (42 U.S.C. 288–6, as redesignated by section 1041(a)(1)), is further amended—

(A) in subsection (a)(1), by striking "$35,000" and inserting "$50,000"; and

(B) in subsection (b), by adding at the end the following new sentence: "Subsection (b) of section 487H shall apply with respect to the maximum amount specified in subsection (a)(1) in the same manner as it applies to the maximum amount specified in such subsection (a) of such section.".

SEC. 1042. REPORT.

Not later than 18 months after the date of the enactment of this Act, the Director of the National Institutes of Health shall submit to Congress a report on efforts of the National Institutes of Health to attract, retain, and develop emerging scientists.

Subtitle D—Capstone Grant Program

SEC. 1061. CAPSTONE AWARD.

Part G of title IV of the Public Health Service Act (42 U.S.C. 288 et seq.) is amended by adding at the end the following:

"SEC. 490. CAPSTONE AWARD.

"(a) IN GENERAL.—The Secretary may make awards (each of which, hereafter in this section, referred to as a 'Capstone Award') to support outstanding scientists who have been funded by the National Institutes of Health.

"(b) PURPOSE.—Capstone Awards shall be made to facilitate the successful transition or conclusion of research programs, or for other purposes, as determined by the Director of NIH, in consultation with the directors of the national research institutes and national centers.

"(c) DURATION AND AMOUNT.—The duration and amount of each Capstone Award shall be determined by the Director of NIH in consultation with the directors of the national research institutes and national centers.

"(d) LIMITATION.—Individuals who have received a Capstone Award shall not be eligible to have principle investigator status on subsequent awards from the National Institutes of Health.".

Subtitle E—Promoting Pediatric Research Through the National Institutes of Health

SEC. 1081. NATIONAL PEDIATRIC RESEARCH NETWORK.

Section 409D(d) of the Public Health Service Act (42 U.S.C. 284h(d)) is amended—

(1) in paragraph (1)—

(A) by striking "in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and in collaboration with other appropriate national research institutes and national centers that carry out activities involving pediatric research" and inserting "in collaboration with the national research institutes and national centers that carry out activities involving pediatric research";

(B) by striking subparagraph (B);

(C) by striking "may be comprised of, as appropriate" and all that follows through "the pediatric research consortia" and inserting "may be comprised of, as appropriate, the pediatric research consortia"; and

(D) by striking "; or" at the end and inserting a period; and

(2) in paragraph (1), paragraph (2)(A), the first sentence of paragraph (2)(E), and paragraph (4), by striking "may" each place it appears and inserting "shall".

SEC. 1082. GLOBAL PEDIATRIC CLINICAL STUDY NETWORK SENSE OF CONGRESS.

It is the sense of Congress that—

(1) the National Institutes of Health should encourage a global pediatric clinical study network through the allocation of grants, contracts, or cooperative agreements to supplement the salaries of new and early investigators who participate in the global pediatric clinical study network;

(2) National Institutes of Health grants, contracts, or cooperative agreements should be awarded, solely for the purpose of supplementing the salaries of new and early investigators, to entities that participate in the global pediatric clinical study network;

(3) the Food and Drug Administration should engage the European Medicines Agency and other foreign regulatory entities during the formation of the global pediatric clinical study network to encourage their participation; and

(4) once a global pediatric clinical study network is established and becomes operational, the Food and Drug Administration should continue to engage the European Medicines Agency and other foreign regulatory entities to encourage and facilitate their participation in the network with the goal of enhancing the global reach of the network.

SEC. 1083. APPROPRIATE AGE GROUPINGS IN CLINICAL RESEARCH.

(a) INPUT FROM EXPERTS.—Not later than 180 days after the date of enactment of this Act, the Director of the National Institutes of Health shall convene a workshop of experts on pediatrics and experts on geriatrics to provide input on—

(1) appropriate age groupings to be included in research studies involving human subjects; and

(2) acceptable scientific justifications for excluding participants from a range of age groups from human subjects research studies.

(b) GUIDELINES.—Not later than 180 days after the conclusion of the workshop under subsection (a), the Director of the National Institutes of Health shall publish guidelines—

(1) addressing the consideration of age as an inclusion variable in research involving human subjects; and

(2) identifying criteria for justifications for any age-related exclusions in such research.

(c) PUBLIC AVAILABILITY OF FINDINGS AND CONCLUSIONS.—The Director of the National Institutes of Health shall—

(1) make the findings and conclusions resulting from the workshop under subsection (a) available to the public on the website of the National Institutes of Health; and

(2) not less than biennially, disclose to the public on such website the number of children included in research that is conducted or supported by the National Institutes of Health, disaggregated by developmentally appropriate age group, race, and gender.

Subtitle F—Advancement of the National Institutes of Health Research and Data Access

SEC. 1101. SHARING OF DATA GENERATED THROUGH NIH-FUNDED RESEARCH.

Section 402 of the Public Health Service Act (42 U.S.C. 282) (as amended by section 1021(2)) is further amended by adding at the end the following:

"(n) SHARING OF DATA GENERATED THROUGH NIH-FUNDED RESEARCH.—

"(1) AUTHORITY.—Subject to paragraph (2), the Director of NIH may require recipients of the award of an NIH grant or other financial support, provided that the research is fully funded through such grant or other support, to share scientific data generated from research conducted through such support for research purposes.

"(2) LIMITATION.—The Director of NIH shall not require the sharing of data that is inconsistent with applicable law and policy protecting—

"(A) privacy and confidentiality;

"(B) proprietary interests;

"(C) business confidential information;

"(D) intellectual property rights; and

"(E) other relevant rights.".

SEC. 1102. STANDARDIZATION OF DATA IN CLINICAL TRIAL REGISTRY DATA BANK ON ELIGIBILITY FOR CLINICAL TRIALS.

(a) STANDARDIZATION.—

(1) IN GENERAL.—Section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)) is amended—

(A) by redesignating paragraph (7) as paragraph (8); and

(B) by inserting after paragraph (6) the following:

"(7) STANDARDIZATION.—The Director of NIH shall—

"(A) ensure that the registry and results data bank is easily used by the public;

"(B) ensure that entries in the registry and results data bank are easily compared;

"(C) ensure that information required to be submitted to the registry and results data bank, including recruitment information under paragraph (2)(A)(ii)(II), is submitted by persons and posted by the Director of NIH in a standardized format and includes at least—

"(i) the disease or indication being studied;

"(ii) inclusion criteria such as age, gender, diagnosis or diagnoses, laboratory values, or imaging results; and

"(iii) exclusion criteria such as specific diagnosis or diagnoses, laboratory values, or prohibited medications; and

"(D) to the extent possible, in carrying out this paragraph, make use of standard health care terminologies, such as the International Classification of Diseases or the Current Procedural Terminology, that facilitate electronic matching to data in electronic health records or other relevant health information technologies.".

(2) CONFORMING AMENDMENT.—Clause (iv) of section 402(j)(2)(B) of the Public Health Service Act (42 U.S.C. 282(j)(2)(B)) is hereby stricken.

(b) CONSULTATION.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall consult with stakeholders (including patients, researchers, physicians, industry representatives, health information technology providers, the Food and Drug Administration, and standard setting organizations such as CDISC that have experience working with Federal agencies to standardize health data submissions) to receive advice on enhancements to the clinical trial registry data bank under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)) (including enhancements to usability, functionality, and search capability) that are necessary to implement paragraph (7) of section 402(j) of such Act, as added by subsection (a).

(c) APPLICABILITY.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall begin implementation of paragraph (7) of section 402(j) of the Public Health Service Act, as added by subsection (a).

Subtitle G—Facilitating Collaborative Research

SEC. 1121. CLINICAL TRIAL DATA SYSTEM.

(a) ESTABLISHMENT.—The Secretary, acting through the Commissioner of Food and Drugs and the Director of the National Institutes of Health, shall enter into a cooperative agreement, contract, or grant for a period of 7 years, to be known as the Clinical Trial Data System Agreement, with one or more eligible entities to implement a pilot program with respect to all clinical trial data obtained from qualified clinical trials for purposes of registered users conducting further research on such data.

(b) APPLICATION.—Eligible entities seeking to enter into a cooperative agreement, contract, or grant with the Secretary under this section shall submit to the Secretary an application in such time and manner, and containing such information, as the Secretary may require in accordance with this section. The Secretary shall not enter into a cooperative agreement, contract, or grant under this section with an eligible entity unless such entity submits an application including the following:

(1) A certification that the eligible entity is not currently and does not plan to be involved in sponsoring, operating, or participating in a clinical trial nor collaborating with another entity for the purposes of sponsoring, operating, or participating in a clinical trial.

(2) Information demonstrating that the eligible entity can compile clinical trial data in standardized formats using terminologies and standards that have been developed by recognized standards developing organizations with input from diverse stakeholder groups, and information demonstrating that the eligible entity can de-identify clinical trial data consistent with the requirements of section 164.514 of title 45, Code of Federal Regulations (or successor regulations).

(3) A description of the system the eligible entity will use to store and maintain such data, and information demonstrating that this system will comply with applicable standards and requirements for ensuring the security of the clinical trial data.

(4) A certification that the eligible entity will allow only registered users to access and use de-identified clinical trial data, gathered from qualified clinical trials, and that the eligible entity will allow each registered user to access and use such data only after such registered user agrees in writing to the terms described in (e)(4)(B), and such other carefully controlled contractual terms as may be defined by the Secretary.

(5) Evidence demonstrating the ability of the eligible entity to ensure that registered users disseminate the results of the research conducted in accordance with this section to interested parties to serve as a guide to future medical product development or scientific research.

(6) The plan of the eligible entity for securing funding for the activities it would conduct under the clinical trial data system agreement from governmental sources and private foundations, entities, and individuals.

(7) Evidence demonstrating a proven track record of—

(A) being a neutral third party in working with medical product manufacturers, academic institutions, and the Food and Drug Administration; and

(B) having the ability to protect confidential data.

(8) An agreement that the eligible entity will work with the Comptroller General of the United States for purposes of the study and report under subsection (d).

(c) EXTENSION, EXPANSION, TERMINATION.—The Secretary, acting through the Commissioner of Food and Drugs and the Director of the National Institutes of Health, upon the expiration of the 7-year period referred to in subsection (a), may extend (including permanently), expand, or terminate the pilot program established under such subsection, in whole or in part.

(d) STUDY AND REPORT.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study and issue a report to the Congress and the Secretary with respect to the pilot program established under subsection (a), not later than 6 years after the date on which the pilot program is established under subsection (a).

(2) STUDY.—The study under paragraph (1) shall—

(A) review the effectiveness of the pilot program established under subsection (a); and

(B) be designed to formulate recommendations on improvements to the program.

(3) REPORT.—The report under paragraph (1) shall contain at least the following information:

(A) The new discoveries, research inquiries, or clinical trials that have resulted from accessing clinical trial data under the pilot program established under subsection (a).

(B) The number of times scientists have accessed such data, disaggregated by research area and clinical trial phase.

(C) An analysis of whether the program has helped to reduce adverse events in clinical trials.

(D) An analysis of whether scientists have raised any concerns about the burden of having to share data with the system established under the program and a description, if any, of such burden.

(E) An analysis of privacy and data integrity practices used in the program.

(e) DEFINITIONS.—In this section:

(1) The term "eligible entity" means an entity that has experienced personnel with clinical and other technical expertise in the biomedical sciences and biomedical ethics and that is—

(A) an institution of higher education (as such term is defined in section 1001 of the Higher Education Act of 1965 (20 U.S.C. 1001)) or a consortium of such institutions; or

(B) an organization described in section 501(c)(3) of title 26 of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such title.

(2) The term "medical product" means a drug (as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(g))), a device (as defined in section 201(h) of such Act (21 U.S.C. 331(h)), a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262)), or any combination thereof.

(3) The term "qualified clinical trial" means a clinical trial sponsored solely by an agency of the Department of Health and Human Services with respect to a medical product—

(A) that—

(i) was approved or cleared under section 505, 510(k), or 515, or has an exemption for investigational use in effect under section 505 or 520(m), of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 301 et seq.); or

(ii) was licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) or has an exemption for investigational use in effect under such section 351; or

(B) that is an investigational product for which the original development was discontinued and with respect to which—

(i) no additional work to support approval, licensure, or clearance of such medical product is being or is planned to be undertaken by the sponsor of the original development program, its successors, assigns, or collaborators; and

(ii) the sponsor of the original investigational development program has provided its consent to the Secretary for inclusion of data regarding such product in the system established under this section.

(4) The term "registered user" means a scientific or medical researcher who has—

(A) a legitimate biomedical research purpose for accessing information from the clinical trials data system and has appropriate qualifications to conduct such research; and

(B) agreed in writing not to transfer to any other person that is not a registered user de-identified clinical trial data from qualified clinical trials accessed through an eligible entity, use such data for reasons not specified in the research proposal, or seek to re-identify qualified clinical trial participants.

(5) The term "Secretary" means the Secretary of Health and Human Services.

SEC. 1122. NATIONAL NEUROLOGICAL DISEASES SURVEILLANCE SYSTEM.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

"SEC. 399V–6 SURVEILLANCE OF NEUROLOGICAL DISEASES.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other agencies as determined appropriate by the Secretary, shall—

"(1) enhance and expand infrastructure and activities to track the epidemiology of neurological diseases, including multiple sclerosis and Parkinson's disease; and

"(2) incorporate information obtained through such activities into a statistically sound, scientifically credible, integrated surveillance system, to be known as the National Neurological Diseases Surveillance System.

"(b) RESEARCH.—The Secretary shall ensure that the National Neurological Diseases Surveillance System is designed in a manner that facilitates further research on neurological diseases.

"(c) CONTENT.—In carrying out subsection (a), the Secretary—

"(1) shall provide for the collection and storage of information on the incidence and prevalence of neurological diseases in the United States;

"(2) to the extent practicable, shall provide for the collection and storage of other available information on neurological diseases, such as information concerning—

"(A) demographics and other information associated or possibly associated with neurological diseases, such as age, race, ethnicity, sex, geographic location, and family history;

"(B) risk factors associated or possibly associated with neurological diseases, including genetic and environmental risk factors; and

"(C) diagnosis and progression markers;

"(3) may provide for the collection and storage of information relevant to analysis on neurological diseases, such as information concerning—

"(A) the epidemiology of the diseases;

"(B) the natural history of the diseases;

"(C) the prevention of the diseases;

"(D) the detection, management, and treatment approaches for the diseases; and

"(E) the development of outcomes measures; and

"(4) may address issues identified during the consultation process under subsection (d).

"(d) CONSULTATION.—In carrying out this section, the Secretary shall consult with individuals with appropriate expertise, including—

"(1) epidemiologists with experience in disease surveillance or registries;

"(2) representatives of national voluntary health associations that—

"(A) focus on neurological diseases, including multiple sclerosis and Parkinson's disease; and

"(B) have demonstrated experience in research, care, or patient services;

"(3) health information technology experts or other information management specialists;

"(4) clinicians with expertise in neurological diseases; and

"(5) research scientists with experience conducting translational research or utilizing surveillance systems for scientific research purposes.

"(e) GRANTS.—The Secretary may award grants to, or enter into contracts or cooperative agreements with, public or private nonprofit entities to carry out activities under this section.

"(f) COORDINATION WITH OTHER FEDERAL, STATE, AND LOCAL AGENCIES.—Subject to subsection (h), the Secretary shall make information and analysis in the National Neurological Diseases Surveillance System available, as appropriate—

"(1) to Federal departments and agencies, such as the National Institutes of Health, the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Agency for Healthcare Research and Quality, the Department of Veterans Affairs, and the Department of Defense; and

"(2) to State and local agencies.

"(g) PUBLIC ACCESS.—Subject to subsection (h), the Secretary shall make information and analysis in the National Neurological Diseases Surveillance System available, as appropriate, to the public, including researchers.

"(h) PRIVACY.—The Secretary shall ensure that privacy and security protections applicable to the National Neurological Diseases Surveillance System are at least as stringent as the privacy and security protections under HIPAA privacy and security law (as defined in section 3009(a)(2)).

"(i) REPORT.—Not later than 4 years after the date of the enactment of this section, the Secretary shall submit a report to the Congress concerning the implementation of this section. Such report shall include information on—

"(1) the development and maintenance of the National Neurological Diseases Surveillance System;

"(2) the type of information collected and stored in the System;

"(3) the use and availability of such information, including guidelines for such use; and

"(4) the use and coordination of databases that collect or maintain information on neurological diseases.

"(j) DEFINITION.—In this section, the term 'national voluntary health association' means a national nonprofit organization with chapters, other affiliated organizations, or networks in States throughout the United States.

"(k) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $5,000,000 for each of fiscal years 2016 through 2020.".

SEC. 1123. DATA ON NATURAL HISTORY OF DISEASES.

(a) SENSE OF CONGRESS.—It is the sense of the Congress that studies on the natural history of diseases can help to facilitate and expedite the development of medical products for such diseases.

(b) AUTHORITY.—Part A of title II of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by adding at the end the following:

"SEC. 229A. DATA ON NATURAL HISTORY OF DISEASES.

"(a) IN GENERAL.—The Secretary may, for the purposes described in subsection (b)—

"(1) participate in public-private partnerships engaged in one or more activities specified in subsection (c); and

"(2) award grants to patient advocacy groups or other organizations determined appropriate by the Secretary.

"(b) PURPOSES DESCRIBED.—The purposes described in this subsection are to establish or facilitate the collection, maintenance, analysis, and interpretation of data regarding the natural history of diseases, with a particular focus on rare diseases.

"(c) ACTIVITIES OF PUBLIC-PRIVATE PARTNERSHIPS.—The activities of public-private partnerships in which the Secretary may participate for purposes of this section include—

"(1) cooperating with other entities that sponsor or maintain disease registries, including disease registries and disease registry platforms for rare diseases;

"(2) developing or enhancing a secure information technology system that—

"(A) has the capacity to support data needs across a wide range of disease studies;

"(B) is easily modified as knowledge is gained during such studies; and

"(C) is capable of handling increasing amounts of data as more studies are carried out; and

"(3) providing advice to clinical researchers, patient advocacy groups, and other entities with respect to—

"(A) the design and conduct of disease studies;

"(B) the modification of any such ongoing studies; and

"(C) addressing associated patient privacy issues.

"(d) AVAILABILITY OF DATA ON NATURAL HISTORY OF DISEASES.—Data relating to the natural history of diseases obtained, aggregated, or otherwise maintained by a public-private partnership in which the Secretary participates under subsection (a) shall be made available, consistent with otherwise applicable Federal and State privacy laws, to the public (including patient advocacy groups, researchers, and drug developers) to help to facilitate and expedite medical product development programs.

"(e) CONFIDENTIALITY.—Notwithstanding subsection (d), nothing in this section authorizes the disclosure of any information that is a trade secret or commercial or financial information that is privileged or confidential and subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

"(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2016 through 2020.".

SEC. 1124. ACCESSING, SHARING, AND USING HEALTH DATA FOR RESEARCH PURPOSES.

(a) IN GENERAL.—(1) The HITECH Act (title XIII of division A of Public Law 111–5) is amended by adding at the end of subtitle D of such Act (42 U.S.C. 17921 et seq.) the following:

"PART 4—ACCESSING, SHARING, AND USING HEALTH DATA FOR RESEARCH PURPOSES

"SEC. 13441. REFERENCES.

"In this part:

"(1) THE RULE.—References to 'the Rule' refer to part 160 or part 164, as appropriate, of title 45, Code of Federal Regulations (or any successor regulation).

"(2) PART 164.—References to a specified section of 'part 164', refer to such specified section of part 164 of title 45, Code of Federal Regulations (or any successor section).

"SEC. 13442. DEFINING HEALTH DATA RESEARCH AS PART OF HEALTH CARE OPERATIONS.

"(a) IN GENERAL.—Subject to subsection (b), the Secretary shall revise or clarify the Rule to allow the use and disclosure of protected health information by a covered entity for research purposes, including studies whose purpose is to obtain generalizable knowledge, to be treated as the use and disclosure of such information for health care operations described in subparagraph (1) of the definition of health care operations in section 164.501 of part 164.

"(b) MODIFICATIONS TO RULES FOR DISCLOSURES FOR HEALTH CARE OPERATIONS.—In applying section 164.506 of part 164 to the disclosure of protected health information described in subsection (a)—

"(1) the Secretary shall revise or clarify the Rule so that the disclosure may be made by the covered entity to only—

"(A) another covered entity for health care operations (as defined in section 164.501 of part 164);

"(B) a business associate that has entered into a contract under section 164.504(e) of part 164 with a disclosing covered entity to perform health care operations; or

"(C) a business associate that has entered into a contract under section 164.504(e) of part 164 for the purpose of data aggregation (as defined in section 164.501 of part 164); and

"(2) the Secretary shall further revise or clarify the Rule so that the limitation specified by section 164.506(c)(4) of part 164 does not apply to disclosures that are described by subsection (a).

"(c) RULE OF CONSTRUCTION.—This section shall not be construed as prohibiting or restricting a use or disclosure of protected health information for research purposes that is otherwise permitted under part 164.

"SEC. 13443. TREATING DISCLOSURES OF PROTECTED HEALTH INFORMATION FOR RESEARCH SIMILARLY TO DISCLOSURES OF SUCH INFORMATION FOR PUBLIC HEALTH PURPOSES.

"(a) REMUNERATION.—The Secretary shall revise or clarify the Rule so that disclosures of protected health information for research purposes are not subject to the limitation on remuneration described in section 164.502(a)(5)(ii)(B)(2)(ii) of part 164.

"(b) PERMITTED USES AND DISCLOSURES.—The Secretary shall revise or clarify the Rule so that research activities, including comparative research activities, related to the quality, safety, or effectiveness of a product or activity that is regulated by the Food and Drug Administration are included as public health activities for purposes of which a covered entity may disclose protected health information to a person described in section 164.512(b)(1)(iii) of part 164.

"SEC. 13444. PERMITTING REMOTE ACCESS TO PROTECTED HEALTH INFORMATION BY RESEARCHERS.

"The Secretary shall revise or clarify the Rule so that subparagraph (B) of section 164.512(i)(1)(ii) of part 164 (prohibiting the removal of protected health information by a researcher) shall not prohibit remote access to health information by a researcher so long as—

"(1) appropriate security and privacy safeguards are maintained by the covered entity and the researcher; and

"(2) the protected health information is not copied or otherwise retained by the researcher.

"SEC. 13445. ALLOWING ONE-TIME AUTHORIZATION OF USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES.

"(a) IN GENERAL.—The Secretary shall revise or clarify the Rule to specify that an authorization for the use or disclosure of protected health information, with respect to an individual, for future research purposes shall be deemed to contain a sufficient description of the purpose of the use or disclosure if the authorization—

"(1) sufficiently describes the purposes such that it would be reasonable for the individual to expect that the protected health information could be used or disclosed for such future research;

"(2) either—

"(A) states that the authorization will expire on a particular date or on the occurrence of a particular event; or

"(B) states that the authorization will remain valid unless and until it is revoked by the individual; and

"(3) provides instruction to the individual on how to revoke such authorization at any time.

"(b) REVOCATION OF AUTHORIZATION.—The Secretary shall revise or clarify the Rule to specify that, if an individual revokes an authorization for future research purposes such as is described by subsection (a), the covered entity may not make any further uses or disclosures based on that authorization, except, as provided in paragraph (b)(5) of section 164.508 of part 164, to the extent that the covered entity has taken action in reliance on the authorization.".

(2) The table of sections in section 13001(b) of such Act is amended by adding at the end of the items relating to subtitle D the following new items:

"PART 4—ACCESSING, SHARING, AND USING HEALTH DATA FOR RESEARCH PURPOSES

"Sec. 13441. References.
"Sec. 13442. Defining health data research as part of health care operations.
"Sec. 13443. Treating disclosures of protected health information for research similarly to disclosures of such information for public health purposes.
"Sec. 13444. Permitting remote access to protected health information by researchers.
"Sec. 13445. Allowing one-time authorization of use and disclosure of protected health information for research purposes.".

(b) REVISION OF REGULATIONS.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall revise and clarify the provisions of title 45, Code of Federal Regulations, for consistency with part 4 of subtitle D of the HITECH Act, as added by subsection (a).

Subtitle H—Council for 21st Century Cures

SEC. 1141. COUNCIL FOR 21ST CENTURY CURES.

Title II of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by adding at the end the following:

"PART E—COUNCIL FOR 21ST CENTURY CURES

"SEC. 281. ESTABLISHMENT.

"A nonprofit corporation to be known as the Council for 21st Century Cures (referred to in this part as the 'Council') shall be established in accordance with this section. The Council shall be a public-private partnership headed by an Executive Director (referred to in this part as the 'Executive Director'), appointed by the members of the Board of Directors. The Council shall not be an agency or instrumentality of the United States Government.

"SEC. 281A. PURPOSE.

"The purpose of the Council is to accelerate the discovery, development, and delivery in the United States of innovative cures, treatments, and preventive measures for patients.

"SEC. 281B. DUTIES.

"For the purpose described in section 281A, the Council shall—

"(1) foster collaboration and coordination among the entities that comprise the Council, including academia, government agencies, industry, health care payors and providers, patient advocates, and others engaged in the cycle of discovery, development, and delivery of life-saving and health-enhancing innovative interventions;

"(2) undertake communication and dissemination activities;

"(3) publish information on the activities funded under section 281D;

"(4) establish a strategic agenda for accelerating the discovery, development, and delivery in the United States of innovative cures, treatments, and preventive measures for patients;

"(5) identify gaps and opportunities within and across the discovery, development, and delivery cycle;

"(6) develop and propose recommendations based on the gaps and opportunities so identified;

"(7) facilitate the interoperability of the components of the discovery, development, and delivery cycle;

"(8) propose recommendations that will facilitate precompetitive collaboration;

"(9) identify opportunities to work with, but not duplicate the efforts of, nonprofit organizations and other public-private partnerships; and

"(10) identify opportunities for collaboration with organizations operating outside of the United States, such as the Innovative Medicines Initiative of the European Union.

"SEC. 281C. ORGANIZATION; ADMINISTRATION.

"(a) BOARD OF DIRECTORS.—

"(1) ESTABLISHMENT.—

"(A) IN GENERAL.—The Council shall have a Board of Directors (in this part referred to as the 'Board of Directors'), which shall be composed of the ex officio members under subparagraph (B) and the appointed members under subparagraph (C). All members of the Board shall be voting members.

"(B) EX OFFICIO MEMBERS.—The ex officio members of the Board shall be the following individuals or their designees:

"(i) The Director of the National Institutes of Health.

"(ii) The Commissioner of Food and Drugs.

"(iii) The Administrator of the Centers for Medicare & Medicaid Services.

"(iv) The heads of five other Federal agencies deemed by the Secretary to be engaged in biomedical research and development.

"(C) APPOINTED MEMBERS.—The appointed members of the Board shall consist of 17 individuals, of whom—

"(i) 8 shall be appointed by the Comptroller General of the United States from a list of nominations submitted by leading trade associations—

"(I) 4 of whom shall be representatives of the biopharmaceutical industry;

"(II) 2 of whom shall be representatives of the medical device industry; and

"(III) 2 of whom shall be representatives of the information and digital technology industry; and

"(ii) 9 shall be appointed by the Comptroller General of the United States, after soliciting nominations—

"(I) 2 of whom shall be representatives of academic researchers;

"(II) 3 of whom shall be representatives of patients;

"(III) 2 of whom shall be representatives of health care providers; and

"(IV) 2 of whom shall be representatives of health care plans and insurers.

"(D) CHAIR.—The Chair of the Board shall be selected by the members of the Board by majority vote from among the members of the Board.

"(2) TERMS AND VACANCIES.—

"(A) IN GENERAL.—The term of office of each member of the Board appointed under paragraph (1)(C) shall be 5 years.

"(B) VACANCY.—Any vacancy in the membership of the Board—

"(i) shall not affect the power of the remaining members to execute the duties of the Board; and

"(ii) shall be filled by appointment by the appointed members described in paragraph (1)(C) by majority vote.

"(C) PARTIAL TERM.—If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed under subparagraph (B) to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

"(3) RESPONSIBILITIES.—Not later than 90 days after the date on which the Council is incorporated and its Board of Directors is fully constituted, the Board of Directors shall establish bylaws and policies for the Council that—

"(A) are published in the Federal Register and available for public comment;

"(B) establish policies for the selection and, as applicable, appointment of—

"(i) the officers, employees, agents, and contractors of the Council; and

"(ii) the members of any committees of the Council;

"(C) establish policies, including ethical standards, for the conduct of programs and other activities under section 281D; and

"(D) establish specific duties of the Executive Director.

"(4) MEETINGS.—

"(A) IN GENERAL.—The Board of Directors shall—

"(i) meet on a quarterly basis; and

"(ii) submit to Congress, and make publicly available, the minutes of such meetings.

"(B) AGENDA.—The Board of Directors shall, not later than 3 months after the incorporation of the Council—

"(i) issue an agenda (in this part referred to as the 'agenda') outlining how the Council will achieve the purpose described in section 281A; and

"(ii) annually thereafter, in consultation with the Executive Director, review and update such agenda.

"(b) APPOINTMENT AND INCORPORATION.—Not later than 6 months after the date of enactment of the 21st Century Cures Act—

"(1) the Comptroller General of the United States shall appoint the appointed members of the Board of Directors under subsection (a)(1)(C); and

"(2) the ex officio members of the Board of Directors under subsection (a)(1)(B) shall serve as incorporators and shall take whatever actions are necessary to incorporate the Council.

"(c) NONPROFIT STATUS.—In carrying out this part, the Board of Directors shall establish such policies and bylaws, and the Executive Director shall carry out such activities, as may be necessary to ensure that the Council maintains status as an organization that—

"(1) is described in subsection (c)(3) of section 501 of the Internal Revenue Code of 1986; and

"(2) is, under subsection (a) of such section, exempt from taxation.

"(d) EXECUTIVE DIRECTOR.—The Executive Director shall—

"(1) be the chief executive officer of the Council; and

"(2) subject to the oversight of the Board of Directors, be responsible for the day-to-day management of the Council.

"SEC. 281D. OPERATIONAL ACTIVITIES AND ASSISTANCE.

"(a) IN GENERAL.—The Council shall establish a sufficient operational infrastructure to fulfill the duties specified in section 281B.

"(b) PRIVATE SECTOR MATCHING FUNDS.—The Council may accept financial or in-kind support from participating entities or private foundations or organizations when such support is deemed appropriate.

"SEC. 281E. TERMINATION; REPORT.

"(a) IN GENERAL.—The Council shall terminate on September 30, 2023.

"(b) REPORT.—Not later than one year after the date on which the Council is established and each year thereafter, the Executive Director shall submit to the appropriate congressional committees a report on the performance of the Council. In preparing such report, the Council shall consult with a nongovernmental consultant with appropriate expertise.

"SEC. 281F. FUNDING.

"For the each of fiscal years 2016 through 2023, there is authorized to be appropriated $10,000,000 to the Council for purposes of carrying out the duties of the Council under this part.".

TITLE II—DEVELOPMENT

Subtitle A—Patient-Focused Drug Development

SEC. 2001. DEVELOPMENT AND USE OF PATIENT EXPERIENCE DATA TO ENHANCE STRUCTURED RISK-BENEFIT ASSESSMENT FRAMEWORK.

(a) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (d), by striking "The Secretary shall implement" and all that follows through "premarket approval of a drug."; and

(2) by adding at the end the following new subsections:

"(x) STRUCTURED RISK-BENEFIT ASSESSMENT FRAMEWORK.—

"(1) IN GENERAL.—The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process—

"(A) to facilitate the balanced consideration of benefits and risks; and

"(B) to develop and implement a consistent and systematic approach to the discussion of, regulatory decisionmaking with respect to, and the communication of, the benefits and risks of new drugs.

"(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall alter the criteria for evaluating an application for premarket approval of a drug.

"(y) DEVELOPMENT AND USE OF PATIENT EXPERIENCE DATA TO ENHANCE STRUCTURED RISK-BENEFIT ASSESSMENT FRAMEWORK.—

"(1) IN GENERAL.—Not later than two years after the date of the enactment of this subsection, the Secretary shall establish and implement processes under which—

"(A) an entity seeking to develop patient experience data may submit to the Secretary—

"(i) initial research concepts for feedback from the Secretary; and

"(ii) with respect to patient experience data collected by the entity, draft guidance documents, completed data, and summaries and analyses of such data;

"(B) the Secretary may request such an entity to submit such documents, data, and summaries and analyses; and

"(C) patient experience data may be developed and used to enhance the structured risk-benefit assessment framework under subsection (x).

"(2) PATIENT EXPERIENCE DATA.—In this subsection, the term 'patient experience data' means data collected by patients, parents, caregivers, patient advocacy organizations, disease research foundations, medical researchers, research sponsors, or other parties determined appropriate by the Secretary that is intended to facilitate or enhance the Secretary's risk-benefit assessments, including information about the impact of a disease or a therapy on patients' lives.".

(b) GUIDANCE.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall publish guidance on the implementation of subsection (y) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as added by subsection (a). Such guidance shall include—

(A) with respect to draft guidance documents, data, or summaries and analyses submitted to the Secretary under paragraph (1)(A) of such subsection, guidance—

(i) specifying the timelines for the review of such documents, data, or summaries and analyses by the Secretary; and

(ii) on how the Secretary will use such documents, data, or summaries and analyses to update any guidance documents published under this subsection or publish new guidance;

(B) with respect to the collection and analysis of patient experience data (as defined in paragraph (2) of such subsection (y)), guidance on—

(i) methodological considerations for the collection of patient experience data, which may include structured approaches to gathering information on—

(I) the experience of a patient living with a particular disease;

(II) the burden of living with or managing the disease;

(III) the impact of the disease on daily life and long-term functioning; and

(IV) the effect of current therapeutic options on different aspects of the disease; and

(ii) the establishment and maintenance of registries designed to increase understanding of the natural history of a disease;

(C) methodological approaches that may be used to assess patients' beliefs with respect to the benefits and risks in the management of the patient's disease; and

(D) methodologies, standards, and potential experimental designs for patient-reported outcomes.

(2) TIMING.—Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue draft guidance on the implementation of subsection (y) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as added by subsection (a). The Secretary shall issue final guidance on the implementation of such subsection not later than one year after the date on which the comment period for the draft guidance closes.

(3) WORKSHOPS.—

(A) IN GENERAL.—Not later than 6 months after the date of the enactment of this Act and once every 6 months during the following 12-month period, the Secretary of Health and Human Services shall convene a workshop to obtain input regarding methodologies for developing the guidance under paragraph (1), including the collection of patient experience data.

(B) ATTENDEES.—A workshop convened under this paragraph shall include—

(i) patients;

(ii) representatives from patient advocacy organizations, biopharmaceutical companies, and disease research foundations;

(iii) representatives of the reviewing divisions of the Food and Drug Administration; and

(iv) methodological experts with significant expertise in patient experience data.

(4) PUBLIC MEETING.—Not later than 90 days after the date on which the draft guidance is published under this subsection, the Secretary of Health and Human Services shall convene a public meeting to solicit input on the guidance.

Subtitle B—Qualification and Use of Drug Development Tools

SEC. 2021. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.

(a) FINDINGS.—Congress finds the following:

(1) Development of new drugs has become increasingly challenging and resource intensive.

(2) Development of drug development tools can benefit the availability of new medical therapies by helping to translate scientific discoveries into clinical applications.

(3) Biomedical research consortia (as defined in section 507(f) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (c)) can play a valuable role in helping to develop and qualify drug development tools.

(b) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) Congress should promote and facilitate a collaborative effort among the biomedical research consortia described in subsection (a)(3)—

(A) to develop, through a transparent public process, data standards and scientific approaches to data collection accepted by the medical and clinical research community for purposes of qualifying drug development tools;

(B) to coordinate efforts toward developing and qualifying drug development tools in key therapeutic areas; and

(C) to encourage the development of accessible databases for collecting relevant drug development tool data for such purposes; and

(2) an entity seeking to qualify a drug development tool should be encouraged, in addition to consultation with the Secretary, to consult with biomedical research consortia and other individuals and entities with expert knowledge and insights that may assist the requestor and benefit the process for such qualification.

(c) QUALIFICATION OF DRUG DEVELOPMENT TOOLS.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 506F the following new section:

"SEC. 507. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.

"(a) PROCESS FOR QUALIFICATION.—

"(1) IN GENERAL.—The Secretary shall establish a process for the qualification of drug development tools for a proposed context of use under which—

"(A)(i) a requestor initiates such process by submitting a letter of intent to the Secretary; and

"(ii) the Secretary shall accept or decline to accept such letter of intent;

"(B)(i) if the Secretary accepts the letter of intent, a requestor shall submit a qualification plan to the Secretary; and

"(ii) the Secretary shall accept or decline to accept the qualification plan; and

"(C)(i) if the Secretary accepts the qualification plan, the requestor submits to the Secretary a full qualification package;

"(ii) the Secretary shall determine whether to accept such qualification package for review; and

"(iii) if the Secretary accepts such qualification package for review, the Secretary shall conduct such review in accordance with this section.

"(2) ACCEPTANCE AND REVIEW OF SUBMISSIONS.—

"(A) IN GENERAL.—The succeeding provisions of this paragraph shall apply with respect to the treatment of a letter of intent, a qualification plan, or a full qualification package submitted under paragraph (1) (referred to in this paragraph as 'qualification submissions').

"(B) ACCEPTANCE FACTORS; NONACCEPTANCE.—The Secretary shall determine whether to accept a qualification submission based on factors which may include the scientific merit of the submission and the available resources of the Food and Drug Administration to review the qualification submission. A determination not to accept a submission under paragraph

(1) shall not be construed as a final determination by the Secretary under this section regarding the qualification of a drug development tool for its proposed context of use.

"(C) PRIORITIZATION OF QUALIFICATION REVIEW.—The Secretary may prioritize the review of a full qualification package submitted under paragraph (1) with respect to a drug development tool, based on factors determined appropriate by the Secretary, including—

"(i) as applicable, the severity, rarity, or prevalence of the disease or condition targeted by the drug development tool and the availability or lack of alternative treatments for such disease or condition; and

"(ii) the identification, by the Secretary or by biomedical research consortia and other expert stakeholders, of such a drug development tool and its proposed context of use as a public health priority.

"(D) ENGAGEMENT OF EXTERNAL EXPERTS.—The Secretary may, for purposes of the review of qualification submissions, through the use of cooperative agreements, grants, or other appropriate mechanisms, consult with biomedical research consortia and may consider the recommendations of such consortia with respect to the review of any qualification plan submitted under paragraph (1) or the review of any full qualification package under paragraph (3).

"(3) REVIEW OF FULL QUALIFICATION PACKAGE.—The Secretary shall—

"(A) conduct a comprehensive review of a full qualification package accepted under paragraph (1)(C); and

"(B) determine whether the drug development tool at issue is qualified for its proposed context of use.

"(4) QUALIFICATION.—The Secretary shall determine whether a drug development tool is qualified for a proposed context of use based on the scientific merit of a full qualification package reviewed under paragraph (3).

"(b) EFFECT OF QUALIFICATION.—

"(1) IN GENERAL.—A drug development tool determined to be qualified under subsection (a)(4) for a proposed context of use specified by the requestor may be used by any person in such context of use for the purposes described in paragraph (2).

"(2) USE OF A DRUG DEVELOPMENT TOOL.—Subject to paragraph (3), a drug development tool qualified under this section may be used for—

"(A) supporting or obtaining approval or licensure (as applicable) of a drug or biological product (including in accordance with section 506(c)) under section 505 of this Act or section 351 of the Public Health Service Act; or

"(B) supporting the investigational use of a drug or biological product under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act.

"(3) RESCISSION OR MODIFICATION.—

"(A) IN GENERAL.—The Secretary may rescind or modify a determination under this section to qualify a drug development tool if the Secretary determines that the drug development tool is not appropriate for the proposed context of use specified by the requestor. Such a determination may be based on new information that calls into question the basis for such qualification.

"(B) MEETING FOR REVIEW.—If the Secretary rescinds or modifies under subparagraph (A) a determination to qualify a drug development tool, the requestor involved shall be granted a request for a meeting with the Secretary to discuss the basis of the Secretary's decision to rescind or modify the determination before the effective date of the rescission or modification.

"(c) TRANSPARENCY.—

"(1) IN GENERAL.—Subject to paragraph (3), the Secretary shall make publicly available, and update on at least a biannual basis, on the Internet website of the Food and Drug Administration the following:

"(A) Information with respect to each qualification submission under the qualification process under subsection (a), including—

"(i) the stage of the review process applicable to the submission;

"(ii) the date of the most recent change in stage status;

"(iii) whether the external scientific experts were utilized in the development of a qualification plan or the review of a full qualification package; and

"(iv) submissions from requestors under the qualification process under subsection (a), including any data and evidence contained in such submissions, and any updates to such submissions.

"(B) The Secretary's formal written determinations in response to such qualification submissions.

"(C) Any rescissions or modifications under subsection (b)(3) of a determination to qualify a drug development tool.

"(D) Summary reviews that document conclusions and recommendations for determinations to qualify drug development tools under subsection (a).

"(E) A comprehensive list of—

"(i) all drug development tools qualified under subsection (a); and

"(ii) all surrogate endpoints which were the basis of approval or licensure (as applicable) of a drug or biological product (including in accordance with section 506(c)) under section 505 of this Act or section 351 of the Public Health Service Act.

"(2) RELATION TO TRADE SECRETS ACT.—Information made publicly available by the Secretary under paragraph (1) shall be considered a disclosure authorized by law for purposes of section 1905 of title 18, United States Code.

"(3) APPLICABILITY.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information contained in an application submitted under section 505 of this Act or section 351 of the Public Health Service Act that is confidential commercial or trade secret information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

"(1) to alter the standards of evidence under subsection (c) or (d) of section 505, including the substantial evidence standard in such subsection (d), or under section 351 of the Public Health Service Act (as applicable); or

"(2) to limit the authority of the Secretary to approve or license products under this Act or the Public Health Service Act, as applicable (as in effect before the date of the enactment of the 21st Century Cures Act).

"(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $10,000,000 for each of fiscal years 2016 through 2020.

"(f) DEFINITIONS.—In this section:

"(1) BIOMARKER.—(A) The term 'biomarker' means a characteristic (such as a physiologic, pathologic, or anatomic characteristic or measurement) that is objectively measured and evaluated as an indicator of normal biologic processes, pathologic processes, or biological responses to a therapeutic intervention; and

"(B) such term includes a surrogate endpoint.

"(2) BIOMEDICAL RESEARCH CONSORTIA.—The term 'biomedical research consortia' means collaborative groups that may take the form of public-private partnerships and may include government agencies, institutions of higher education (as defined in section 101(a) of the Higher Education Act of 1965, patient advocacy groups, industry representatives, clinical and scientific experts, and other relevant entities and individuals.

"(3) CLINICAL OUTCOME ASSESSMENT.—(A) The term 'clinical outcome assessment' means a measurement of a patient's symptoms, overall mental state, or the effects of a disease or condition on how the patient functions; and

"(B) such term includes a patient-reported outcome.

"(4) CONTEXT OF USE.—The term 'context of use' means, with respect to a drug development tool, a statement that describes the circumstances under which the drug development tool is to be used in drug development and regulatory review.

"(5) DRUG DEVELOPMENT TOOL.—The term 'drug development tool' includes—

"(A) a biomarker;

"(B) a clinical outcome assessment; and

"(C) any other method, material, or measure that the Secretary determines aids drug development and regulatory review for purposes of this section.

"(6) PATIENT-REPORTED OUTCOME.—The term 'patient-reported outcome' means a measurement based on a report from a patient regarding the status of the patient's health condition without amendment or interpretation of the patient's report by a clinician or any other person.

"(7) QUALIFICATION.—The terms 'qualification' and 'qualified' mean a determination by the Secretary that a drug development tool and its proposed context of use can be relied upon to have a specific interpretation and application in drug development and regulatory review under this Act.

"(8) REQUESTOR.—The term 'requestor' means an entity or entities, including a drug sponsor or a biomedical research consortia, seeking to qualify a drug development tool for a proposed context of use under this section.

"(9) SURROGATE ENDPOINT.—The term 'surrogate endpoint' means a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure, that is not itself a direct measurement of clinical benefit, and—

"(A) is known to predict clinical benefit and could be used to support traditional approval of a drug or biological product; or

"(B) is reasonably likely to predict clinical benefit and could be used to support the accelerated approval of a drug or biological product in accordance with section 506(c).".

(d) GUIDANCE.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall, in consultation with biomedical research consortia (as defined in subsection (f) of section 507 the Federal Food, Drug, and Cosmetic Act (as added by subsection (c))) and other interested parties through a collaborative public process, issue guidance to implement such section 507 that—

(A) provides a conceptual framework describing appropriate standards and scientific approaches to support the development of biomarkers delineated under the taxonomy established under paragraph (3);

(B) makes recommendations for demonstrating that a surrogate endpoint is reasonably likely to predict clinical benefit for the purpose of supporting the accelerated approval of a drug under section 506(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c));

(C) with respect to the qualification process under such section 507—

(i) describes the requirements that entities seeking to qualify a drug development tool under such section shall observe when engaging in such process;

(ii) outlines reasonable timeframes for the Secretary's review of letters, qualification plans, or full qualification packages submitted under such process; and

(iii) establishes a process by which such entities or the Secretary may consult with biomedical research consortia and other individuals and entities with expert knowledge and insights that may assist the Secretary in the review of qualification plans and full qualification submissions under such section; and

(D) includes such other information as the Secretary determines appropriate.

(2) TIMING.—Not later than 24 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue draft guidance under paragraph (1) on the implementation of section 507 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (c)). The Secretary shall issue final guidance on the implementation of such section not later than 6 months after the date on which the comment period for the draft guidance closes.

(3) TAXONOMY.—

(A) IN GENERAL.—For purposes of informing guidance under this subsection, the Secretary of Health and Human Services shall, in consultation with biomedical research consortia and other interested parties through a collaborative public process, establish a taxonomy for the classification of biomarkers (and related scientific concepts) for use in drug development.

(B) PUBLIC AVAILABILITY.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall make such taxonomy publicly available in draft form for public comment. The Secretary shall finalize the taxonomy not later than 12 months after the close of the public comment period.

(e) MEETING AND REPORT.—

(1) MEETING.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall convene a public meeting to describe and solicit public input regarding the qualification process under section 507 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (c).

(2) REPORT.—Not later than 5 years after the date of the enactment of this Act, the Secretary shall make publicly available on the Internet website of the Food and Drug Administration a report. Such report shall include, with respect to the qualification process under section 507 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (c), information on—

(A) the number of requests submitted, as a letter of intent, for qualification of a drug development tool (as defined in subsection (f) of such section);

(B) the number of such requests accepted and determined to be eligible for submission of a qualification plan or full qualification package (as such terms are defined in such subsection), respectively;

(C) the number of such requests for which external scientific experts were utilized in the development of a qualification plan or review of a full qualification package; and

(D) the number of qualification plans and full qualification packages, respectively, submitted to the Secretary; and

(3) the drug development tools qualified through such qualification process, specified by type of tool, such as a biomarker or clinical outcome assessment (as such terms are defined in subsection (f) of such section 507).

SEC. 2022. ACCELERATED APPROVAL DEVELOPMENT PLAN.

(a) IN GENERAL.—Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended by adding the following subsection:

"(g) ACCELERATED APPROVAL DEVELOPMENT PLAN.—

"(1) IN GENERAL.—In the case of a drug that the Secretary determines may be eligible for accelerated approval in accordance with subsection (c), the sponsor of such drug may request, at any time after the submission of an application for the investigation of the drug under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act, that the Secretary agree to an accelerated approval development plan described in paragraph (2).

"(2) PLAN DESCRIBED.—A plan described in this paragraph, with respect to a drug described in paragraph (1), is an accelerated approval development plan, which shall include agreement on—

"(A) the surrogate endpoint to be assessed under such plan;

"(B) the design of the study that will utilize the surrogate endpoint; and

"(C) the magnitude of the effect of the drug on the surrogate endpoint that is the subject of the agreement that would be sufficient to form the primary basis of a claim that the drug is effective.

"(3) MODIFICATION; TERMINATION.—The Secretary may require the sponsor of a drug that is the subject of an accelerated approval development plan to modify or terminate the plan if additional data or information indicates that—

"(A) the plan as originally agreed upon is no longer sufficient to demonstrate the safety and effectiveness of the drug involved; or

"(B) the drug is no longer eligible for accelerated approval under subsection (c).

"(4) SPONSOR CONSULTATION.—If the Secretary requires the modification or termination of an accelerated approval development plan under paragraph (3), the sponsor shall be granted a request for a meeting to discuss the basis of the Secretary's decision before the effective date of the modification or termination.

"(5) DEFINITION.—In this section, the term 'accelerated approval development plan' means a development plan agreed upon by the Secretary and the sponsor submitting the plan that contains study parameters for the use of a surrogate endpoint that—

"(A) is reasonably likely to predict clinical benefit; and

"(B) is intended to be the basis of the accelerated approval of a drug in accordance with subsection (c).".

(b) TECHNICAL AMENDMENTS.—Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended—

(1) by striking "(f) AWARENESS EFFORTS" and inserting "(e) AWARENESS EFFORTS"; and

(2) by striking "(e) CONSTRUCTION" and inserting "(f) CONSTRUCTION".

Subtitle C—FDA Advancement of Precision Medicine

SEC. 2041. PRECISION MEDICINE GUIDANCE AND OTHER PROGRAMS OF FOOD AND DRUG ADMINISTRATION.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"Subchapter J—Precision Medicine

"SEC. 591. GENERAL AGENCY GUIDANCE ON PRECISION MEDICINE.

"(a) IN GENERAL.—The Secretary shall issue and periodically update guidance to assist sponsors in the development of a precision drug or biological product. Such guidance shall—

"(1) define the term 'precision drug or biological product'; and

"(2) address the topics described in subsection (b).

"(b) CERTAIN ISSUES.—The topics to be addressed by guidance under subsection (a) are—

"(1) the evidence needed to support the use of biomarkers (as defined in section 507(e)) that identify subsets of patients as likely responders to therapies in order to streamline the conduct of clinical trials;

"(2) recommendations for the design of studies to demonstrate the validity of a biomarker as a predictor of drug or biological product response;

"(3) the manner and extent to which a benefit-risk assessment may be affected when clinical trials are limited to patient population subsets that are identified using biomarkers;

"(4) the development of companion diagnostics in the context of a drug development program; and

"(5) considerations for developing biomarkers that inform prescribing decisions for a drug or biological product, and when information regarding a biomarker may be included in the approved prescription labeling for a precision drug or biological product.

"(c) DATE CERTAIN FOR INITIAL GUIDANCE.—The Secretary shall issue guidance under subsection (a) not later than 18 months after the date of the enactment of the 21st Century Cures Act.

"SEC. 592. PRECISION MEDICINE REGARDING ORPHAN-DRUG AND EXPEDITED-APPROVAL PROGRAMS.

"(a) IN GENERAL.—In the case of a precision drug or biological product that is the subject of an application submitted under section 505(b)(1), or section 351(a) of the Public Health Service Act, for the treatment of a serious or life-threatening disease or condition and has been designated under section 526 as a drug for a rare disease or condition, the Secretary may—

"(1) consistent with applicable standards for approval, rely upon data or information previously submitted by the sponsor of the precision drug or biological product, or another sponsor, provided that the sponsor of the precision drug or biological product has obtained a contractual right of reference to such other sponsor's data and information, in an application approved under section 505(c) or licensed under section 351(a) of the Public Health Service Act, as applicable—

"(A) for a different drug or biological product; or

"(B) for a different indication for such precision drug or biological product, in order to expedite clinical development for a precision drug or biological product that is using the same or similar approach as that used to support approval of the prior approved application or license, as appropriate; and

"(2) as appropriate, consider the application for approval of such precision drug or biological product to be eligible for expedited review and approval programs described in section 506, including accelerated approval in accordance with subsection (c) of such section.

"(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

"(1) limit the authority of the Secretary to approve products pursuant to this Act and the Public Health Service Act as authorized prior to the date of enactment of this section; or

"(2) confer any new rights, beyond those authorized under this Act prior to enactment of this section, with respect to a sponsor's ability to reference information contained in another application submitted under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act.".

Subtitle D—Modern Trial Design and Evidence Development

SEC. 2061. BROADER APPLICATION OF BAYESIAN STATISTICS AND ADAPTIVE TRIAL DESIGNS.

(a) PROPOSALS FOR USE OF INNOVATIVE STATISTICAL METHODS IN CLINICAL PROTOCOLS FOR DRUGS AND BIOLOGICAL PRODUCTS.—For purposes of assisting sponsors in incorporating adaptive trial design and Bayesian methods into proposed clinical protocols and applications for new drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and biological products under section 351 of the Public Health Service Act (42 U.S.C. 262), the Secretary shall conduct a public meeting and issue guidance in accordance with subsection (b).

(b) GUIDANCE ADDRESSING USE OF ADAPTIVE TRIAL DESIGNS AND BAYESIAN METHODS.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs (in this subsection referred to as the "Secretary"), shall—

(A) update and finalize the draft guidance addressing the use of adaptive trial design for drugs and biological products; and

(B) issue draft guidance on the use of Bayesian methods in the development and regulatory review and approval or licensure of drugs and biological products.

(2) CONTENTS.—The guidances under paragraph (1) shall address—

(A) the use of adaptive trial designs and Bayesian methods in clinical trials, including clinical trials proposed or submitted to help to satisfy the substantial evidence standard under section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d));

(B) how sponsors may obtain feedback from the Secretary on technical issues related to modeling and simulations prior to—

(i) completion of such modeling or simulations; or

(ii) the submission of resulting information to the Secretary;

(C) the types of quantitative and qualitative information that should be submitted for review; and

(D) recommended analysis methodologies.

(3) PUBLIC MEETING.—Prior to updating or developing the guidances required by paragraph (1), the Secretary shall consult with stakeholders, including representatives of regulated industry, academia, patient advocacy organizations, and disease research foundations, through a public meeting to be held not later than 1 year after the date of enactment of this Act.

(4) SCHEDULE.—The Secretary shall publish—

(A) the final guidance required by paragraph (1)(A) not later than 18 months after the date of the public meeting required by paragraph (3); and

(B) the guidance required by paragraph (1)(B) not later than 48 months after the date of the public meeting required by paragraph (3).

SEC. 2062. UTILIZING EVIDENCE FROM CLINICAL EXPERIENCE.

Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 505E of such Act (21 U.S.C. 355f) the following:

"SEC. 505F. UTILIZING EVIDENCE FROM CLINICAL EXPERIENCE.

"(a) IN GENERAL.—The Secretary shall establish a program to evaluate the potential use of evidence from clinical experience—

"(1) to help to support the approval of a new indication for a drug approved under section 505(b); and

"(2) to help to support or satisfy postapproval study requirements.

"(b) EVIDENCE FROM CLINICAL EXPERIENCE DEFINED.—In this section, the term 'evidence from clinical experience' means data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than randomized clinical trials, including from observational studies, registries, and therapeutic use.

"(c) PROGRAM FRAMEWORK.—

"(1) IN GENERAL.—Not later than 18 months after the date of enactment of this section, the Secretary shall establish a draft framework for implementation of the program under this section.

"(2) CONTENTS OF FRAMEWORK.—The framework shall include information describing—

"(A) the current sources of data developed through clinical experience, including ongoing safety surveillance, registry, claims, and patient-centered outcomes research activities;

"(B) the gaps in current data collection activities;

"(C) the current standards and methodologies for collection and analysis of data generated through clinical experience; and

"(D) the priority areas, remaining challenges, and potential pilot opportunities that the program established under this section will address.

"(3) CONSULTATION.—

"(A) IN GENERAL.—In developing the program framework under this subsection, the Secretary shall consult with regulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, disease research foundations, and other interested parties.

"(B) PROCESS.—The consultation under subparagraph (A) may be carried out through approaches such as—

"(i) a public-private partnership with the entities described in such subparagraph in which the Secretary may participate; or

"(ii) a contract, grant, or other arrangement, as determined appropriate by the Secretary with such a partnership or an independent research organization.

"(d) PROGRAM IMPLEMENTATION.—The Secretary shall, not later than 24 months after the date of enactment of this section and in accordance with the framework

established under subsection (c), implement the program to evaluate the potential use of evidence from clinical experience.

"(e) GUIDANCE FOR INDUSTRY.—The Secretary shall—

"(1) utilize the program established under subsection (a), its activities, and any subsequent pilots or written reports, to inform a guidance for industry on—

"(A) the circumstances under which sponsors of drugs and the Secretary may rely on evidence from clinical experience for the purposes described in subsection (a)(1) or (a)(2); and

"(B) the appropriate standards and methodologies for collection and analysis of evidence from clinical experience submitted for such purposes;

"(2) not later than 36 months after the date of enactment of this section, issue draft guidance for industry as described in paragraph (1); and

"(3) not later than 48 months after the date of enactment of this section, after providing an opportunity for public comment on the draft guidance, issue final guidance.

"(f) RULE OF CONSTRUCTION.—

"(1) Subject to paragraph (2), nothing in this section prohibits the Secretary from using evidence from clinical experience for purposes not specified in this section, provided the Secretary determines that sufficient basis exists for any such nonspecified use.

"(2) This section shall not be construed to alter—

"(A) the standards of evidence under—

"(i) subsection (c) or (d) of section 505, including the substantial evidence standard in such subsection (d); or

"(ii) section 351(a) of the Public Health Service Act; or

"(B) the Secretary's authority to require postapproval studies or clinical trials, or the standards of evidence under which studies or trials are evaluated.

"SEC. 505G. COLLECTING EVIDENCE FROM CLINICAL EXPERIENCE THROUGH TARGETED EXTENSIONS OF THE SENTINEL SYSTEM.

"(a) IN GENERAL.—The Secretary shall, in parallel to implementing the program established under section 505F and in order to build capacity for utilizing the evidence from clinical experience described in that section, identify and execute pilot demonstrations to extend existing use of the Sentinel System surveillance infrastructure authorized under section 505(k).

"(b) PILOT DEMONSTRATIONS.—

"(1) IN GENERAL.—The Secretary—

"(A) shall design and implement pilot demonstrations to utilize data captured through the Sentinel System surveillance infrastructure authorized under section 505(k) for purposes of, as appropriate—

"(i) generating evidence from clinical experience to improve characterization or assessment of risks or benefits of a drug approved under section 505(c);

"(ii) protecting the public health; or

"(iii) advancing patient-centered care; and

"(B) may make strategic linkages with sources of complementary public health data and infrastructure the Secretary determines appropriate and necessary.

"(2) CONSULTATION.—In developing the pilot demonstrations under this subsection, the Secretary shall—

"(A) consult with regulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, disease research foundations, and other interested parties through a public process; and

"(B) develop a framework to promote appropriate transparency and dialogue about research conducted under these pilot demonstrations, including by—

"(i) providing adequate notice to a sponsor of a drug approved under section 505 or section 351 of the Public Health Service Act of the Secretary's intent to conduct analyses of such sponsor's drug or drugs under these pilot demonstrations;

"(ii) providing adequate notice of the findings related to analyses described in clause (i) and an opportunity for the sponsor of such drug or drugs to comment on such findings; and

"(iii) ensuring the protection from public disclosure of any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

"(3) PUBLIC HEALTH EXEMPTION.—The Secretary may—

"(A) deem such pilot demonstrations public health activities, permitting the use and disclosure of protected health information as described in section 164.512(b)(1)(iii) of title 45, Code of Federal Regulations (or any successor regulation) and exempted as a public health activity as described in section 46.101(b)(5) of title 46, Code of Federal Regulations (or any successor regulation); and

"(B) deem safety surveillance performed at the request of the Food and Drug Administration or under such jurisdiction by a sponsor with responsibility for a drug approved under this section or section 351 of the Public Health Services Act using the Sentinel System surveillance infrastructure authorized under section 505(k), including use of analytic tools and querying capabilities developed to implement the active postmarket surveillance system described in this section, public health activities as described in section 164.512(b)(1)(iii) of title 45, Code of Federal Regulations (or any successor regulation) and exempted as a public health activity as described in section 46.101(b)(5) of title 46, Code of Federal Regulations (or any successor regulation).

"(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $3,000,000 for each of fiscal years 2016 through 2020.".

SEC. 2063. STREAMLINED DATA REVIEW PROGRAM.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by section 2062, is further amended by inserting after section 505G of such Act the following:

"SEC. 505H. STREAMLINED DATA REVIEW PROGRAM.

"(a) IN GENERAL.—The Secretary shall establish a streamlined data review program under which a holder of an approved application submitted under section 505(b)(1) or under section 351(a) of the Public Health Service Act may, to support the approval or licensure (as applicable) of the use of the drug that is the subject of such approved application for a new qualified indication, submit qualified data summaries.

"(b) ELIGIBILITY.—In carrying out the streamlined data review program under subsection (a), the Secretary may authorize the holder of the approved application to include one or more qualified data summaries described in subsection (a) in a supplemental application if—

"(1) the drug has been approved under section 505(c) of this Act or licensed under section 351(a) of the Public Health Service Act for one or more indications, and such approval or licensure remains in effect;

"(2) the supplemental application is for approval or licensure (as applicable) under such section 505(c) or 351(a) of the use of the drug for a new qualified indication under such section 505(c) or 351(a);

"(3) there is an existing database acceptable to the Secretary regarding the safety of the drug developed for one or more indications of the drug approved under such section 505(c) or licensed under such section 351(a);

"(4) the supplemental application incorporates or supplements the data submitted in the application for approval or licensure referred to in paragraph (1); and

"(5) the full data sets used to develop the qualified data summaries are submitted, unless the Secretary determines that the full data sets are not required.

"(c) PUBLIC AVAILABILITY OF INFORMATION ON PROGRAM.—The Secretary shall post on the public website of the Food and Drug Administration and update annually—

"(1) the number of applications reviewed under the streamlined data review program;

"(2) the average time for completion of review under the streamlined data review program versus other review of applications for new indications; and

"(3) the number of applications reviewed under the streamlined data review program for which the Food and Drug Administration made use of full data sets in addition to the qualified data summary.

"(d) DEFINITIONS.—In this section:

"(1) The term 'qualified indication' means—

"(A) an indication for the treatment of cancer, as determined appropriate by the Secretary; or

"(B) such other types of indications as the Secretary determines to be subject to the streamlined data review program under this section.

"(2) The term 'qualified data summary' means a summary of clinical data intended to demonstrate safety and effectiveness with respect to a qualified indication for use of a drug.".

(b) SENSE OF CONGRESS.—It is the sense of Congress that the streamlined data review program under section 505H of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), should enable the Food and Drug Administration to make approval decisions for certain supplemental applications based on qualified data summaries (as defined in such section 505H).

(c) GUIDANCE; REGULATIONS.—The Commissioner of Food and Drugs—

(1) shall—

(A) issue final guidance for implementation of the streamlined data review program established under section 505H of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), not later than 24 months after the date of enactment of this Act; and

(B) include in such guidance the process for expanding the types of indications to be subject to the streamlined data review program, as authorized by section 505H(c)(1)(B) of such Act; and

(2) in addition to issuing guidance under paragraph (1), may issue such regulations as may be necessary for implementation of the program.

Subtitle E—Expediting Patient Access

SEC. 2081. SENSE OF CONGRESS.

It is the sense of Congress that the Food and Drug Administration should continue to expedite the approval of drugs designated as breakthrough therapies pursuant to section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)) by approving drugs so designated as early as possible in the clinical development process, regardless of the phase of development, provided that the Secretary of Health and Human Services determines that an application for such a drug meets the standards of evidence of safety and effectiveness under section 505 of such Act (21 U.S.C. 355), including the substantial evidence standard under subsection (d) of such section or under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

SEC. 2082. EXPANDED ACCESS POLICY.

Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 561 (21 U.S.C. 360bbb) the following:

"SEC. 561A. EXPANDED ACCESS POLICY REQUIRED FOR INVESTIGATIONAL DRUGS.

"(a) IN GENERAL.—The manufacturer or distributor of one or more investigational drugs for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions shall make publicly available the policy of the manufacturer or distributor on evaluating and responding to requests submitted under section 561(b) for provision of such a drug. A manufacturer or distributor may satisfy the requirement of the preceding sentence by posting such policy as generally applicable to all of such manufacturer's or distributor's investigational drugs.

"(b) CONTENT OF POLICY.—A policy described in subsection (a) shall include making publicly available—

"(1) contact information for the manufacturer or distributor to facilitate communication about requests described in subsection (a);

"(2) procedures for making such requests;

"(3) the general criteria the manufacturer or distributor will consider or use to approve such requests; and

"(4) the length of time the manufacturer or distributor anticipates will be necessary to acknowledge receipt of such requests.

"(c) NO GUARANTEE OF ACCESS.—The posting of policies by manufacturers and distributors under subsection (a) shall not serve as a guarantee of access to any specific investigational drug by any individual patient.

"(d) REVISED POLICY.—A manufacturer or distributor that has made a policy publicly available as required by this section may revise the policy at any time.

"(e) APPLICATION.—This section shall apply to a manufacturer or distributor with respect to an investigational drug beginning on the later of—

"(1) the date that is 60 days after the date of enactment of the 21st Century Cures Act; or

"(2) the first initiation of a phase 2 or phase 3 study (as such terms are defined in section 312.21(b) and (c) of title 21, Code of Federal Regulations (or any successor regulations)) with respect to such investigational new drug.".

SEC. 2083. FINALIZING DRAFT GUIDANCE ON EXPANDED ACCESS.

(a) IN GENERAL.—Not later than 12 months after the date of enactment of this Act, the Secretary of Health and Human Services shall finalize the draft guidance

entitled "Expanded Access to Investigational Drugs for Treatment Use—Qs & As" and dated May 2013.

(b) CONTENTS.—The final guidance referred to in subsection (a) shall clearly define how the Secretary of Health and Human Services interprets and uses adverse drug event data reported by investigators in the case of data reported from use under a request submitted under section 561(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb(b)).

Subtitle F—Facilitating Responsible Manufacturer Communications

SEC. 2101. FACILITATING DISSEMINATION OF HEALTH CARE ECONOMIC INFORMATION.

Section 502(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(a)) is amended—

(1) by striking "(a) If its" and inserting "(a)(1) If its";

(2) by striking "a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations" and inserting "a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement";

(3) by striking "directly relates" and inserting "relates";

(4) by striking "and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a) or in section 351(a) of the Public Health Service Act shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph" and inserting ", is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug under section 505 or under section 351 of the Public Health Service Act. The requirements set forth in section 505(a) or in subsections (a) and (k) of section 351 of the Public Health Service Act shall not apply to health care economic information provided to such a payor, committee, or entity in accordance with this paragraph"; and

(5) by striking "In this paragraph, the term" and all that follows and inserting the following:

"(2)(A) For purposes of this paragraph, the term 'health care economic information' means any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences, which may be based on the separate or aggregated clinical consequences of the represented health outcomes, of the use of a drug. Such analysis may be comparative to the use of another drug, to another health care intervention, or to no intervention.

"(B) Such term does not include any analysis that relates only to an indication that is not approved under section 505 or under section 351 of the Public Health Service Act for such drug.".

SEC. 2102. FACILITATING RESPONSIBLE COMMUNICATION OF SCIENTIFIC AND MEDICAL DEVELOPMENTS.

(a) GUIDANCE.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue draft guidance on facilitating the responsible dissemination of truthful and nonmisleading scientific and medical information not included in the approved labeling of drugs and devices.

(b) DEFINITION.—In this section, the terms "drug" and "device" have the meaning given to such terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Subtitle G—Antibiotic Drug Development

SEC. 2121. APPROVAL OF CERTAIN DRUGS FOR USE IN A LIMITED POPULATION OF PATIENTS.

(a) PURPOSE.—The purpose of this section is to help to expedite the development and availability of treatments for serious or life-threatening bacterial or fungal infections in patients with unmet needs, while maintaining safety and effectiveness standards for such treatments, taking into account the severity of the infection and the availability or lack of alternative treatments.

(b) APPROVAL OF CERTAIN ANTIBACTERIAL AND ANTIFUNGAL DRUGS.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 2001, is further amended by adding at the end the following new subsection:

"(z) APPROVAL OF CERTAIN ANTIBACTERIAL AND ANTIFUNGAL DRUGS FOR USE IN A LIMITED POPULATION OF PATIENTS.—

"(1) PROCESS.—At the request of the sponsor of an antibacterial or antifungal drug that is intended to treat a serious or life-threatening infection, the Secretary—

"(A) may execute a written agreement with the sponsor on the process for developing data to support an application for approval of such drug, for use in a limited population of patients in accordance with this subsection;

"(B) shall proceed in accordance with this subsection only if a written agreement is reached under subparagraph (A);

"(C) shall provide the sponsor with an opportunity to request meetings under paragraph (2);

"(D) if a written agreement is reached under subparagraph (A), may approve the drug under this subsection for such use—

"(i) in a limited population of patients for which there is an unmet medical need;

"(ii) based on a streamlined development program; and

"(iii) only if the standards for approval under subsections (c) and (d) of this section or licensure under section 351 of the Public Health Service Act, as applicable, are met; and

"(E) in approving a drug in accordance with this subsection, subject to subparagraph (D)(iii), may rely upon—

"(i) traditional endpoints, alternate endpoints, or a combination of traditional and alternate endpoints, and, as appropriate, data sets of a limited size; and

"(ii)(I) additional data, including preclinical, pharmacologic, or pathophysiologic evidence;

"(II) nonclinical susceptibility and pharmacokinetic data;

"(III) data from phase 2 clinical trials; and

"(IV) such other confirmatory evidence as the Secretary determines appropriate to approve the drug.

"(2) FORMAL MEETINGS.—

"(A) IN GENERAL.—To help to expedite and facilitate the development and review of a drug for which a sponsor intends to request approval in accordance with this subsection, the Secretary may, at the request of the sponsor, conduct meetings that provide early consultation, timely advice, and sufficient opportunities to develop an agreement described in paragraph (1)(A) and help the sponsor design and conduct a drug development program as efficiently as possible, including the following types of meetings:

"(i) An early consultation meeting.

"(ii) An assessment meeting.

"(iii) A postapproval meeting.

"(B) NO ALTERING OF GOALS.—Nothing in this paragraph shall be construed to alter agreed upon goals and procedures identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012.

"(C) BREAKTHROUGH THERAPIES.—In the case of a drug designated as a breakthrough therapy under section 506(a), the sponsor of such drug may elect to utilize meetings provided under such section with respect to such drug in lieu of meetings described in subparagraph (A).

"(3) LABELING REQUIREMENT.—The labeling of an antibacterial or antifungal drug approved in accordance with this subsection shall contain the statement 'Limited Population' in a prominent manner and adjacent to, and not more prominent than, the brand name of the product. The prescribing information for such antibacterial or antifungal drug required by section 201.57 of title 21, Code of Federal Regulations (or any successor regulation) shall also include the following statement: 'This drug is indicated for use in a limited and specific population of patients.'.

"(4) PROMOTIONAL MATERIALS.—The provisions of section 506(c)(2)(B) shall apply with respect to approval in accordance with this subsection to the same extent and in the same manner as such provisions apply with respect to accelerated approval in accordance with section 506(c)(1).

"(5) TERMINATION OF REQUIREMENTS OR CONDITIONS.—If a drug is approved in accordance with this subsection for an indication in a limited population of patients and is subsequently approved or licensed under this section or section

351 of the Public Health Service Act, other than in accordance with this subsection, for—

"(A) the same indication and the same conditions of use, the Secretary shall remove any labeling requirements or postmarketing conditions that were made applicable to the drug under this subsection; or

"(B) a different indication or condition of use, the Secretary shall not apply the labeling requirements and postmarketing conditions that were made applicable to the drug under this subsection to the subsequent approval of the drug for such different indication or condition of use.

"(6) RELATION TO OTHER PROVISIONS.—Nothing in this subsection shall be construed to prohibit the approval of a drug for use in a limited population of patients in accordance with this subsection, in combination with—

"(A) an agreement on the design and size of a clinical trial pursuant to subparagraphs (B) and (C) of subsection (b)(5);

"(B) designation and treatment of the drug as a breakthrough therapy under section 506(a);

"(C) designation and treatment of the drug as a fast track product under section 506(b); or

"(D) accelerated approval of the drug in accordance with section 506(c).

"(7) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed—

"(A) to alter the standards of evidence under subsection (c) or (d) (including the substantial evidence standard in subsection (d));

"(B) to waive or otherwise preclude the application of requirements under subsection (o);

"(C) to otherwise, in any way, limit the authority of the Secretary to approve products pursuant to this Act and the Public Health Service Act as authorized prior to the date of enactment of this subsection; or

"(D) to restrict in any manner, the prescribing of antibiotics or other products by health care providers, or to otherwise limit or restrict the practice of health care.

"(8) EFFECTIVE IMMEDIATELY.—The Secretary shall have the authorities vested in the Secretary by this subsection beginning on the date of enactment of this subsection, irrespective of when and whether the Secretary promulgates final regulations or guidance.

"(9) DEFINITIONS.—In this subsection:

"(A) EARLY CONSULTATION MEETING.—The term 'early consultation meeting' means a pre-investigational new drug meeting or an end-of-phase-1 meeting that—

"(i) is conducted to review and reach a written agreement—

"(I) on the scope of the streamlined development plan for a drug for which a sponsor intends to request approval in accordance with this subsection; and

"(II) which, as appropriate, may include agreement on the design and size of necessary preclinical and clinical studies early in the development process, including clinical trials whose data are intended to form the primary basis for an effectiveness claim; and

"(ii) provides an opportunity to discuss expectations of the Secretary regarding studies or other information that the Secretary deems appropriate for purposes of applying paragraph (5), relating to the termination of labeling requirements or postmarketing conditions.

"(B) ASSESSMENT MEETING.—The term 'assessment meeting' means an end-of-phase 2 meeting, pre-new drug application meeting, or pre-biologics license application meeting conducted to resolve questions and issues raised during the course of clinical investigations, and details addressed in the written agreement regarding postapproval commitments or expansion of approved uses.

"(C) POSTAPPROVAL MEETING.—The term 'postapproval meeting' means a meeting following initial approval or licensure of the drug for use in a limited population, to discuss any issues identified by the Secretary or the sponsor regarding postapproval commitments or expansion of approved uses.".

(c) GUIDANCE.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue draft guidance describing criteria, process, and other general considerations for demonstrating the safety and effectiveness of antibacterial and antifungal drugs to be approved for use in a limited population in accordance with section 505(z) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b).

(d) CONFORMING AMENDMENTS.—

(1) LICENSURE OF CERTAIN BIOLOGICAL PRODUCTS.—Section 351(j) of the Public Health Service Act (42 U.S.C. 262(j)) is amended—

(A) by striking "(j)" and inserting "(j)(1)";

(B) by inserting "505(z)," after "505(p),"; and

(C) by adding at the end the following new paragraph:

"(2) In applying section 505(z) of the Federal Food, Drug, and Cosmetic Act to the licensure of biological products under this section—

"(A) references to an antibacterial or antifungal drug that is intended to treat a serious or life-threatening infection shall be construed to refer to a biological product intended to treat a serious or life-threatening bacterial or fungal infection; and

"(B) references to approval of a drug under section 505(c) of such Act shall be construed to refer to a licensure of a biological product under subsection (a) of this section.".

(2) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following new subsection:

"(dd) If it is a drug approved in accordance with section 505(z) and its labeling does not meet the requirements under paragraph (3) of such subsection, subject to paragraph (5) of such subsection.".

(e) EVALUATION.—

(1) ASSESSMENT.—Not later than 48 months after the date of enactment of this Act, the Secretary of Health and Human Services shall publish for public comment an assessment of the program established under section 505(z) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b). Such assessment shall determine if the limited-use pathway established under such section 505(z) has improved or is likely to improve patient access to novel antibacterial or antifungal treatments and assess how the pathway could be expanded to cover products for serious or life-threatening diseases or conditions beyond bacterial and fungal infections.

(2) MEETING.—Not later than 90 days after the date of the publication of such assessment, the Secretary, acting through the Commissioner of Food and Drugs, shall hold a public meeting to discuss the findings of the assessment, during which public stakeholders may present their views on the success of the program established under section 505(z) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b), and the appropriateness of expanding such program.

(f) EXPANSION OF PROGRAM.—If the Secretary of Health and Human Services determines, based on the assessment under subsection (e)(1), evaluation of the assessment, and any other relevant information, that the public health would benefit from expansion of the limited-use pathway established under section 505(z) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (b)) beyond the drugs approved in accordance with such section, the Secretary may expand such limited-use pathway in accordance with such a determination. The approval of any drugs under any such expansion shall be subject to the considerations and requirements described in such section 505(z) for purposes of expansion to other serious or life-threatening diseases or conditions.

(g) MONITORING.—The Public Health Service Act is amended by inserting after section 317T (42 U.S.C. 247b–22) the following:

"SEC. 317U. MONITORING ANTIBACTERIAL AND ANTIFUNGAL DRUG USE AND RESISTANCE.

"(a) MONITORING.—The Secretary shall use an appropriate monitoring system to monitor—

"(1) the use of antibacterial and antifungal drugs, including those receiving approval or licensure for a limited population pursuant to section 505(z) of the Federal Food, Drug, and Cosmetic Act; and

"(2) changes in bacterial and fungal resistance to drugs.

"(b) PUBLIC AVAILABILITY OF DATA.—The Secretary shall make summaries of the data derived from monitoring under this section publicly available for the purposes of—

"(1) improving the monitoring of important trends in antibacterial and antifungal resistance; and

"(2) ensuring appropriate stewardship of antibacterial and antifungal drugs, including those receiving approval or licensure for a limited population pursuant to section 505(z) of the Federal Food, Drug, and Cosmetic Act.".

SEC. 2122. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS.

(a) IN GENERAL.—Section 511 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a) is amended to read as follows:

"SEC. 511. IDENTIFYING AND UPDATING SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS.

"(a) PURPOSE; IDENTIFICATION OF CRITERIA.—

"(1) PURPOSE.—The purpose of this section is to provide the Secretary with an expedited, flexible method for—

"(A) clearance or premarket approval of antimicrobial susceptibility testing devices utilizing updated, recognized susceptibility test interpretive criteria to characterize the in vitro susceptibility of particular bacteria, fungi, or other microorganisms to antimicrobial drugs; and

"(B) providing public notice of the availability of recognized interpretive criteria to meet premarket submission requirements or other requirements under this Act for antimicrobial susceptibility testing devices.

"(2) IN GENERAL.—The Secretary shall identify appropriate susceptibility test interpretive criteria with respect to antimicrobial drugs—

"(A) if such criteria are available on the date of approval of the drug under section 505 of this Act or licensure of the drug under section 351 of the Public Health Service Act (as applicable), upon such approval or licensure; or

"(B) if such criteria are unavailable on such date, on the date on which such criteria are available for such drug.

"(3) BASES FOR INITIAL IDENTIFICATION.—The Secretary shall identify appropriate susceptibility test interpretive criteria under paragraph (2), based on the Secretary's review of, to the extent available and relevant—

"(A) preclinical and clinical data, including pharmacokinetic, pharmacodynamic, and epidemiological data;

"(B) Bayesian and pharmacometric statistical methodologies; and

"(C) such other evidence and information as the Secretary considers appropriate.

"(b) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA WEBSITE.—

"(1) IN GENERAL.—Not later than 1 year after the date of the enactment of the 21st Century Cures Act, the Secretary shall establish, and maintain thereafter, on the website of the Food and Drug Administration, a dedicated website that contains a list of any appropriate new or updated susceptibility test interpretive criteria standards in accordance with paragraph (2) (referred to in this section as the 'Interpretive Criteria Website').

"(2) LISTING OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA STANDARDS.—

"(A) IN GENERAL.—The list described in paragraph (1) shall consist of any new or updated susceptibility test interpretive criteria standards that are—

"(i) established by a nationally or internationally recognized standard development organization that—

"(I) establishes and maintains procedures to address potential conflicts of interest and ensure transparent decisionmaking;

"(II) holds open meetings to ensure that there is an opportunity for public input by interested parties, and establishes and maintains processes to ensure that such input is considered in decisionmaking; and

"(III) permits its standards to be made publicly available, through the National Library of Medicine or another similar source acceptable to the Secretary; and

"(ii) recognized in whole, or in part, by the Secretary under subsection (c).

"(B) OTHER LIST.—The Interpretive Criteria Website shall, in addition to the list described in subparagraph (A), include a list of interpretive criteria, if any, that the Secretary has determined to be appropriate with respect to legally marketed antimicrobial drugs, where—

"(i) the Secretary does not recognize, in whole or in part, an interpretive criteria standard described under subparagraph (A) otherwise applicable to such a drug;

"(ii) the Secretary withdraws under subsection (c)(1)(B) recognition of a standard, in whole or in part, otherwise applicable to such a drug;

"(iii) the Secretary approves an application under section 505 of this Act or section 351 of the Public Health Service Act, as applicable, with respect to marketing of such a drug for which there are no relevant interpretive criteria included in a standard recognized by the Secretary under subsection (c); or

"(iv) because the characteristics of such a drug differ from other drugs with the same active ingredient, the interpretive criteria with respect to such drug—

"(I) differ from otherwise applicable interpretive criteria included in a standard listed under subparagraph (A) or interpretive criteria otherwise listed under this subparagraph; and

"(II) are determined by the Secretary to be appropriate for the drug.

"(C) REQUIRED STATEMENTS OF LIMITATIONS OF INFORMATION.—The Interpretive Criteria Website shall include the following:

"(i) A statement that—

"(I) the website provides information about the susceptibility of bacteria, fungi, or other microorganisms to a certain drug (or drugs); and

"(II) the safety and efficacy of the drug in treating clinical infections due to such bacteria, fungi, or other microorganisms may not have been established in adequate and well-controlled clinical trials and the clinical significance of such susceptibility information in such trials is unknown.

"(ii) A statement that directs health care practitioners to consult the approved product labeling for specific drugs to determine the uses for which the Food and Drug Administration has approved the product.

"(iii) Any other statement that the Secretary determines appropriate to adequately convey the limitations of the data supporting susceptibility test interpretive criteria standard listed on the website.

"(3) NOTICE.—Not later than the date on which the Interpretive Criteria Website is established, the Secretary shall publish a notice of that establishment in the Federal Register.

"(4) INAPPLICABILITY OF MISBRANDING PROVISION.—The inclusion in the approved labeling of an antimicrobial drug of a reference or hyperlink to the Interpretive Criteria Website, in and of itself, shall not cause the drug to be misbranded in violation of section 502, or the regulations promulgated thereunder.

"(5) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code.

"(c) RECOGNITION OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FROM STANDARD DEVELOPMENT ORGANIZATIONS.—

"(1) IN GENERAL.—Beginning on the date of the establishment of the Interpretive Criteria Website, and at least every 6 months thereafter, the Secretary shall—

"(A) evaluate any appropriate new or updated susceptibility test interpretive criteria standards established by a nationally or internationally recognized standard development organization described in subsection (b)(2)(A)(i); and

"(B) publish on the public website of the Food and Drug Administration a notice—

"(i) withdrawing recognition of any different susceptibility test interpretive criteria standard, in whole or in part;

"(ii) recognizing the new or updated standards;

"(iii) recognizing one or more parts of the new or updated interpretive criteria specified in such a standard and declining to recognize the remainder of such standard; and

"(iv) making any necessary updates to the lists under subsection (b)(2).

"(2) BASES FOR UPDATING INTERPRETIVE CRITERIA STANDARDS.—In evaluating new or updated susceptibility test interpretive criteria standards under paragraph (1)(A), the Secretary may consider—

"(A) the Secretary's determination that such a standard is not applicable to a particular drug because the characteristics of the drug differ from other drugs with the same active ingredient;

"(B) information provided by interested third parties, including public comment on the annual compilation of notices published under paragraph (3);

"(C) any bases used to identify susceptibility test interpretive criteria under subsection (a)(2); and

"(D) such other information or factors as the Secretary determines appropriate.

"(3) ANNUAL COMPILATION OF NOTICES.—Each year, the Secretary shall compile the notices published under paragraph (1)(B) and publish such compilation in the Federal Register and provide for public comment. If the Secretary receives comments, the Secretary will review such comments and, if the Secretary

determines appropriate, update pursuant to this subsection susceptibility test interpretive criteria standards—

"(A) recognized by the Secretary under this subsection; or

"(B) otherwise listed on the Interpretive Criteria Website under subsection (b)(2).

"(4) RELATION TO SECTION 514(c).—Any susceptibility test interpretive standard recognized under this subsection or any criteria otherwise listed under subsection (b)(2)(B) shall be deemed to be recognized as a standard by the Secretary under section 514(c)(1).

"(5) VOLUNTARY USE OF INTERPRETIVE CRITERIA.—Nothing in this section prohibits a person from seeking approval or clearance of a drug or device, or changes to the drug or the device, on the basis of susceptibility test interpretive criteria standards which differ from those recognized pursuant to paragraph (1).

"(d) ANTIMICROBIAL DRUG LABELING.—

"(1) DRUGS MARKETED PRIOR TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—With respect to an antimicrobial drug lawfully introduced or delivered for introduction into interstate commerce for commercial distribution before the establishment of the Interpretive Criteria Website, a holder of an approved application under section 505 of this Act or section 351 of the Public Health Service Act, as applicable, for each such drug—

"(A) not later than 1 year after establishment of the Interpretive Criteria Website, shall submit to the Secretary a supplemental application for purposes of changing the drug's labeling to substitute a reference or hyperlink to such Website for any susceptibility test interpretive criteria and related information; and

"(B) may begin distribution of the drug involved upon receipt by the Secretary of the supplemental application for such change.

"(2) DRUGS MARKETED SUBSEQUENT TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—With respect to antimicrobial drugs lawfully introduced or delivered for introduction into interstate commerce for commercial distribution on or after the date of the establishment of the Interpretive Criteria Website, the labeling for such a drug shall include, in lieu of susceptibility test interpretive criteria and related information, a reference to such Website.

"(e) SPECIAL CONDITION FOR MARKETING OF ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

"(1) IN GENERAL.—Notwithstanding sections 501, 502, 510, 513, and 515, if the conditions specified in paragraph (2) are met (in addition to other applicable provisions under this chapter) with respect to an antimicrobial susceptibility testing device described in subsection (f)(1), the Secretary may authorize the marketing of such device for a use described in such subsection.

"(2) CONDITIONS APPLICABLE TO ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—The conditions specified in this paragraph are the following:

"(A) The device is used to make a determination of susceptibility using susceptibility test interpretive criteria that are—

"(i) included in a standard recognized by the Secretary under subsection (c); or

"(ii) otherwise listed on the Interpretive Criteria Website under subsection (b)(2).

"(B) The labeling of such device prominently and conspicuously—

"(i) includes a statement that—

"(I) the device provides information about the susceptibility of bacteria and fungi to certain drugs; and

"(II) the safety and efficacy of such drugs in treating clinical infections due to such bacteria or fungi may not have been established in adequate and well-controlled clinical trials and the clinical significance of such susceptibility information in those instances is unknown;

"(ii) includes a statement directing health care practitioners to consult the approved labeling for drugs tested using such a device, to determine the uses for which the Food and Drug Administration has approved such drugs; and

"(iii) includes any other statement the Secretary determines appropriate to adequately convey the limitations of the data supporting the interpretive criteria described in subparagraph (A).

"(f) DEFINITIONS.—In this section:

"(1) The term 'antimicrobial susceptibility testing device' means a device that utilizes susceptibility test interpretive criteria to determine and report the in vitro susceptibility of certain microorganisms to a drug (or drugs).

"(2) The term 'qualified infectious disease product' means a qualified infectious disease product designated under section 505E(d).

"(3) The term 'susceptibility test interpretive criteria' means—

"(A) one or more specific numerical values which characterize the susceptibility of bacteria or other microorganisms to the drug tested; and

"(B) related categorizations of such susceptibility, including categorization of the drug as susceptible, intermediate, resistant, or such other term as the Secretary determines appropriate.

"(4)(A) The term 'antimicrobial drug' means, subject to subparagraph (B), a systemic antibacterial or antifungal drug that—

"(i) is intended for human use in the treatment of a disease or condition caused by a bacterium or fungus;

"(ii) may include a qualified infectious disease product designated under section 505E(d); and

"(iii) is subject to section 503(b)(1).

"(B) If provided by the Secretary through regulations, such term may include—

"(i) drugs other than systemic antibacterial and antifungal drugs; and

"(ii) biological products (as such term is defined in section 351 of the Public Health Service Act) to the extent such products exhibit antimicrobial activity.

"(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

"(1) to alter the standards of evidence—

"(A) under subsection (c) or (d) of section 505, including the substantial evidence standard in section 505(d), or under section 351 of the Public Health Service Act (as applicable); or

"(B) with respect to marketing authorization for devices, under section 510, 513, or 515;

"(2) to apply with respect to any drug, device, or biological product, in any context other than—

"(A) an antimicrobial drug; or

"(B) an antimicrobial susceptibility testing device that uses susceptibility test interpretive criteria to characterize and report the in vitro susceptibility of certain bacteria, fungi, or other microorganisms to antimicrobial drugs in accordance with this section; or

"(3) unless specifically stated, to have any effect on authorities provided under other sections of this Act, including any regulations issued under such sections.".

(b) CONFORMING AMENDMENTS.—

(1) REPEAL OF RELATED AUTHORITY.—Section 1111 of the Food and Drug Administration Amendments Act of 2007 (42 U.S.C. 247d–5a; relating to identification of clinically susceptible concentrations of antimicrobials) is repealed.

(2) CLERICAL AMENDMENT.—The table of contents in section 2 of the Food and Drug Administration Amendments Act of 2007 is amended by striking the item relating to section 1111.

(3) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352), as amended by section 2121, is further amended by adding at the end the following:

"(ee) If it is an antimicrobial drug and its labeling fails to conform with the requirements under section 511(d).".

(4) RECOGNITION OF INTERPRETIVE CRITERIA AS DEVICE STANDARD.—Section 514(c)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)(1)(A)) is amended by inserting after "the Secretary shall, by publication in the Federal Register" the following: "(or, with respect to susceptibility test interpretive criteria or standards recognized or otherwise listed under section 511, by posting on the Interpretive Criteria Website in accordance with such section)".

(c) REPORT TO CONGRESS.—Not later than two years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report on the progress made in implementing section 511 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a), as amended by this section.

(d) REQUESTS FOR UPDATES TO INTERPRETIVE CRITERIA WEBSITE.—Chapter 35 of title 44, United States Code, shall not apply to the collection of information from interested parties regarding the updating of lists under paragraph (2) of subsection (b) section 511 of the Federal Food, Drug, and Cosmetic Act (as amended by subsection (a)) and posted on the Interpretive Criteria Website established under paragraph (1) of such subsection (b).

(e) NO EFFECT ON HEALTH CARE PRACTICE.—Nothing in this subtitle (including the amendments made by this subtitle) shall be construed to restrict, in any manner, the prescribing or administering of antibiotics or other products by health care practitioners, or to limit the practice of health care.

SEC. 2123. ENCOURAGING THE DEVELOPMENT AND USE OF NEW ANTIMICROBIAL DRUGS.

(a) ADDITIONAL PAYMENT FOR NEW ANTIMICROBIAL DRUGS UNDER MEDICARE.—

(1) IN GENERAL.—Section 1886(d)(5) of the Social Security Act (42 U.S.C. 1395ww(d)(5)) is amended by adding at the end the following new subparagraph:

"(M)(i) As part of the annual rulemaking under this subsection for payment for subsection (d) hospitals for each fiscal year beginning with fiscal year 2018, the Secretary shall—

"(I) include publication of a list of the new antimicrobial drugs for such fiscal year; and

"(II) with respect to discharges by eligible hospitals that involve a drug so published, provide for an additional payment to be made under this subsection in accordance with the provisions of this subparagraph.

"(ii) Additional payments may not be made for a drug under this subparagraph—

"(I) other than during the 5-fiscal-year period beginning with the fiscal year for which the drug is first included in the publication described in clause (i)(I); and

"(II) with respect to which payment has ever been made pursuant to subparagraph (K).

"(iii) For purposes of this subparagraph, the term 'new antimicrobial drug' means a product that is approved for use, or a product for which an indication is first approved for use, by the Food and Drug Administration on or after December 1, 2014, and that the Food and Drug Administration determines—

"(I) either—

"(aa) is intended to treat an infection caused by, or likely to be caused by, a qualifying pathogen (as defined under section 505E(f) of the Federal Food, Drug, and Cosmetic Act); or

"(bb) meets the definition of a qualified infectious disease product under section 505E(g) of the Federal Food, Drug, and Cosmetic Act; and

"(II) is intended to treat an infection—

"(aa) for which there is an unmet medical need; and

"(bb) which is associated with high rates of mortality or significant patient morbidity, as determined in consultation with the Director of the Centers for Disease Control and Prevention and the infectious disease professional community.

Such determination may be revoked only upon a finding that the request for such determination contained an untrue statement of material fact.

"(iv) For purposes of this subparagraph, the term 'eligible hospital' means a subsection (d) hospital that participates in the National Healthcare Safety Network of the Centers for Disease Control and Prevention (or, to the extent a similar surveillance system reporting program that includes reporting about antimicrobial drugs is determined by the Secretary to be available to such hospitals, such similar surveillance system as the Secretary may specify).

"(v)(I) Subject to the succeeding provisions of this clause, the additional payment under this subparagraph, with respect to a drug, shall be in the amount provided for such drug under section 1847A.

"(II) The Secretary shall, as part of the rulemaking referred to in clause (i) for each fiscal year, estimate—

"(aa) the total amount of the additional payments that will be made under this subsection pursuant to this subparagraph for discharges in such fiscal year without regard to the application of subclause (III); and

"(bb) the total program payments to be made under this subsection for all discharges in such fiscal year.

"(III) If the estimated total amount described in subclause (II)(aa) for a fiscal year exceeds the applicable percentage of the estimated total program payments described in subclause (II)(bb) for such fiscal year, the Secretary shall reduce in a pro rata manner the amount of each additional payment under this subsection pursuant to this subparagraph for such fiscal year in order to ensure that the total amount of the additional payments under this subsection pursuant to this subparagraph for such fiscal year do not exceed the applicable percentage of the estimated total program payments described in subclause (II)(bb) for such fiscal year.

"(IV) For purposes of subclause (III), the term 'applicable percentage' means 0.03 percent.".

(2) CONFORMING AMENDMENTS.—

(A) NO DUPLICATIVE NTAP PAYMENTS.—Section 1886(d)(5)(K)(vi) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)(vi)) is amended by inserting "if additional payment has never been made under this subsection pursuant to subparagraph (M) with respect to the service or technology" after "if the service or technology".

(B) ACCESS TO PRICE INFORMATION.—Section 1927(b)(3)(A)(iii) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(A)(iii)) is amended—

(i) in subclause (II), by inserting "or under section 1886(d) pursuant to paragraph (5)(M) of such section," after "1847A,"; and

(ii) in the matter following subclause (III), by inserting "or section 1886(d)(5)(M)" after "1881(b)(13)(A)(ii)".

(b) STUDY AND REPORT ON REMOVING BARRIERS TO DEVELOPMENT OF NEW ANTIMICROBIAL DRUGS.—

(1) STUDY.—The Comptroller General of the United States shall, in consultation with the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the Director of the Centers for Disease Control and Prevention, conduct a study to—

(A) identify and examine the barriers that prevent the development of new antimicrobial drugs, as defined in section 1886(d)(5)(M)(iii) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(M)(iii)), as added by subsection (a)(1); and

(B) develop recommendations for actions to be taken in order to overcome any barriers identified under subparagraph (A).

(2) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).

Subtitle H—Vaccine Access, Certainty, and Innovation

SEC. 2141. TIMELY REVIEW OF VACCINES BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.

Section 2102(a) of the Public Health Service Act (42 U.S.C. 300aa–2(a)) is amended by adding at the end the following:

"(10) ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.—

"(A) STANDARD PERIODS OF TIME FOR MAKING RECOMMENDATIONS.—Upon the licensure of any vaccine or any new indication for a vaccine, the Director of the Program shall direct the Advisory Committee on Immunization Practices, at its next regularly scheduled meeting, to consider the use of the vaccine.

"(B) EXPEDITED REVIEW PURSUANT TO REQUEST BY SPONSOR OR MANUFACTURER.—If the Advisory Committee does not make recommendations with respect to the use of a vaccine at the Advisory Committee's first regularly scheduled meeting after the licensure of the vaccine or any new indication for the vaccine, the Advisory Committee, at the request of the sponsor of the vaccine, shall make such recommendations on an expedited basis.

"(C) EXPEDITED REVIEW FOR BREAKTHROUGH THERAPIES AND FOR USE DURING PUBLIC HEALTH EMERGENCIES.—If a vaccine is designated as a breakthrough therapy under section 506 of the Federal Food, Drug, and Cosmetic Act and is licensed under section 351 of this Act, the Advisory Committee shall make recommendations with respect to the use of the vaccine on an expedited basis.

"(D) DEFINITION.—In this paragraph, the terms 'Advisory Committee on Immunization Practices' and 'Advisory Committee' mean the advisory committee on immunization practices established by the Secretary pursuant to section 222, acting through the Director of the Centers for Disease Control and Prevention.".

SEC. 2142. REVIEW OF PROCESSES AND CONSISTENCY OF ACIP RECOMMENDATIONS.

(a) REVIEW.—The Director of the Centers for Disease Control and Prevention shall conduct a review of the process used by the Advisory Committee on Immunization Practices to evaluate consistency in formulating and issuing recommendations pertaining to vaccines.

(b) CONSIDERATIONS.—The review under subsection (a) shall include assessment of—

(1) the criteria used to evaluate new and existing vaccines;

(2) the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach to the review and analysis of scientific and economic data, including the scientific basis for such approach; and

(3) the extent to which the processes used by the working groups of the Advisory Committee on Immunization Practices are consistent among groups.

(c) STAKEHOLDERS.—In carrying out the review under subsection (a), the Director of the Centers for Disease Control and Prevention shall solicit input from vaccine stakeholders.

(d) REPORT.—Not later than 18 months after the date of enactment of this Act, the Director of the Centers for Disease Control and Prevention shall submit to the appropriate committees of the Congress and make publicly available a report on the results of the review under subsection (a), including recommendations on improving the consistency of the process described in such subsection.

(e) DEFINITION.—In this section, the term "Advisory Committee on Immunization Practices" means the advisory committee on immunization practices established by the Secretary of Health and Human Services pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a), acting through the Director of the Centers for Disease Control and Prevention.

SEC. 2143. MEETINGS BETWEEN CDC AND VACCINE DEVELOPERS.

Section 310 of the Public Health Service Act (42 U.S.C. 242o) is amended by adding at the end the following:

"(c)(1) In this subsection, the term 'vaccine developer' means a nongovernmental entity engaged in—

"(A)(i) the development of a vaccine with the intent to pursue licensing of the vaccine by the Food and Drug Administration; or

"(ii) the production of a vaccine licensed by the Food and Drug Administration; and

"(B) vaccine research.

"(2)(A) Upon the submission of a written request for a meeting by a vaccine developer, that includes a justification for the meeting, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall convene a meeting of representatives of the vaccine developer and experts from the Centers for Disease Control and Prevention in immunization programs, epidemiology, and other relevant areas at which the Director (or the Director's designee), for the purpose of informing the vaccine developer's understanding of public health needs and priorities, shall provide the perspectives of the Centers for Disease Control and Prevention and other relevant Federal agencies regarding—

"(i) public health needs, epidemiology, and implementation considerations with regard to a vaccine developer's potential vaccine profile; and

"(ii) potential implications of such perspectives for the vaccine developer's vaccine research and development planning.

"(B) In addition to the representatives specified in subparagraph (A), the Secretary may, with the agreement of the vaccine developer requesting a meeting under such subparagraph, include in such meeting representatives of—

"(i) the Food and Drug Administration; and

"(ii) the National Vaccine Program.

"(C) The Secretary shall convene a meeting requested under subparagraph (A) not later than 120 days after receipt of the request for the meeting.

"(3)(A) Upon the submission of a written request by a vaccine developer, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall provide to the vaccine developer any age-based or other demographically assessed disease epidemiological analyses or data that—

"(i) are specified in the request;

"(ii) have been published;

"(iii) have been performed by or are in the possession of the Centers;

"(iv) are not a trade secret or commercial or financial information that is privileged or confidential and subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code; and

"(v) do not contain individually identifiable information.

"(B) The Secretary shall provide analyses requested by a vaccine manufacturer under subparagraph (A) not later than 120 calendar days after receipt of the request for the analyses.

"(4) The Secretary shall promptly notify a vaccine developer if—

"(A) the Secretary becomes aware of any change to information that was—

"(i) shared by the Secretary with the vaccine developer during a meeting under paragraph (2); or

"(ii) provided by the Secretary to the vaccine developer in one or more analyses under paragraph (3); and

"(B) the change to such information may have implications for the vaccine developer's vaccine research and development.".

Subtitle I—Orphan Product Extensions Now; Incentives for Certain Products for Limited Populations

SEC. 2151. EXTENSION OF EXCLUSIVITY PERIODS FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by sections 2062 and 2063, is further amended by inserting after section 505H of such Act the following:

"SEC. 505I. EXTENSION OF EXCLUSIVITY PERIODS FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.

"(a) DESIGNATION.—

"(1) IN GENERAL.—The Secretary shall designate a drug as a drug approved for a new indication to prevent, diagnose, or treat a rare disease or condition for purposes of granting the extensions under subsection (b) if—

"(A) prior to approval of an application or supplemental application for the new indication, the drug was approved or licensed for marketing under section 505(c) of this Act or section 351(a) of the Public Health Service Act, but was not so approved or licensed for the new indication;

"(B)(i) the sponsor of the approved or licensed drug files an application or a supplemental application for approval of the new indication for use of the drug to prevent, diagnose, or treat the rare disease or condition; and

"(ii) the Secretary approves the application or supplemental application; and

"(C) the application or supplemental application for the new indication contains the consent of the applicant to notice being given by the Secretary under paragraph (4) respecting the designation of the drug.

"(2) REVOCATION OF DESIGNATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), a designation under paragraph (1) shall not be revoked for any reason.

"(B) EXCEPTION.—The Secretary may revoke a designation of a drug under paragraph (1) if the Secretary finds that the application or supplemental application resulting in such designation contained an untrue statement of material fact.

"(3) NOTIFICATION PRIOR TO DISCONTINUANCE OF PRODUCTION FOR SOLELY COMMERCIAL REASONS.—A designation of a drug under paragraph (1) shall be subject to the condition that the sponsor of the drug will notify the Secretary of any discontinuance of the production of the drug for solely commercial reasons at least one year before such discontinuance.

"(4) NOTICE TO PUBLIC.—Notice respecting the designation of a drug under paragraph (1) shall be made available to the public.

"(b) EXTENSION.—If the Secretary designates a drug as a drug approved for a new indication for a rare disease or condition, as described in subsection (a)(1)—

"(1)(A) the 4-, 5-, and 7½-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 505, and the 7-year period described in section 527, as applicable, shall be extended by 6 months; or

"(B) the 4- and 12-year periods described in subparagraphs (A) and (B) of section 351(k)(7) of the Public Health Service Act and the 7-year period described in section 527, as applicable, shall be extended by 6 months; and

"(2)(A) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 or a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of 6 months after the date the patent expires (including any patent extensions); or

"(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or sec-

tion 505(j)(5)(B) shall be extended by a period of 6 months after the date the patent expires (including any patent extensions).

"(c) RELATION TO PEDIATRIC AND QUALIFIED INFECTIOUS DISEASE PRODUCT EXCLUSIVITY.—Any extension under subsection (b) of a period shall be in addition to any extension of the periods under sections 505A and 505E of this Act and section 351(m) of the Public Health Service Act, as applicable, with respect to the drug.

"(d) LIMITATIONS.—The extension described in subsection (b) shall not apply if the drug designated under subsection (a)(1) has previously received an extension by operation of subsection (b).

"(e) DEFINITION.—In this section, the term 'rare disease or condition' has the meaning given to such term in section 526(a)(2).".

(b) APPLICATION.—Section 505G of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to a drug for which an application or supplemental application described in subsection (a)(1)(B)(i) of such section 505G is first approved under section 505(c) of such Act (21 U.S.C. 355(c)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) on or after the date of the enactment of this Act.

(c) CONFORMING AMENDMENTS.—

(1) RELATION TO PEDIATRIC EXCLUSIVITY FOR DRUGS.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(A) in subsection (b), by adding at the end the following:

"(3) RELATION TO EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in paragraph (1) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in paragraph (1) shall be in addition to any extensions under section 505G."; and

(B) in subsection (c), by adding at the end the following:

"(3) RELATION TO EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in paragraph (1) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in paragraph (1) shall be in addition to any extensions under section 505G.".

(2) RELATION TO EXCLUSIVITY FOR NEW QUALIFIED INFECTIOUS DISEASE PRODUCTS THAT ARE DRUGS.—Subsection (b) of section 505E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355f) is amended—

(A) by amending the subsection heading to read as follows: "RELATION TO PEDIATRIC EXCLUSIVITY AND EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—"; and

(B) by striking "any extension of the period under section 505A" and inserting "any extension of the periods under sections 505A and 505G, as applicable,".

(3) RELATION TO PEDIATRIC EXCLUSIVITY FOR BIOLOGICAL PRODUCTS.—Section 351(m) of the Public Health Service Act (42 U.S.C. 262(m)) is amended by adding at the end the following:

"(5) RELATION TO EXCLUSIVITY FOR A BIOLOGICAL PRODUCT APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in paragraphs (2)(A), (2)(B), (3)(A), and (3)(B) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in such paragraphs shall be in addition to any extensions under section 505G.".

SEC. 2152. REAUTHORIZATION OF RARE PEDIATRIC DISEASE PRIORITY REVIEW VOUCHER INCENTIVE PROGRAM.

(a) IN GENERAL.—Section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) is amended—

(1) in subsection (a)—

(A) in paragraph (3), by amending subparagraph (A) to read as follows:

"(A) The disease is a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents."; and

(B) in paragraph (4)—

(i) in subparagraph (E), by striking "and" at the end;

(ii) in subparagraph (F), by striking the period at the end and inserting "; and"; and

(iii) by adding at the end the following:

"(G) is for a drug or biological product for which a priority review voucher has not been issued under section 524 (relating to tropical disease products)."; and

(2) in subsection (b), by striking paragraph (5) and inserting the following:

"(5) TERMINATION OF AUTHORITY.—The Secretary may not award any priority review vouchers under paragraph (1) after December 31, 2018.".

(b) GAO STUDY AND REPORT.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on the effectiveness of awarding priority review vouchers under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) in providing incentives for the development of drugs that treat or prevent rare pediatric diseases (as defined in subsection (a)(3) of such section) that would not otherwise have been developed. In conducting such study, the Comptroller General shall examine the following:

(A) The indications for which each drug for which a priority review voucher was awarded under such section 529 was approved under section 505 of such Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(B) Whether the priority review voucher impacted a sponsor's decision to invest in developing a drug to treat or prevent a rare pediatric disease.

(C) An analysis of the drugs that utilized such priority review vouchers, which shall include—

(i) the indications for which such drugs were approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262);

(ii) whether unmet medical needs were addressed through the approval of such drugs, including, for each such drug—

(I) if an alternative therapy was previously available to treat the indication; and

(II) the benefit or advantage the drug provided over another available therapy;

(iii) the number of patients potentially treated by such drugs;

(iv) the value of the priority review voucher if transferred; and

(v) the length of time between the date on which a priority review voucher was awarded and the date on which it was used.

(D) With respect to the priority review voucher program under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff)—

(i) the resources used by, and burden placed on, the Food and Drug Administration in implementing such program, including the effect of such program on the Food and Drug Administration's review of drugs for which a priority review voucher was not awarded or used;

(ii) the impact of the program on the public health as a result of the expedited review of applications for drugs that treat or prevent non-serious indications that are generally used by the broader public; and

(iii) alternative approaches to improving such program so that the program is appropriately targeted toward providing incentives for the development of clinically important drugs that—

(I) prevent or treat rare pediatric diseases; and

(II) would likely not otherwise have been developed to prevent or treat such diseases.

(2) REPORT.—Not later than December 31, 2017, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report containing the results of the study of conducted under paragraph (1).

Subtitle J—Domestic Manufacturing and Export Efficiencies

SEC. 2161. GRANTS FOR STUDYING THE PROCESS OF CONTINUOUS DRUG MANUFACTURING.

(a) IN GENERAL.—The Commissioner of Food and Drugs may award grants to institutions of higher education and nonprofit organizations for the purpose of studying and recommending improvements to the process of continuous manufacturing of drugs and biological products and similar innovative monitoring and control techniques.

(b) DEFINITIONS.—In this section:

(1) The term "drug" has the meaning given to such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(2) The term "biological product" has the meaning given to such term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(3) The term "institution of higher education" has the meaning given to such term in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001).

(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2016 through 2020.

SEC. 2162. RE-EXPORTATION AMONG MEMBERS OF THE EUROPEAN ECONOMIC AREA.

Section 1003 of the Controlled Substances Import and Export Act (21 U.S.C. 953) is amended—

(1) in subsection (f)—

(A) in paragraph (5)—

(i) by striking "(5)" and inserting "(5)(A)";

(ii) by inserting ", except that the controlled substance may be exported from the second country to another country that is a member of the European Economic Area" before the period at the end; and

(iii) by adding at the end the following:

"(B) Subsequent to any re-exportation described in subparagraph (A), a controlled substance may continue to be exported from any country that is a member of the European Economic Area to any other such country, provided that—

"(i) the conditions applicable with respect to the first country under paragraphs (1), (2), (3), (4), (6), and (7) are met by each subsequent country from which the controlled substance is exported pursuant to this paragraph; and

"(ii) the conditions applicable with respect to the second country under such paragraphs are met by each subsequent country to which the controlled substance is exported pursuant to this paragraph."; and

(B) in paragraph (6)—

(i) by striking "(6)" and inserting "(6)(A)"; and

(ii) by adding at the end the following:

"(B) In the case of re-exportation among members of the European Economic Area, within 30 days after each re-exportation, the person who exported the controlled substance from the United States delivers to the Attorney General—

"(i) documentation certifying that such re-exportation has occurred; and

"(ii) information concerning the consignee, country, and product."; and

(2) by adding at the end the following:

"(g) LIMITATION.—The Attorney General shall not promulgate nor enforce any regulation, subregulatory guidance, or enforcement policy which impedes re-exportation among European Economic Area countries (as provided in subsection (f)(5)), including by promulgating or enforcing any requirement that—

"(1) re-exportation from the first country to the second country or re-exportation from the second country to another country (as such terms are used in subsection (f)) occur within a specified period of time; or

"(2) information concerning the consignee, country, and product be provided prior to exportation of the controlled substance from the United States or prior to each re-exportation among members of the European Economic Area.".

Subtitle K—Enhancing Combination Products Review

SEC. 2181. ENHANCING COMBINATION PRODUCTS REVIEW.

Section 503(g)(4)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)(4)(C)) is amended by adding at the end the following new clause:

"(iii) Not later than 18 months after the date of the enactment of the 21st Century Cures Act, the Secretary shall issue final guidance that describes the responsibilities of each agency center regarding its review of combination products. The Secretary shall, after soliciting public comment, review and update the guidance periodically.".

Subtitle L—Priority Review for Breakthrough Devices

SEC. 2201. PRIORITY REVIEW FOR BREAKTHROUGH DEVICES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 515(d)—

(A) by striking paragraph (5); and

(B) by redesignating paragraph (6) as paragraph (5); and

(2) by inserting after section 515A (21 U.S.C. 360e–1) the following:

"SEC. 515B. PRIORITY REVIEW FOR BREAKTHROUGH DEVICES.

"(a) IN GENERAL.—In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, the Secretary shall establish a program to provide priority review for devices—

"(1) representing breakthrough technologies;

"(2) for which no approved alternatives exist;

"(3) offering significant advantages over existing approved or cleared alternatives, including the potential to, compared to existing approved or cleared alternatives, reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

"(4) the availability of which is in the best interest of patients.

"(b) REQUEST FOR DESIGNATION.—A sponsor of a device may request that the Secretary designate the device for priority review under this section. Any such request for designation may be made at any time prior to the submission of an application under section 515(c), a petition for classification under section 513(f)(2), or a notification under section 510(k).

"(c) DESIGNATION PROCESS.—

"(1) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under subsection (b), the Secretary shall determine whether the device that is the subject of the request meets the criteria described in subsection (a). If the Secretary determines that the device meets the criteria, the Secretary shall designate the device for priority review.

"(2) REVIEW.—Review of a request under subsection (b) shall be undertaken by a team that is composed of experienced staff and managers of the Food and Drug Administration and is chaired by a senior manager.

"(3) DESIGNATION DETERMINATION.—A determination approving or denying a request under subsection (b) shall be considered a significant decision under section 517A and the Secretary shall provide a written, substantive summary of the basis for the determination in accordance with section 517A(a).

"(4) RECONSIDERATION.—

"(A) REQUEST FOR RECONSIDERATION.—Any person whose request under subsection (b) is denied may, within 30 days of the denial, request reconsideration of the denial in accordance with section 517A(b)—

"(i) based upon the submission of documents by such person; or

"(ii) based upon such documents and a meeting or teleconference.

"(B) RESPONSE.—Reconsideration of a designation determination under this paragraph shall be conducted in accordance with section 517A(b).

"(5) WITHDRAWAL.—If the Secretary approves a priority review designation for a device under this section, the Secretary may not withdraw the designation based on the fact that the criteria specified in subsection (a) are no longer met because of the subsequent clearance or approval of another device that was designated under—

"(A) this section; or

"(B) section 515(d)(5) (as in effect immediately prior to the enactment of the 21st Century Cures Act).

"(d) PRIORITY REVIEW.—

"(1) ACTIONS.—For purposes of expediting the development and review of devices designated under subsection (c), the Secretary shall—

"(A) assign a team of staff, including a team leader with appropriate subject matter expertise and experience, for each device for which a request is submitted under subsection (b);

"(B) provide for oversight of the team by senior agency personnel to facilitate the efficient development of the device and the efficient review of any submission described in subsection (b) for the device;

"(C) adopt an efficient process for timely dispute resolution;

"(D) provide for interactive communication with the sponsor of the device during the review process;

"(E) expedite the Secretary's review of manufacturing and quality systems compliance, as applicable;

"(F) disclose to the sponsor in advance the topics of any consultation concerning the sponsor's device that the Secretary intends to undertake with external experts or an advisory committee and provide the sponsor an opportunity to recommend such external experts;

"(G) for applications submitted under section 515(c), provide for advisory committee input, as the Secretary determines appropriate (including in response to the request of the sponsor); and

"(H) assign staff to be available within a reasonable time to address questions posed by institutional review committees concerning the conditions and clinical testing requirements applicable to the investigational use of the device pursuant to an exemption under section 520(g).

"(2) ADDITIONAL ACTIONS.—In addition to the actions described in paragraph (1), for purposes of expediting the development and review of devices designated under subsection (c), the Secretary, in collaboration with the device sponsor, may, as appropriate—

"(A) coordinate with the sponsor regarding early agreement on a data development plan;

"(B) take steps to ensure that the design of clinical trials is as efficient as practicable, such as through adoption of shorter or smaller clinical trials, application of surrogate endpoints, and use of adaptive trial designs and Bayesian statistics, to the extent scientifically appropriate;

"(C) facilitate, to the extent scientifically appropriate, expedited and efficient development and review of the device through utilization of timely postmarket data collection, with regard to applications for approval under section 515(c); and

"(D) agree to clinical protocols that the Secretary will consider binding on the Secretary and the sponsor, subject to—

"(i) changes agreed to by the sponsor and the Secretary;

"(ii) changes that the Secretary determines are required to prevent an unreasonable risk to the public health; or

"(iii) the identification of a substantial scientific issue determined by the Secretary to be essential to the safety or effectiveness of the device involved.

"(e) PRIORITY REVIEW GUIDANCE.—

"(1) CONTENT.—The Secretary shall issue guidance on the implementation of this section. Such guidance shall include the following:

"(A) The process for a person to seek a priority review designation.

"(B) A template for requests under subsection (b).

"(C) The criteria the Secretary will use in evaluating a request for priority review.

"(D) The standards the Secretary will use in assigning a team of staff, including team leaders, to review devices designated for priority review, including any training required for such personnel on effective and efficient review.

"(2) PROCESS.—Prior to finalizing the guidance under paragraph (1), the Secretary shall propose such guidance for public comment.

"(f) CONSTRUCTION.—

"(1) PURPOSE.—This section is intended to encourage the Secretary and provide the Secretary sufficient authorities to apply efficient and flexible approaches to expedite the development of, and prioritize the agency's review of, devices that represent breakthrough technologies.

"(2) CONSTRUCTION.—Nothing in this section shall be construed to alter the criteria and standards for evaluating an application pursuant to section 515(c), a report and request for classification under section 513(f)(2), or a report under section 510(k), including the recognition of valid scientific evidence as described in section 513(a)(3)(B), and consideration of the least burdensome means of evaluating device effectiveness or demonstrating substantial equivalence between devices with differing technological characteristics, as applicable. Nothing in this section alters the authority of the Secretary to act on an application pursuant to section 515(d) before completion of an establishment inspection, as the Secretary deems appropriate.".

(b) CONFORMING AMENDMENT RELATED TO DESIGNATION DETERMINATIONS.—Section 517A(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–1(a)(1)) is amended by inserting "a request for designation under section 515B," after "an application under section 515,".

Subtitle M—Medical Device Regulatory Process Improvements

SEC. 2221. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.

(a) ESTABLISHMENT OF THIRD-PARTY QUALITY SYSTEM ASSESSMENT PROGRAM.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 524A (21 U.S.C. 360n–1) the following new section:

"SEC. 524B. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.

"(a) ACCREDITATION AND ASSESSMENT.—

"(1) IN GENERAL; CERTIFICATION OF DEVICE QUALITY SYSTEM.—The Secretary shall, in accordance with this section, establish a third-party quality system assessment program—

"(A) to accredit persons to assess whether a requestor's quality system, including its design controls, can reasonably assure the safety and effectiveness of in-scope devices subject to device-related changes;

"(B) under which accredited persons shall (as applicable) certify that a requestor's quality system meets the criteria included in the guidance issued under paragraph (5) with respect to the in-scope devices at issue; and

"(C) under which the Secretary shall rely on such certifications for purposes of determining the safety and effectiveness (or as applicable, substantial equivalence) of in-scope devices subject to the device-related changes involved, in lieu of compliance with the following submission requirements:

"(i) A premarket notification.

"(ii) A thirty-day notice.

"(iii) A Special PMA supplement.

"(2) DEFINITIONS.—For purposes of this section-

"(A) the term 'device-related changes' means changes made by a requestor with respect to in-scope devices, which are—

"(i) changes to a device found to be substantially equivalent under sections 513(i) and 510(k) to a predicate device, that—

"(I) would otherwise be subject to a premarket notification; and

"(II) do not alter—

"(aa) the intended use of the changed device; or

"(bb) the fundamental scientific technology of such device;

"(ii) manufacturing changes subject to a 30-day notice;

"(iii) changes that qualify for a Special PMA Supplement; and

"(iv) such other changes relating to the devices or the device manufacturing process as the Secretary determines appropriate;

"(B) the term 'in-scope device' means a device within the scope of devices agreed to by the requestor and the accredited person for purposes of a request for certification under this section;

"(C) the term 'premarket notification' means a premarket notification under section 510(k);

"(D) the term 'quality system' means the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of devices, as described in section 520(f);

"(E) the term 'requestor' means a device manufacturer that is seeking certification under this section of a quality system used by such manufacturer;

"(F) the term 'Special PMA' means a Special PMA supplement under section 814.39(d) of title 21, Code of Federal Regulations (or any successor regulations); and

"(G) the term 'thirty-day notice' means a notice described in section 515(d)(6).

"(3) ACCREDITATION PROCESS; ACCREDITATION RENEWAL.—Except as inconsistent with this section, the process and qualifications for accreditation of persons and renewal of such accreditation under section 704(g) shall apply with respect to accreditation of persons and renewal of such accreditation under this section.

"(4) USE OF ACCREDITED PARTIES TO CONDUCT ASSESSMENTS.—

"(A) INITIATION OF ASSESSMENT SERVICES.—

"(i) DATE ASSESSMENTS AUTHORIZED.—Beginning after the date on which the final guidance is issued under paragraph (5), an accredited person may conduct an assessment under this section.

"(ii) INITIATION OF ASSESSMENTS.—Use of one or more accredited persons to assess a requestor's quality system under this section with re-

spect to in-scope devices shall be at the initiation of the person who registers and lists the devices at issue under section 510.

"(B) COMPENSATION.—Compensation for such accredited persons shall—

"(i) be determined by agreement between the accredited person and the person who engages the services of the accredited person; and

"(ii) be paid by the person who engages such services.

"(C) ACCREDITED PERSON SELECTION.—Each person who chooses to use an accredited person to assess a requestor's quality system, as described in this section, shall select the accredited person from a list of such persons published by the Secretary in accordance with section 704(g)(4).

"(5) GUIDANCE; CRITERIA FOR CERTIFICATION.—

"(A) IN GENERAL.—The criteria for certification of a quality system under this section shall be as specified by the Secretary in guidance issued under this paragraph.

"(B) CONTENTS; CERTIFICATION CRITERIA.—The guidance under this paragraph shall include specification of—

"(i) evaluative criteria to be used by an accredited person to assess and, as applicable, certify a requestor's quality system under this section with respect to in-scope devices; and

"(ii) criteria for accredited persons to apply for a waiver of, and exemptions from, the certification criteria under clause (i).

"(C) TIMEFRAME FOR ISSUING GUIDANCE.—The Secretary shall issue under this paragraph—

"(i) draft guidance not later than 12 months after the enactment of the 21st Century Cures Act; and

"(ii) final guidance not later than 12 months after issuance of the draft guidance under clause (i).

"(b) USE OF THIRD-PARTY ASSESSMENT.—

"(1) ASSESSMENT SUMMARY; CERTIFICATION.—

"(A) SUBMISSION OF ASSESSMENT TO SECRETARY.—An accredited person who assesses a requestor's quality system under subsection (a) shall submit to the Secretary a summary of the assessment—

"(i) within 30 days of the assessment; and

"(ii) which shall include (as applicable)—

"(I) the accredited person's certification that the requestor has satisfied the criteria specified in the guidance issued under subsection (a)(5) for quality system certification with respect to the in-scope devices at issue; and

"(II) any waivers or exemptions from such criteria applied by the accredited person.

"(B) TREATMENT OF ASSESSMENTS.—Subject to action by the Secretary under subparagraph (C), with respect to assessments which include a certification under this section—

"(i) the Secretary's review of the assessment summary shall be deemed complete on the day that is 30 days after the date on which the Secretary receives the summary under subparagraph (A); and

"(ii) the assessment summary and certification of the quality system of a requestor shall be deemed accepted by the Secretary on such 30th day.

"(C) ACTIONS BY SECRETARY.—

"(i) IN GENERAL.—Within 30 days of receiving an assessment summary and certification under subparagraph (A), the Secretary may, by written notice to the accredited person submitting such assessment certification, deem any such certification to be provisional beyond such 30-day period, suspended pending further review by the Secretary, or otherwise qualified or cancelled, based on the Secretary's determination that (as applicable)—

"(I) additional information is needed to support such certification;

"(II) such assessment or certification is unwarranted; or

"(III) such action with regard to the certification is otherwise justified according to such factors and criteria as the Secretary finds appropriate.

"(ii) ACCEPTANCE OF CERTIFICATION.—If following action by the Secretary under clause (i) with respect to a certification, the Secretary determines that such certification is acceptable, the Secretary shall issue written notice to the applicable accredited person indicating such acceptance.

"(2) NOTIFICATIONS TO SECRETARY BY CERTIFIED REQUESTORS OR ACCREDITED PERSONS FOR PROGRAM EVALUATION PURPOSES.—

"(A) ANNUAL SUMMARY REPORT FOR DEVICE-RELATED CHANGES OTHERWISE SUBJECT TO PREMARKET NOTIFICATION.—A requestor whose quality system is certified under this section that effectuates device-related changes with respect to in-scope devices, without prior submission of a premarket notification, shall ensure that an annual summary report is submitted to the Secretary by the accredited person which—

"(i) describes the changes made to the in-scope device; and

"(ii) indicates the effective dates of such changes.

"(B) PERIODIC NOTIFICATION FOR MANUFACTURING CHANGES OTHERWISE SUBJECT TO THIRTY-DAY NOTICE.—A requestor whose quality system is certified under this section that effectuates device-related changes with respect to in-scope devices, without prior submission of a thirty-day notice, shall provide notification to the Secretary of such changes in the requestor's next periodic report under section 814.84(b) of title 21, Code of Federal Regulations (or any successor regulation). Such notification shall—

"(i) describe the changes made; and

"(ii) indicate the effective dates of such changes.

"(C) PERIODIC NOTIFICATION FOR DEVICE-RELATED CHANGES OTHERWISE SUBJECT TO SPECIAL PMA SUPPLEMENT.—A requestor whose quality system is certified under this section that effectuates device-related changes with respect to in-scope devices, without prior submission of a Special PMA Supplement, shall provide notification to the Secretary of such changes in the requestor's next periodic report under section 814.84(b) of title 21, Code of Federal Regulations (or any successor regulation). Such notification shall—

"(i) describe the changes made, including a full explanation of the basis for the changes; and

"(ii) indicate the effective dates of such changes.

"(D) USE OF NOTIFICATIONS FOR PROGRAM EVALUATION PURPOSES.—Information submitted to the Secretary under subparagraphs (A) through (C) shall be used by the Secretary for purposes of the program evaluation under subsection (d).

"(c) DURATION AND EFFECT OF CERTIFICATION.—A certification under this section—

"(1) shall remain in effect for a period of 2 years from the date such certification is accepted by the Secretary, subject to paragraph (6);

"(2) may be renewed through the process described in subsection (a)(3);

"(3) shall continue to apply with respect to device-related changes made during such 2-year period, provided the certification remains in effect, irrespective of whether such certification is renewed after such 2-year period;

"(4) shall have no effect on the need to comply with applicable submission requirements specified in subsection (a)(1)(C) with respect to any change pertaining to in-scope devices which is not a device-related change under subsection (a)(2);

"(5) shall have no effect on the authority of the Secretary to conduct an inspection or otherwise determine whether the requestor has complied with the applicable requirements of this Act; and

"(6) may be revoked by the Secretary upon a determination that the requestor's quality system no longer meets the certification criteria specified in the guidance issued under subsection (a)(5) with respect to the in-scope devices at issue.

"(d) NOTICE OF REVOCATION.—The Secretary shall provide written notification to the requestor of a revocation pursuant to subsection (c)(6) not later than 10 business days after the determination described in such subsection. Upon receipt of the written notification, the requestor shall satisfy the applicable submission requirements specified in subsection (a)(1)(C) for any device-related changes effectuated after the date of such determination. After such revocation, such requestor is eligible to seek re-certification under this section of its quality system.

"(e) PROGRAM EVALUATION; SUNSET.—

"(1) PROGRAM EVALUATION AND REPORT.—

"(A) EVALUATION.—The Secretary shall complete an evaluation of the third-party quality system assessment program under this section no later than January 31, 2021, based on—

"(i) analysis of information from a representative group of device manufacturers obtained from notifications provided by certified requestors or accredited persons under subsection (b)(2); and

"(ii) such other available information and data as the Secretary determines appropriate.

"(B) REPORT.—No later than 1 year after completing the evaluation under subparagraph (A), the Secretary shall issue a report of the evaluation's

findings on the website of the Food and Drug Administration, which shall include the Secretary's recommendations with respect to continuation and as applicable expansion of the program under this section to encompass—

"(i) device submissions beyond those identified in subsection (a)(1)(C); and

"(ii) device changes beyond those described in subsection (a)(2)(A).

"(2) SUNSET.—This section shall cease to be effective October 1, 2022.

"(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the authority of the Secretary to request and review the complete assessment of a certified requestor under this section on a for-cause basis.".

(b) CONFORMING AMENDMENTS.—

(1) REQUIREMENTS FOR PREMARKET APPROVAL SUPPLEMENTS.—Section 515(d)(5)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)(5)(A)(i)), as redesignated by section 2201, is further amended by inserting ", subject to section 524B" after "that affects safety or effectiveness".

(2) REQUIREMENTS FOR THIRTY-DAY NOTICE.—Section 515(d)(5)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)(5)(A)(ii)), as redesignated by section 2201, is further amended by inserting ", subject to section 524B" after "the date on which the Secretary receives the notice".

(3) REQUIREMENTS FOR PREMARKET NOTIFICATION; TECHNICAL CORRECTION TO REFERENCE TO SECTION 510(K).—Section 510(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is amended by striking "of this subsection under subsection (m)" and inserting "of subsection (k) under subsection (m) or section 524B".

(4) MISBRANDED DEVICES.—Section 502(t) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(t)) is amended by inserting "or 524B" after "section 519".

SEC. 2222. VALID SCIENTIFIC EVIDENCE.

Section 513(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(a)(3)(B)) is amended—

(1) by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively;

(2) by striking "(B) If the Secretary" and inserting "(B)(i) If the Secretary"; and

(3) by adding at the end the following:

"(ii) For purposes of clause (i), valid scientific evidence may include—

"(I) evidence described in well-documented case histories, including registry data, that are collected and monitored under an acceptable protocol;

"(II) studies published in peer-reviewed journals; and

"(III) data collected in countries other than the United States so long as such data otherwise meet the criteria specified in this subparagraph.

"(iii) In the case of a study published in a peer-reviewed journal that is offered as valid scientific evidence for purposes of clause (i), the Secretary may request data underlying the study if—

"(I) the Secretary, in making such request, complies with the requirement of subparagraph (D)(ii) to consider the least burdensome appropriate means of evaluating device effectiveness or subsection (i)(1)(D) to consider the least burdensome means of determining substantial equivalence, as applicable;

"(II) the Secretary furnishes a written rationale for so requesting the underlying data together with such request; and

"(III) if the requested underlying data for such a study are unavailable, the Secretary shall consider such study to be part of the totality of the evidence with respect to the device, as the Secretary determines appropriate.".

SEC. 2223. TRAINING AND OVERSIGHT IN LEAST BURDENSOME APPROPRIATE MEANS CONCEPT.

(a) IN GENERAL.—Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by adding at the end the following:

"(j) TRAINING AND OVERSIGHT IN LEAST BURDENSOME APPROPRIATE MEANS CONCEPT.—

"(1) TRAINING.—Each employee of the Food and Drug Administration who is involved in the review of premarket submissions under section 515 or section 510(k), including supervisors, shall receive training regarding the meaning and implementation of the least burdensome appropriate means concept in the context of the use of that term in subsections (a)(3)(D) and (i)(1)(D) of this section and in section 515(c)(5).

"(2) GUIDANCE DOCUMENTS.—

"(A) DRAFT UPDATED GUIDANCE.—Not later than 12 months after the date of enactment of the 21st Century Cures Act, the Secretary shall issue a draft guidance document updating the October 4, 2002, guidance document

entitled 'The Least Burdensome Provision of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry'.

"(B) MEETING OF STAKEHOLDERS.—In developing such draft guidance document, the Secretary shall convene a meeting of stakeholders to ensure a full record to support the publication of such document.

"(3) OMBUDSMAN AUDIT.—Not later than 18 months after the date of issuance of final version of the draft guidance under paragraph (2), the ombudsman for the organizational unit of the Food and Drug Administration responsible for the premarket review of devices shall—

"(A) conduct, or have conducted, an audit of the training described in paragraph (1); and

"(B) include in such audit interviews with a representative sample of persons from industry regarding their experience in the device premarket review process.".

(b) ADDITIONAL INFORMATION REGARDING PREMARKET APPLICATIONS.—Subsection (c) of section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) is amended by adding at the end the following:

"(5)(A) Whenever the Secretary requests additional information from an applicant regarding an application under paragraph (1), the Secretary shall consider the least burdensome appropriate means necessary to demonstrate device safety and effectiveness, and request information accordingly.

"(B) For purposes of subparagraph (A), the term 'necessary' means the minimum required information that would support a determination by the Secretary that an application provides a reasonable assurance of the safety and effectiveness of the device.

"(C) Nothing in this paragraph alters the standards for premarket approval of a device.".

SEC. 2224. RECOGNITION OF STANDARDS.

Section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)) is amended—

(1) in paragraph (1), by inserting after subparagraph (B) the following new subparagraphs:

"(C)(i) Any person may submit a request for recognition under subparagraph (A) of all or part of an appropriate standard established by a nationally or internationally recognized standard organization.

"(ii) Not later than 60 days after the Secretary receives such a request, the Secretary shall—

"(I) make a determination to recognize all, part, or none of the standard that is the subject of the request; and

"(II) issue to the person who submitted such request a response in writing that states the Secretary's rationale for that determination, including the scientific, technical, regulatory, or other basis for such determination.

"(iii) The Secretary shall make a response issued under clause (ii)(II) publicly available, in such manner as the Secretary determines appropriate.

"(iv) The Secretary shall take such actions as may be necessary to implement all or part of a standard recognized under clause (i)(I), in accordance with subparagraph (A).

"(D) The Secretary shall make publicly available, in such manner as the Secretary determines appropriate, the rationale for recognition under subparagraph (A) of part of a standard, including the scientific, technical, regulatory, or other basis for such recognition."; and

(2) by adding at the end the following new paragraphs:

"(4) TRAINING ON USE OF STANDARDS.—The Secretary shall provide to all employees of the Food and Drug Administration who review premarket submissions for devices periodic training on the concept and use of recognized standards for purposes of meeting a premarket submission requirement or other applicable requirement under this Act, including standards relevant to an employee's area of device review.

"(5) GUIDANCE.—

"(A) DRAFT GUIDANCE.—The Secretary shall publish guidance identifying the principles for recognizing standards under this section. In publishing such guidance, the Secretary shall consider—

"(i) the experience with, and reliance on, a standard by other Federal regulatory authorities and the device industry; and

"(ii) whether recognition of a standard will promote harmonization among regulatory authorities in the regulation of devices.

"(B) TIMING.—The Secretary shall publish—

"(i) draft guidance under subparagraph (A) not later than 12 months after the date of the enactment of the 21st Century Cures Act; and

"(ii) final guidance not later than 12 months after the close of the public comment period for the draft guidance under clause (i).".

SEC. 2225. EASING REGULATORY BURDEN WITH RESPECT TO CERTAIN CLASS I AND CLASS II DEVICES.

(a) CLASS I DEVICES.—Section 510(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is amended—

(1) by striking "A report under subsection (k)" and inserting "(1) A report under subsection (k)"; and

(2) by adding at the end the following new paragraph:

"(2) Not later than 120 days after the date of the enactment of the 21st Century Cures Act, the Secretary shall identify, through publication in the Federal Register, any type of class I device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Upon such publication—

"(A) each type of class I device so identified shall be exempt from the requirement for a report under subsection (k); and

"(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.".

(b) CLASS II DEVICES.—Section 510(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)) is amended—

(1) by striking paragraph (1) and inserting the following new paragraph: "(1) The Secretary shall—

"(A) not later than 60 days after the date of the enactment of the 21st Century Cures Act—

"(i) publish in the Federal Register a notice that contains a list of each type of class II device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness; and

"(ii) provide for a period of not less than 60 days for public comment beginning on the date of the publication of such notice; and

"(B) not later than 180 days after the date of the enactment of 21st Century Cures Act, publish in the Federal Register a list representing the Secretary's final determination with respect to the devices included in the list published under subparagraph (A).";

(2) in paragraph (2)—

(A) by striking "1 day after the date of the publication of a list under this subsection," and inserting "1 day after the date of publication of the final list under paragraph (1)(B),"; and

(B) by striking "30-day period" and inserting "60-day period"; and

(3) by adding at the end the following new paragraph:

"(3) Upon the publication of the final list under paragraph (1)(B)—

"(A) each type of class II device so listed shall be exempt from the requirement for a report under subsection (k); and

"(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.".

SEC. 2226. ADVISORY COMMITTEE PROCESS.

(a) CLASSIFICATION PANELS.—Paragraph (5) of section 513(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)) is amended—

(1) by striking "(5)" and inserting "(5)(A)"; and

(2) by adding at the end the following:

"(B) When a device is specifically the subject of review by a classification panel, the Secretary shall—

"(i) ensure that adequate expertise is represented on the classification panel to assess—

"(I) the disease or condition which the device is intended to cure, treat, mitigate, prevent, or diagnose; and

"(II) the technology of the device; and

"(ii) as part of the process to ensure adequate expertise under clause (i), give due consideration to the recommendations of the person whose premarket submission is subject to panel review on the expertise needed among the voting members of the panel.

"(C) For review by a classification panel of a premarket submission for a device, the Secretary shall—

"(i) provide an opportunity for the person whose premarket submission is subject to panel review to provide recommendations on the expertise needed among the voting members of the panel; and

"(ii) give due consideration to such recommendations and ensure that adequate expertise is represented on advisory panels to assess—

"(I) the disease or condition for which the device is intended to cure, treat, mitigate, prevent, or diagnose; and

"(II) the technology of the device.

"(D) For purposes of subparagraph (B)(ii), the term 'adequate expertise' means, with respect to the membership of the classification panel reviewing a premarket submission, that such membership includes—

"(i) two or more voting members, with a specialty or other expertise clinically relevant to the device under review; and

"(ii) at least one voting member who is knowledgeable about the technology of the device.".

(b) PANEL REVIEW PROCESS.—Section 513(b)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)(6)) is amended—

(1) in subparagraph (A)(iii), by inserting before the period at the end ", including by designating a representative who will be provided a time during the panel meeting to address the panel individually (or accompanied by experts selected by such representative) for the purpose of correcting misstatements of fact or providing clarifying information, subject to the discretion of the panel chairperson"; and

(2) by striking subparagraph (B) and inserting the following new subparagraph:

"(B)(i) Any meeting of a classification panel for a device that is specifically the subject of review shall—

"(I) provide adequate time for initial presentations by the person whose device is specifically the subject of a classification panel review and by the Secretary; and

"(II) encourage free and open participation by all interested persons.

"(ii) Following the initial presentations described in clause (i), the panel may—

"(I) pose questions to a designated representative described in subparagraph (A)(iii); and

"(II) consider the responses to such questions in the panel's review of the device that is specifically the subject of review by the panel.".

SEC. 2227. HUMANITARIAN DEVICE EXEMPTION APPLICATION.

(a) IN GENERAL.—Section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended—

(1) in paragraph (1) by striking "fewer than 4,000" and inserting "not more than 8,000";

(2) in paragraph (2)(A) by striking "fewer than 4,000" and inserting "not more than 8,000"; and

(3) in paragraph (6)(A)(ii), by striking "4,000" and inserting "8,000"

(b) GUIDANCE DOCUMENT ON PROBABLE BENEFIT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a draft guidance document that defines the criteria for establishing "probable benefit" as that term is used in section 520(m)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)(C)).

SEC. 2228. CLIA WAIVER STUDY DESIGN GUIDANCE FOR IN VITRO DIAGNOSTICS.

(a) DRAFT REVISED GUIDANCE.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall publish a draft guidance that—

(1) revises "Section V. Demonstrating Insignificant Risk of an Erroneous Result—'Accuracy'" of the guidance entitled "Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices" and dated January 30, 2008; and

(2) includes guidance on the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy.

(b) FINAL REVISED GUIDANCE.—The Secretary of Health and Human Services shall finalize the draft guidance published under subsection (a) not later than 12 months after the comment period for such draft guidance closes.

Subtitle N—Sensible Oversight for Technology Which Advances Regulatory Efficiency

SEC. 2241. HEALTH SOFTWARE.

Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

"(ss)(1) The term 'health software' means software that does not, through use of an in vitro diagnostic device or signal acquisition system, acquire, process, or analyze an image or physiological signal, is not an accessory, is not an integral part of a device necessary to support the use of the device, is not used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans, and—

"(A) is intended for use for administrative or operational support or the processing and maintenance of financial records;

"(B) is intended for use in clinical, laboratory, or administrative workflow and related recordkeeping;

"(C)(i) is intended for use solely in the transfer, aggregation, conversion (in accordance with a present specification), storage, management, retrieval, or transmission of data or information;

"(ii) utilizes a connectivity software platform, electronic or electrical hardware, or a physical communications infrastructure; and

"(iii) is not intended for use—

"(I) in active patient monitoring; or

"(II) in controlling or altering the functions or parameters of a device that is connected to such software;

"(D) is intended for use to organize and present information for health or wellness education or for use in maintaining a healthy lifestyle, including medication adherence and health management tools;

"(E) is intended for use to analyze information to provide general health information that does not include patient-specific recommended options to consider in the prevention, diagnosis, treatment, cure, or mitigation of a particular disease or condition; or

"(F) is intended for use to analyze information to provide patient-specific recommended options to consider in the prevention, diagnosis, treatment, cure, or mitigation of a particular disease or condition.

"(2) The term 'accessory' means a product that—

"(A) is intended for use with one or more parent devices;

"(B) is intended to support, supplement, or augment the performance of one or more parent devices; and

"(C) shall be classified by the Secretary—

"(i) according to its intended use; and

"(ii) independently of any classification of any parent device with which it is used.".

SEC. 2242. APPLICABILITY AND INAPPLICABILITY OF REGULATION.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), as amended by section 2221(a), is further amended by adding at the end the following:

"SEC. 524C. HEALTH SOFTWARE.

"(a) INAPPLICABILITY OF REGULATION TO HEALTH SOFTWARE.—Except as provided in subsection (b), health software shall not be subject to regulation under this Act.

"(b) EXCEPTION.—

"(1) IN GENERAL.—Subsection (a) shall not apply with respect to a software product—

"(A) of a type described in subparagraph (F) of section 201(ss)(1); and

"(B) that the Secretary determines poses a significant risk to patient safety.

"(2) CONSIDERATIONS.—In making a determination under subparagraph (B) of paragraph (1) with respect to a product to which such paragraph applies, the Secretary shall consider the following:

"(A) The likelihood and severity of patient harm if the product were to not perform as intended.

"(B) The extent to which the product is intended to support the clinical judgment of a medical professional.

"(C) Whether there is a reasonable opportunity for a medical professional to review the basis of the information or treatment recommendation provided by the product.

"(D) The intended user and user environment, such as whether a medical professional will use a software product of a type described in subparagraph (F) of section 201(ss)(1).

"(c) DELEGATION.—The Secretary shall delegate primary jurisdiction for regulating a software product determined under subsection (b) to be subject to regulation under this Act to the center at the Food and Drug Administration charged with regulating devices.

"(d) REGULATION OF SOFTWARE.—

"(1) IN GENERAL.—The Secretary shall review existing regulations and guidance regarding the regulation of software under this Act. The Secretary may implement a new framework for the regulation of software and shall, as appropriate, modify such regulations and guidance or issue new regulations or guidance.

"(2) ISSUANCE BY ORDER.—Notwithstanding subchapter II of chapter 5 of title 5, United States Code, the Secretary may modify or issue regulations for the regulation of software under this Act by administrative order published in the Federal Register following the publication of a proposed order.

"(3) AREAS UNDER REVIEW.—The review of existing regulations and guidance under paragraph (1) may include review of the following areas:

"(A) Classification of software.

"(B) Standards for development of software.

"(C) Standards for validation and verification of software.

"(D) Review of software.

"(E) Modifications to software.

"(F) Manufacturing of software.

"(G) Quality systems for software.

"(H) Labeling requirements for software.

"(I) Postmarketing requirements for reporting of adverse events.

"(4) PROCESS FOR ISSUING PROPOSED REGULATIONS, ADMINISTRATIVE ORDER, AND GUIDANCE.—Not later than 18 months after the date of enactment of this section, the Secretary shall consult with external stakeholders (including patients, industry, health care providers, academia, and government) to gather input before issuing regulations, an administrative order, and guidance under this subsection.

"(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as providing the Secretary with the authority to regulate under this Act any health software product of the type described in subparagraph (F) of section 201(ss)(1) unless and until the Secretary has made a determination described in subsection (b)(1)(B) with respect to such product.".

SEC. 2243. EXCLUSION FROM DEFINITION OF DEVICE.

Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended—

(1) in subparagraph (2), by striking "or" after "or other animals,";

(2) in subparagraph (3), by striking "and" and inserting "or"; and

(3) by inserting after subparagraph (3) the following:

"(4) not health software (other than software determined to be a risk to patient safety under section 524B(b)), and".

Subtitle O—Streamlining Clinical Trials

SEC. 2261. PROTECTION OF HUMAN SUBJECTS IN RESEARCH; APPLICABILITY OF RULES.

(a) IN GENERAL.—In order to simplify and facilitate compliance by researchers with applicable regulations for the protection of human subjects in research, the Secretary of Health and Human Services shall, to the extent possible and consistent with other statutory provisions, harmonize differences between the HHS Human Subject Regulations and the FDA Human Subject Regulations in accordance with subsection (b).

(b) AVOIDING REGULATORY DUPLICATION AND UNNECESSARY DELAYS.—

(1) IN GENERAL.—The Secretary shall—

(A) make such modifications to the provisions of the HHS Human Subject Regulations, the FDA Human Subject Regulations, and the vulnerable-populations rules as may be necessary—

(i) to reduce regulatory duplication and unnecessary delays;

(ii) to modernize such provisions in the context of multisite and cooperative research projects; and

(iii) to incorporate local considerations, community values, and mechanisms to protect vulnerable populations; and

(B) ensure that human subject research that is subject to the HHS Human Subject Regulations or to the FDA Human Subject Regulations may—

(i) use joint or shared review;

(ii) rely upon the review of—

(I) an independent institutional review board; or

(II) an institutional review board of an entity other than the sponsor of the research; or

(iii) use similar arrangements to avoid duplication of effort.

(2) REGULATIONS AND GUIDANCE.—Not later than 36 months after the date of enactment of this Act, the Secretary, acting through the relevant agencies and offices of the Department of Health and Human Services, including the Office for Human Research Protections and relevant agencies and offices of the Food and Drug Administration, shall issue such regulations and guidance and take such other actions as may be necessary to implement this section and help to facilitate the broader use of single, central, or lead institutional review boards. Such regulations and guidance shall clarify the requirements and policies relating to the following:

(A) Arrangements to avoid duplication described in paragraph (1)(A)(i), including—

(i) delineating the roles of institutional review boards in multisite or cooperative, multisite studies where one or more local institutional review boards are relied upon, or similar arrangements are used;

(ii) the risks and benefits to human subjects;

(iii) standardizing the informed consent and other processes and legal documents; and

(iv) incorporating community values through the use of local institutional review boards while continuing to use central or lead institutional review boards.

(B) Concerns about regulatory and legal liability contributing to decisions by the sponsors of research to rely on local institutional review boards for multisite research.

(3) CONSULTATION.—In issuing regulations or guidance under paragraph (2), the Secretary shall consult with stakeholders (including researchers, academic organizations, hospitals, institutional research boards, pharmaceutical, biotechnology and medical device developers, clinical research organizations, patient groups, and others).

(c) TIMING.—The Secretary shall complete the harmonization described in subsection (a) not later than 36 months after the date of enactment of this Act.

(d) PROGRESS REPORT.—Not later than 24 months after the date of enactment of this Act, the Secretary shall submit to Congress a report on the progress made toward completing such harmonization.

(e) DRAFT NIH POLICY.—Not later than 12 months after the date of enactment of this Act, the Secretary, acting through the Director of the National Institutes of Health, shall finalize the draft policy entitled "Draft NIH Policy on Use of a Single Institutional Review Board for Multi-Site Research".

(f) DEFINITIONS.—

(1) HUMAN SUBJECT REGULATIONS.—In this section:

(A) FDA HUMAN SUBJECT REGULATIONS.—The term "FDA Human Subject Regulations" means the provisions of parts 50, 56, 312, and 812 of title 21, Code of Federal Regulations (or any successor regulations).

(B) HHS HUMAN SUBJECT REGULATIONS.—The term "HHS Human Subject Regulations" means the provisions of subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations).

(C) VULNERABLE-POPULATIONS RULES.—The term "vulnerable-populations rules"—

(i) subject to clause (ii), means the provisions of subparts B through D of such part 46 (or any successor regulations); or

(ii) as applicable to research that is subject to the FDA Human Subject Regulations, means the provisions applicable to vulnerable populations under part 56 of such title 21 (or any successor regulations) and subpart D of part 50 of such title 21 (or any successor regulations).

(2) OTHER DEFINITIONS.—In this section:

(A) INSTITUTIONAL REVIEW BOARD.—The term "institutional review board" has the meaning that applies to the term "institutional review board" under the HHS Human Subject Regulations.

(B) LEAD INSTITUTIONAL REVIEW BOARD.—The term "lead institutional review board" means an institutional review board that otherwise meets the requirements of the HHS Human Subject Regulations and enters into a

written agreement with an institution, another institutional review board, a sponsor, or a principal investigator to approve and oversee human subject research that is conducted at multiple locations. References to an institutional review board include an institutional review board that serves a single institution as well as a lead institutional review board.

SEC. 2262. USE OF NON-LOCAL INSTITUTIONAL REVIEW BOARDS FOR REVIEW OF INVESTIGATIONAL DEVICE EXEMPTIONS AND HUMAN DEVICE EXEMPTIONS.

(a) IN GENERAL.—Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)) is amended—

(1) in subsection (g)(3)—

(A) by striking "local" each place it appears; and

(B) in subparagraph (A)(i), by striking "which has been"; and

(2) in subsection (m)(4)—

(A) by striking "local" each place it appears; and

(B) by striking subparagraph (A) and inserting the following new subparagraph:

"(A) in facilities in which clinical testing of devices is supervised by an institutional review committee established in accordance with the regulations of the Secretary, and".

(b) REGULATIONS.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall revise or issue such regulations or guidance as may be necessary to carry out the amendments made by subsection (a).

SEC. 2263. ALTERATION OR WAIVER OF INFORMED CONSENT FOR CLINICAL INVESTIGATIONS.

(a) DEVICES.—Section 520(g)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(3)) is amended—

(1) in subparagraph (D), by striking "except where subject to such conditions as the Secretary may prescribe, the investigator" and inserting the following: "except where, subject to such conditions as the Secretary may prescribe—

"(i) the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject; or

"(ii) the investigator"; and

(2) in the matter following subparagraph (D), by striking "subparagraph (D)" and inserting "subparagraph (D)(ii)".

(b) DRUGS.—Section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) is amended by striking "except where it is not feasible or it is contrary to the best interests of such human beings" and inserting "except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings".

Subtitle P—Improving Scientific Expertise and Outreach at FDA

SEC. 2281. SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH SERVICE.

(a) HIRING AND RETENTION AUTHORITY.—Section 228 of the Public Health Service Act (42 U.S.C. 237) is amended—

(1) in the section heading, by inserting "AND BIOMEDICAL PRODUCT ASSESSMENT" after "RESEARCH";

(2) in subsection (a)(1), by striking "Silvio O. Conte Senior Biomedical Research Service, not to exceed 500 members" and inserting "Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service (in this section referred to as the 'Service'), the purpose of which is to recruit and retain competitive and qualified scientific and technical experts outstanding in the field of biomedical research, clinical research evaluation, and biomedical product assessment";

(3) by amending subsection (a)(2) to read as follows:

"(2) The authority established in paragraph (1) may not be construed to require the Secretary to reduce the number of employees serving under any other employment system in order to offset the number of members serving in the Service.";

(4) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking "or clinical research evaluation" and inserting ", clinical research evaluation or biomedical product assessment"; and

(B) in paragraph (1), by inserting "or a master's level degree in engineering, bioinformatics, or a related or emerging field," after the comma;

(5) in subsection (d)(2), by striking "and shall not exceed the rate payable for level I of the Executive Schedule unless approved by the President under section 5377(d)(2) of title 5, United States Code" and inserting "and shall not exceed the rate payable for the President";

(6) by striking subsection (e); and

(7) by redesignating subsections (f) and (g) as subsections (e) and (f), respectively.

(b) REPORT.—Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit, and publish on the website of the Department of Health and Human Services a report on the implementation of the amendments made by subsection (a), including whether the amendments have improved the ability of the Food and Drug Administration to hire and retain qualified experts to fulfill obligations specified under user fee agreements.

SEC. 2282. ENABLING FDA SCIENTIFIC ENGAGEMENT.

It is the sense of Congress that the participation in, or sponsorship of, scientific conferences and meetings is essential to the mission of the Food and Drug Administration.

SEC. 2283. REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION.

(a) BOARD OF DIRECTORS.—

(1) COMPOSITION AND SIZE.—Section 770(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(C)) is amended—

(A) by redesignating clause (ii) as clause (iii);

(B) by inserting after clause (i) the following:

"(ii) ADDITIONAL MEMBERS.—The Board, through amendments to the bylaws of the Foundation, may provide that the number of voting members of the Board shall be a number (to be specified in such amendment) greater than 14. Any Board positions that are established by any such amendment shall be appointed (by majority vote) by the individuals who, as of the date of such amendment, are voting members of the Board and persons so appointed may represent any of the categories specified in subclauses (I) through (V) of clause (i), so long as no more than 30 percent of the total voting members of the Board (including members whose positions are established by such amendment) are representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries."; and

(C) in clause (iii)(I), as redesignated by subparagraph (A), by striking "The ex officio members shall ensure" and inserting "The ex officio members, acting pursuant to clause (i), and the Board, acting pursuant to clause (ii), shall ensure".

(2) FEDERAL EMPLOYEES ALLOWED TO SERVE ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(C)), as redesignated by paragraph (1)(A), is amended by adding at the end the following: "For purposes of this section, the term 'employee of the Federal Government' does not include a 'special Government employee', as that term is defined in section 202(a) of title 18, United States Code.".

(3) STAGGERED TERMS.—Subparagraph (A) of section 770(d)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(3)) is amended to read as follows:

"(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C)(i), and the term of office of any member of the Board whose position is established pursuant to paragraph (1)(C)(ii), shall be 4 years, except that—

"(i) the terms of offices for the members of the Board initially appointed under paragraph (1)(C)(i) shall expire on a staggered basis as determined by the ex officio members; and

"(ii) the terms of office for the persons initially appointed to positions established pursuant to paragraph (1)(C)(ii) may be made to expire on a staggered basis, as determined by the individuals who, as of the date of the amendment establishing such positions, are members of the Board.".

(b) EXECUTIVE DIRECTOR COMPENSATION.—Section 770(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(g)(2)) is amended by striking "but shall not be greater than the compensation of the Commissioner".

(c) SEPARATION OF FUNDS.—Section 770(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(m)) is amended by striking "are held in separate ac-

counts from funds received from entities under subsection (i)" and inserting "are managed as individual programmatic funds under subsection (i), according to best accounting practices".

SEC. 2284. COLLECTION OF CERTAIN VOLUNTARY INFORMATION EXEMPTED FROM PAPERWORK REDUCTION ACT.

Chapter VII of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 708 of such Act (21 U.S.C. 379) the following:

"SEC. 708A. COLLECTION OF CERTAIN VOLUNTARY INFORMATION EXEMPTED FROM PAPERWORK REDUCTION ACT.

"Chapter 35 of title 44, United States Code, shall not apply to the collection from patients, industry, academia, and other stakeholders, of voluntary information such as through voluntary surveys or questionnaires, initiated by the Secretary.".

SEC. 2285. HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL, AND PROFESSIONAL PERSONNEL.

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 714 (21 U.S.C. 379d–3) the following:

"SEC. 714A. ADDITIONAL HIRING AUTHORITY.

"(a) IN GENERAL.—The Secretary may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, appoint qualified candidates to scientific, technical, or professional positions within the following centers of the Food and Drug Administration:

"(1) The Center for Drug Evaluation and Research.

"(2) The Center for Biologics Evaluation and Research.

"(3) The Center for Devices and Radiological Health.

Such positions shall be within the competitive service.

"(b) COMPENSATION.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, including any requirement with respect to General Schedule pay rates under subchapter III of chapter 53 of title 5, United States Code, and consistent with the requirements of paragraph (2), the Secretary may determine and fix—

"(A) the annual rate of pay of any individual appointed under subsection (a); and

"(B) for purposes of retaining qualified employees, the annual rate of pay for any highly qualified scientific, technical, or professional personnel appointed to a position at any of the centers listed under subsection (a) before the date of enactment of this section.

"(2) LIMITATION.—The annual rate of pay established pursuant to paragraph (1) may not exceed the annual rate of pay of the President.

"(c) SUNSET.—The authority to appoint employees under this section shall terminate on September 30, 2022.

"(d) REPORT.—

"(1) IN GENERAL.—Not later than September 30, 2021, the Secretary shall submit a report to Congress that examines the extent to which the authority to appoint and retain personnel under this section enhanced the Food and Drug Administration's ability to meet the agency's critical need for highly qualified individuals for scientific, technical, or professional positions.

"(2) RECOMMENDATIONS.—The report under paragraph (1) shall include the recommendations of the Secretary on—

"(A) whether the authority to appoint personnel under this section should be reauthorized; and

"(B) other personnel authorities that would help the Food and Drug Administration to better recruit and retain highly qualified individuals for scientific, technical, or professional positions in the agency's medical product centers.".

(b) RULE OF CONSTRUCTION.—The authority provided by section 714A of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) shall not be construed to affect the authority provided under section 714 of such Act.

Subtitle Q—Exempting From Sequestration Certain User Fees

SEC. 2301. EXEMPTING FROM SEQUESTRATION CERTAIN USER FEES OF FOOD AND DRUG ADMINISTRATION.

The Balanced Budget and Emergency Deficit Control Act of 1985 is amended—

(1) in section 255(g)(1)(A) (2 U.S.C. 905(g)(1)(A)), by inserting after the item relating to "Financial Agent Services" the following new item:

"Food and Drug Administration, Salaries and Expenses, but only the portion of appropriations under such account corresponding to fees collected under sections 736, 738, 740, 741, 744B, and 744H of the Federal Food, Drug, and Cosmetic Act (75–9911–0–1–554).."; and

(2) in section 256(h) (2 U.S.C. 906(h)), by adding at the end the following new paragraph:

"(5) Notwithstanding any other provision of law, this subsection shall not apply with respect to the portion of administrative expenses incurred by the Food and Drug Administration that are funded through fees collected under sections 736, 738, 740, 741, 744B, and 744H of the Federal Food, Drug, and Cosmetic Act.".

TITLE III—DELIVERY

Subtitle A—Interoperability

SEC. 3001. ENSURING INTEROPERABILITY OF HEALTH INFORMATION TECHNOLOGY.

(a) INTEROPERABILITY STANDARDS.—

(1) IN GENERAL.—Subtitle A of title XXX of the Public Health Service Act (42 U.S.C. 300jj–11 et seq.) is amended by adding at the end the following new section:

"SEC. 3010. ENSURING INTEROPERABILITY OF HEALTH INFORMATION TECHNOLOGY.

"(a) INTEROPERABILITY.—In order for health information technology to be considered interoperable, such technology must satisfy the following criteria:

"(1) SECURE TRANSFER.—The technology allows the secure transfer of the entirety of a patient's data from any and all health information technology for authorized use under applicable law.

"(2) COMPLETE ACCESS TO HEALTH DATA.—The technology allows access to the entirety of a patient's available data for authorized use under applicable law without special effort, as defined by recommendations for interoperability standards adopted under section 3004, by the requestor of such data unless such data is not disclosable under applicable law.

"(3) NO INFORMATION BLOCKING.—The technology is not configured, set up, or implemented to engage in information blocking, as defined in section 3010A(f).

"(b) CATEGORIES FOR INTEROPERABILITY STANDARDS.—The categories described in this subsection, with respect to standards for determining if health information technology is interoperable, consistent with the criteria described in subsection (a), include the following categories of standards:

"(1) Standards with respect to vocabulary and terminology.

"(2) Standards with respect to content and structure.

"(3) Standards with respect to transport of information.

"(4) Security standards.

"(5) Service standards.".

(2) GUIDANCE.—Not later than January 1, 2017, the Secretary of Health and Human Services, through the National Coordinator of the Office of the National Coordinator for Health Information Technology, shall issue guidance with respect to the implementation of section 3010 of the Public Health Service Act, as added by paragraph (1), including with respect to defining and providing examples of authorized use of health information technology, as described in such section.

(b) IMPROVEMENTS TO RECOMMENDATION PROCESS.—

(1) HIT POLICY COMMITTEE TO INCORPORATE POLICIES FOR UPDATES TO INTEROPERABILITY STANDARDS.—Section 3002 of the Public Health Service Act (42 U.S.C. 300jj–12) is amended—

(A) in subsection (a)—

(i) by striking "National Coordinator" and inserting "Secretary, in consultation with the National Coordinator,"; and

(ii) by adding at the end the following new sentence: "The HIT Policy Committee is authorized only to provide policy and priority recommendations to the Secretary and not authorized to otherwise affect the development or modification of any standard, implementation specification, or certification criterion under this title."; and

(B) in subsection (b)(2)—

(i) in subparagraph (A), in the first sentence—

(I) by striking "The HIT Policy Committee" and inserting "Subject to subparagraph (D), the HIT Policy Committee"; and

(II) by inserting "(including the areas in which modifications and additions to interoperability standards under section 3010 are needed for the electronic exchange and use of health information for purposes of adoption of such modifications and additions under section 3004)" after "section 3004".

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

"(D) SPECIAL RULE RELATED TO INTEROPERABILITY.—Any recommendation made by the HIT Policy Committee on or after the date of the enactment of this subparagraph with respect to interoperability of health information technology shall be consistent with the criteria described in subsection (a) of section 3010.".

(2) SUNSET OF HIT STANDARDS COMMITTEE.—Section 3003 of the Public Health Service Act (42 U.S.C. 300jj–13) is amended by adding at the end the following new subsection:

"(f) TERMINATION.—The HIT Standards Committee shall terminate on the date that is 90 days after the date of the enactment of this subsection.".

(3) STANDARDS DEVELOPMENT ORGANIZATIONS.—Title XXX of the Public Health Service Act is amended by inserting after section 3003 the following new section:

"SEC. 3003A. RECOMMENDATIONS FOR STANDARDS THROUGH CONTRACTS WITH STANDARDS DEVELOPMENT ORGANIZATIONS.

"(a) CONTRACTS.—

"(1) IN GENERAL.—For purposes of activities conducted under this title, the Secretary shall enter into contracts with health care standards development organizations accredited by the American National Standards Institute to carry out the duties described in subsection (b), as applicable.

"(2) 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 paragraph (1).

"(3) PERIOD OF CONTRACT.—Each contract under paragraph (1) shall be for a period determined necessary by the Secretary, in consultation with the National Coordinator, to carry out the applicable duties described in subsection (b).

"(4) APPROPRIATE ORGANIZATIONS.—The Secretary shall ensure the most appropriate organizations described in paragraph (1) are selected for each contract under such paragraph.

"(5) ALLOWANCE FOR VARIATIONS.—Standards developed pursuant to a contract under this subsection, and the methods to test such standards, shall allow for variations on such standards as long as such variations are consistent with the standards so developed under this section.

"(b) DUTIES.—

"(1) INITIAL CONTRACT.—Under the initial contract under subsection (a)(1), the standards development organizations—

"(A) shall provide to the Secretary, in consultation with the National Coordinator, for adoption under section 3004, recommendations, in accordance with section 3010, for interoperability standards, and methods to test such standards, consistent with the criteria described in subsection (a) of such section and with respect to the categories described in subsection (b)(1) of such section; and

"(B) may provide to the Secretary recommendations described in paragraph (2).

"(2) SUBSEQUENT CONTRACTS.—Under each subsequent contract, the organizations shall provide to the Secretary, in consultation with the National Coordinator, for adoption under section 3004 recommendations for any standards (including interoperability standards and methods to test such standards), implementation specifications, and certification criteria (and modifications, including additions, to such standards, specifications, and criteria), which are in accordance with the policies and priorities developed by the Secretary, in consultation with the National Coordinator.

"(3) MULTIPLE METHODS TO TEST INTEROPERABILITY STANDARDS.—For the purposes of developing methods to test interoperability standards for adoption under section 3004, the Secretary shall ensure that contracts under this section allow for multiple methods to test such standards to account for variations in the adoption of such standards that do not conflict with section 3010(a).

"(c) MODIFICATIONS AND SUBSEQUENT CONTRACTS.—

"(1) IN GENERAL.—The Secretary, in consultation with the National Coordinator, shall periodically conduct hearings to evaluate and review the standards, implementation specifications, and certification criteria adopted under section

3004 for purposes of determining if modifications, including any additions, are needed with respect to such standards, specifications, and criteria.

"(2) CONTRACT TRIGGER.—Based on the needs for standards, implementation specifications, and certification criteria (and modifications, including additions, to such standards, specifications, and criteria) under this title, as determined by the Secretary, in consultation with the National Coordinator, the Secretary shall, as needed, enter into contracts under subsection (a) in addition to the initial contract.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $10,000,000 for contracts under subsection (a), to remain available until expended.".

(4) MODIFICATIONS TO ROLE OF ONCHIT.—Section 3001(c)(1)(A) of the Public Health Service Act (42 U.S.C. 300jj–11(c)(1)(A)) is amended by inserting "for recommendations made before the date of the enactment of the 21st Century Cures Act," before "review and determine".

(c) ADOPTION.—Section 3004 of the Public Health Service Act (42 U.S.C. 300jj–14) is amended—

(1) in subsection (a)—

(A) in paragraph (1), by inserting after "section 3001(c)" the following: "(or, subject to subsection (c), in the case of a standard, specification, or criterion recommended on or after the date of the enactment of the 21st Century Cures Act, after the date of submission of the recommendation to the Secretary under section 3003A)"; and

(B) in paragraph (2)(B), by striking "and the HIT Standards Committee";

(2) in subsection (b), by adding at the end the following new paragraph:

"(4) LIMITATION.—The Secretary may not adopt any standards, implementation specifications, or certification criteria under this subsection or subsection (a) that are inconsistent with or duplicative of an interoperability standard adopted under this section, in accordance with subsections (c) and (d). In the case of a standard, specification, or criterion that has been adopted under this section and is inconsistent or duplicative of such an interoperability standard that is subsequently adopted under this section, such interoperability standard shall supercede such other standard, specification, or criterion and such other standard, specification, or criterion shall no longer be considered adopted under this section beginning on the date that such interoperability standard becomes effective."; and

(3) by adding at the end the following new subsections:

"(c) ADOPTION OF INITIAL INTEROPERABILITY STANDARDS.—Notwithstanding the previous subsections of this section, the following shall apply in the case of the initial set of interoperability standards recommended under section 3003A:

"(1) REVIEW OF STANDARDS.—Not later than 90 days after the date of receipt of recommendations for such interoperability standards, the Secretary, in consultation with the National Coordinator and representatives of other relevant Federal agencies, shall jointly review such standards and shall determine whether or not to propose adoption of such standards.

"(2) DETERMINATION TO ADOPT.—If the Secretary determines—

"(A) to propose adoption of such standards, the Secretary shall, by regulation under section 553 of title 5, United States Code, determine whether or not to adopt such standards; or

"(B) not to propose adoption of such standards, the Secretary shall notify the applicable standards development organizations with a contract under section 3003A in writing of such determination and the reasons for not proposing the adoption of the recommendation for such standards.

"(3) PUBLICATION.—The Secretary shall provide for publication in the Federal Register of all determinations made by the Secretary under paragraph (1).

"(4) APPLICATION.—Any standard adopted under this subsection shall be effective 12 months after the date of publication of the determination to adopt such standard.

"(d) RULES FOR ADOPTION.—In the case of a standard (including interoperability standard), implementation specification, or certification criteria adopted under this section on or after the date of the enactment of the 21st Century Cures Act, the following shall apply:

"(1) IN GENERAL.—Except as provided in paragraph (2), any such standard (including interoperability standard), implementation specification, or certification criterion shall be a standard, specification, or criterion that has been recommended by the standards development organizations with which the Secretary has entered into a contract under section 3003A.

"(2) SPECIAL RULE IF NO STANDARD, SPECIFICATION, OR CRITERION RECOMMENDED.—If no standard is recommended under paragraph (1)—

"(A) in the case of interoperability standards, relating to a category described in section 3010(b)—

"(i) paragraph (1) shall not apply; and

"(ii) paragraph (4) shall apply; or

"(B) in the case of any other standard, implementation specification, or certification criteria, relating to a policy or priority to carry out this title, as determined by the Secretary, in consultation with the National Coordinator—

"(i) paragraph (1) shall not apply; and

"(ii) paragraph (4) shall apply.

"(3) EFFECTIVE DATE.—Any standard, implementation specification, or certification criterion adopted under this section shall be effective 12 months after the date of publication of the final rule to adopt such standard, implementation specification, or certification criterion.

"(4) ASSISTANCE TO THE SECRETARY.—In complying with the requirements of this subsection, the Secretary shall rely on the recommendations of the National Committee on Vital and Health Statistics established under section 306(k), and shall consult with appropriate Federal and State agencies and private organizations. The Secretary shall publish in the Federal Register any recommendation of the National Committee on Vital and Health Statistics regarding the adoption of a standard, implementation specification, or certification criterion under this section. Any standard, implementation specification, or certification criterion adopted pursuant to this paragraph shall be promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of title 5, United States Code.".

(d) REPORTS AND NOTIFICATIONS.—Section 3010 of the Public Health Service Act, as added by subsection (a), is amended by adding at the end the following new subsection:

"(c) DISSEMINATION OF INFORMATION.—

"(1) INITIAL SUMMARY REPORT.—Not later than July 1, 2017, the Secretary, after consultation with relevant stakeholders, shall submit to Congress and provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of a report on the following:

"(A) The initial set of interoperability standards adopted under section 3004(c).

"(B) The strategies for achieving widespread interoperability.

"(C) An overview of the extent to which electronic health records and health information technology offered as of such date satisfy such initial set.

"(D) Any barriers that are preventing widespread interoperability.

"(E) The plan and milestones, including specific steps, to achieve widespread interoperability.

"(2) FOLLOWUP DETERMINATION AND REPORT ON WIDESPREAD INTEROPERABILITY.—Not later than December 31, 2019, the Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of the following:

"(A) A determination by the Secretary whether the goal of widespread interoperability has been achieved.

"(B) A list identifying the vendors of, or other entities offering, qualified electronic health records, which categorizes such entities, with respect to such records, as in compliance or not in compliance with the certification criteria described in section 3001(c)(5)(B)(ii) and with the requirements under clause (i) of section 3001(c)(5)(C) (including with the terms of the attestation and other requirements under such clause).

"(C) Actions that may be taken by entities identified under subparagraph (B) as not being in compliance with such criteria and requirements in order for such entities to become in compliance with such criteria and requirements.

"(D) Penalties described in section 3010A(d) to which entities, with respect to such qualified electronic health records, beginning January 1, 2019, are subject if such technology and entities are not in compliance with the certification criteria described in section 3001(c)(5)(B)(ii) and with the requirements under clause (i) of section 3001(c)(5)(C), respectively.

"(3) ONGOING PUBLICATION OF RECOMMENDATIONS.—The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of all recommendations made under this section.".

(e) CERTIFICATION AND OTHER ENFORCEMENT PROVISIONS.—

(1) CERTIFICATION OF QUALIFIED ELECTRONIC HEALTH RECORDS.—

(A) IN GENERAL.—Section 3007(b) of the Public Health Service Act (42 U.S.C. 300jj–17(b)) is amended by striking "under section 3001(c)(3) to be in compliance with" and all that follows through the period at the end and inserting "under section 3001(c)(3)—

"(1) for certifications made before January 1, 2018, to be in compliance with applicable standards adopted under subsections (a) and (b) of section 3004; and

"(2) for certifications made on or after January 1, 2018, to be in compliance with applicable standards adopted under subsections (a) and (b) of section 3004 and to be interoperable in accordance with section 3010, including by being in compliance with interoperability standards adopted under section 3004.".

(B) REQUIREMENTS OF SECRETARY.—Section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj–11(c)(5)) is amended—

(i) by amending subparagraph (B) of such section to read as follows:

"(B) CERTIFICATION CRITERIA DESCRIBED.—In this title, the term 'certification criteria' means, with respect to qualified electronic health records—

"(i) for certifications made before January 1, 2018, criteria to establish that the records meet standards and implementation specifications adopted under subsections (a) and (b) of section 3004 for qualified electronic health records; and

"(ii) for certifications made on or after January 1, 2018, criteria described in clause (i) and criteria to establish that the records are interoperable, in accordance with section 3010, including by being in compliance with interoperability standards adopted under section 3004."; and

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

"(C) ENFORCEMENT; DECERTIFICATIONS.—

"(i) REQUIREMENTS.—Under any program kept or recognized under subparagraph (A), the Secretary shall ensure that any vendor of or other entity offering qualified electronic health records seeking a certification of such records under such program on or after January 1, 2018, shall, as a condition of certification (and maintenance of certification) of such a record under such program—

"(I) provide to the Secretary an attestation—

"(aa) that the entity, unless for a legitimate purpose specified by the Secretary, has not taken any action, including through any financial, administrative, or technological barrier, which the entity knows or should know (as defined in section 1128A(i)(7) of the Social Security Act), is to limit or restrict the exchange of information or to prevent or disincentivize widespread interoperability between any providers using such records or other health information technology in connection with such record;

"(bb) on the pricing information described in clause (v) for purposes of the portal created under paragraph (9); that such information will be available on a public Web site of such entity and in marketing materials, communications statements, and other assertions of such entity related to such record; and that the entity will voluntarily provide such information to customers prior to providing any qualified electronic health records or related product or service (including subsequent updates, add-ons, or additional products or services to be provided during the course of an on-going contract), prospective customers (such as persons who request or receive a quotation, estimate, or other similar marketing or promotional material), and other persons who request such information;

"(cc) that the software with respect to such records have published application programming interfaces for medical records data, search and indexing, semantic harmonization and vocabulary translation, and user interface applications;

"(dd) that the entity has successfully tested the use of the record in the type of setting in which it would be marketed;

"(ee) the entity has in place implementation guidelines for such record that support interoperability, consistent with section 3010; and

"(ff) that the entity has in place data sharing programs or capabilities based on common data elements through application programming interfaces without the requirement for vendor-specific interfaces;

"(II) publish application programming interfaces and associated documentation, with respect to such records, for medical records data, search and indexing, semantic harmonization and vocabulary translation, and user interface applications; and

"(III) demonstrate to the satisfaction of the Secretary that data from such records are able to be exchanged through the use of application programming interfaces and used in a manner that allows for exchange and everyday use, as authorized under applicable law, of such records.

"(ii) DECERTIFICATION.—Under any program kept or recognized under subparagraph (A), the Secretary shall ensure that beginning January 1, 2019, any qualified electronic health records that do not satisfy the certification criteria described in section 3001(c)(5)(B)(ii) or with respect to which the vendor or other entity described in clause (i) does not satisfy the requirements under such clause (or is determined to be in violation of the terms of the attestation or other requirements under such clause) shall no longer be considered as certified under such program.

"(iii) ANNUAL PUBLICATION.—For 2019 and each subsequent year, the Secretary shall post on the public Internet website of the Department of Health and Human Services a list of any vendors of or other entities offering qualified electronic health records with respect to which certification has been withdrawn under clause (ii) during such year.

"(iv) PERIODIC REVIEW.—The Secretary shall periodically review and confirm that vendors of and other entities offering qualified electronic health records have publicly published application programming interfaces and associated documentation as required by clause (i)(II) for purposes of certification and maintaining certification under any program kept or recognized under subparagraph (A).

"(v) PRICING INFORMATION.—For purposes of clause (i)(I)(bb), the pricing information described in this clause, with respect to a vendor of or other entity offering a qualified electronic health record, is the following:

"(I) Additional types of costs or fees (whether fixed, recurring, transaction based, or otherwise) imposed by the entity (or any third-party from whom the entity purchases, licenses, or obtains any technology, products, or services in connection with the qualified electronic health record) to purchase, license, implement, maintain, upgrade, use, or otherwise enable and support the use of capabilities to which such record is to be certified under this section; or in connection with any data generated in the course of using any capability to which the record is to be so certified.

"(II) Limitations, whether by contract or otherwise, on the use of any capability to which the record is to be certified under this section for any purpose within the scope of the record's certification; or in connection with any data generated in the course of using any capability to which the record is to be certified under this section.

"(III) Limitations, including technical or practical limitations of technology or its capabilities, that could prevent or impair the successful implementation, configuration, customization, maintenance, support, or use of any capabilities to which the record is to be certified under this section; or that could prevent or limit the use, exchange, or portability of any data generated in the course of using any capability to which the record is to be so certified.".

(2) ADDITIONAL ENFORCEMENT PROVISIONS UNDER THE PUBLIC HEALTH SERVICE ACT.—Subtitle A of title XXX of the Public Health Service Act (42 U.S.C. 300jj–11 et seq.), as amended by subsections (a)(1) and (d), is further amended by adding at the end the following new section:

"SEC. 3010A. ENFORCEMENT MECHANISMS.

"(a) INSPECTOR GENERAL AUTHORITY.—The Inspector General of the Department of Health and Human Services shall have the authority to investigate claims of—

"(1) vendors of, or other entities offering, qualified electronic health records—

"(A) being in violation of an attestation made under section 3001(c)(5)(C)(i)(I), with respect to the use of such records by a health care provider under a specified meaningful use incentive program; and

"(B) having engaged in information blocking (as defined in subsection (f)), unless for a legitimate purpose specified by the Secretary, with respect to the use of such records by a health care provider under such a program;

"(2) health care providers, with respect to the use of such records under a specified meaningful use incentive program, having, unless for a legitimate purpose specified by the Secretary, engaged in information blocking (as so defined);

"(3) health information system providers described in subsection (b) having engaged in information blocking (as so defined), unless for a legitimate purpose specified by the Secretary, with respect to the use of such records under a specified meaningful use incentive program; and

"(4) vendors of, or other entities offering, health information technology (other than technology described in paragraph (1)), health care providers, with respect to the use of such technology, and health information system providers, with respect to such technology, unless for a legitimate purpose specified by the Secretary, having engaged in information blocking (as so defined).

"(b) HEALTH INFORMATION SYSTEM PROVIDERS.—The Inspector General of the Department of Health and Human Services shall, in coordination with the Federal Trade Commission, ensure that health information system providers (such as operators of health information exchanges and other systems that facilitate the exchange of information) investigate claims of information blocking, with respect to the use of such records under a specified meaningful use incentive program.

"(c) INFORMATION SHARING PROVISIONS.—

"(1) IN GENERAL.—The National Coordinator may serve as a technical consultant to the Inspector General of the Department of Health and Human Services and the Federal Trade Commission for purposes of carrying out this section. As such technical consultant, the National Coordinator may, notwithstanding any other provision of law, share information related to claims or investigations under subsection (a) or (b) with the Federal Trade Commission for purposes of such investigations.

"(2) PROTECTION FROM DISCLOSURE OF INFORMATION.—Any information shared by the National Coordinator under paragraph (1) shall not be subject to the provisions of section 552 of title 5, United States Code (commonly referred to as the Freedom of Information Act). Any information acquired pursuant to paragraph (1) shall be held in confidence and shall not be disclosed to any person except as may be necessary to carry out the purposes of subsection (a).

"(3) NON-APPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code (commonly referred to as the Paperwork Reduction Act of 1995) shall not apply to the National Coordinator or to the Office of the National Coordinator for Health Information Technology with respect to the collection of complaints relating to claims described in subsection (a).

"(d) PENALTY.—Any person or entity determined to have committed an act described in paragraph (1), (2), or (3) of subsection (a), in connection with a specified meaningful use incentive program, shall be subject to a civil monetary penalty of not more than $10,000 for each such act. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty applied under this subsection in the same manner as they apply to a civil money penalty or proceeding under section 1128A(a).

"(e) SPECIFIED MEANINGFUL USE INCENTIVE PROGRAM.—For purposes of this section, the term 'specified meaningful use incentive program' includes the following:

"(1) The incentive payments under subsection (o) of section 1848 of the Social Security Act (42 U.S.C. 1395w–4) and adjustments under subsection (a)(7) of such section.

"(2) The incentive payments under subsection (n) of section 1848 of such Act (42 U.S.C. 1395ww) and adjustments under subsection (b)(3)(B) of such section.

"(3) The incentive payments and adjustments made under subsections (l) and (m) of section 1853 of such Act (42 U.S.C. 1395w–23).

"(4) The incentive payment under paragraph (3) of section 1814(l) of such Act (42 U.S.C. 1395f(l)) and adjustment under paragraph (4) of such section.

"(5) The shared savings program under section 1899 of such Act (42 U.S.C. 1395jjj).

"(6) The payments to Medicaid providers described in section 1903(t) of such Act (42 U.S.C. 1396b(t)).

"(f) INFORMATION BLOCKING.—

"(1) IN GENERAL.—For purposes of this section and section 3010, the term 'information blocking' means, with respect to the use of qualified electronic health records or other health information technology under a specified meaningful use incentive program, business, technical, and organizational practices, including practices described in paragraph (2), that—

"(A) prevent or materially discourage the exchange of electronic health information;

"(B) the actor knows or should know (as defined in section 1128A(i)(7) of the Social Security Act) are likely to interfere with the exchange or use of electronic health information; and

"(C) do not serve to protect patient safety, maintain the privacy and security of individuals' health information or promote competition and consumer welfare.

"(2) PRACTICES DESCRIBED.—For purposes of paragraph (1), the practices described in this paragraph are the following:

"(A) Contract terms, policies, or other business or organizational practices that restrict individuals' access to their electronic health information or restrict the exchange or use of that information for treatment and other permitted purposes.

"(B) Charging prices or fees (such as for data exchange, portability, and interfaces) that make exchanging and using electronic health information cost prohibitive.

"(C) Developing or implementing health information technology in nonstandard ways that are likely to substantially increase the costs, complexity, or burden of sharing electronic health information, especially in cases in which relevant interoperability standards or methods to measure interoperability have been adopted by the Secretary.

"(D) Developing or implementing health information technology in ways that are likely to lock in users or electronic health information, such as not allowing for the full export of data; lead to fraud, waste, or abuse; or impede innovations and advancements in health information exchange and health information technology-enabled care delivery.

"(g) TREATMENT OF VENDORS WITH RESPECT TO PATIENT SAFETY ORGANIZATIONS.—In applying part C of title IX—

"(1) vendors shall be treated as a provider (as defined in section 921) for purposes of reporting requirements under such part, to the extent that such reports are related to attestation requirements under section 3001(c)(5)(C)(i)(I);

"(2) claims of information blocking described in subsection (a) shall be treated as a patient safety activity under such part for purposes of reporting requirements under such part; and

"(3) health care providers that are not members of patient safety organizations shall be treated in the same manner as health care providers that are such members for purposes of such reporting requirements with respect to claims of information blocking described in subsection (a).".

(3) ONCHIT.—

(A) PORTAL.—Section 3001(c) of the Public Health Service Act (42 U.S.C. 300jj–11(c)) is amended by adding at the end the following new paragraph:

"(9) PORTAL.—Not later than January 1, 2019, the National Coordinator shall create a portal to make the information described in paragraph (5)(C)(I)(i)(bb) available to the public in a manner that allows for comparison of price information among health information technology products and that aids in making informed decisions for purchasing such a product.".

(B) INFORMATION BLOCKING.—Not later than 12 months after the date of the enactment of this Act, the National Coordinator of the Office of the National Coordinator of Health Information Technology shall, through rulemaking, implement the provisions of this section, and amendments made by this section, relating to information blocking.

(C) HIPAA.—Not later than January 1, 2017, the National Coordinator shall publish guidance to clarify the relationship of the HIPAA privacy and security law, as defined in section 3009(a)(2) of the Public Health Service Act (42 U.S.C. 300jj–19(a)(2)) as such provisions relate to information blocking (as defined in section 3010A(f) of such Act, as added by paragraph (2)), including examples of how such provisions may result in information blocking.

(4) DEMONSTRATION REQUIRED FOR MEANINGFUL EHR USE INCENTIVES UNDER MEDICARE.—

(A) INCENTIVES FOR PROFESSIONALS.—

(i) IN GENERAL.—Section 1848(o)(2)(C) of the Social Security Act (42 U.S.C. 1395w–4(o)(2)(C)) is amended by adding at the end the following new clause:

"(iii) INTEROPERABILITY.—With respect to EHR reporting periods for payment years beginning with 2018, the means described in clause (i) specified by the Secretary shall include a demonstration, through means such as an attestation, that the professional has not taken any action described in subsection (a)(2) of section 3010A of the Public

Health Service Act, with respect to the use of any certified EHR technology.".

(ii) HARDSHIP EXEMPTION IN CASE OF DECERTIFIED EHR.—Subparagraph (B) of section 1848(a)(7) of the Social Security Act (42 U.S.C. 1395w–4(a)(7)) is amended to read as follows:

"(B) SIGNIFICANT HARDSHIP EXCEPTION.—

"(i) IN GENERAL.—The Secretary may, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment under subparagraph (A) if the Secretary determines, subject to annual renewal, that compliance with the requirement for being a meaningful EHR user would result in a significant hardship, such as in the case of an eligible professional who practices in a rural area without sufficient Internet access.

"(ii) DECERTIFICATION.—

"(I) IN GENERAL.—The Secretary may, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment under subparagraph (A) if the Secretary determines that such professional was determined to not be a meaningful EHR user because the qualified electronic health record used by such professional was decertified under section 3001(c)(5)(C) of the Public Health Service Act. An exemption under the previous sentence may be applied to an eligible professional only, subject to subclause (II), during the first payment year with respect to the first EHR reporting period to which such decertification applies.

"(II) DURATION.—

"(aa) IN GENERAL.—In no case shall an exemption by reason of this clause be for a period of less than 12 months.

"(bb) EXTENSION.—An exemption under this clause may be extended for a period of an additional 12 months subject to the limitation described in clause (ii).

"(iii) LIMITATION.—Subject to clause (ii)(II)(aa), in no case may an eligible professional be granted an exemption under this subparagraph for more than 5 years.".

(B) INCENTIVES FOR HOSPITALS.—

(i) IN GENERAL.—Section 1886(o)(1) of the Social Security Act (42 U.S.C. 1395ww(o)(1)) is amended—

(I) in subparagraph (A), by inserting before the period at the end the following: "and, for performance periods for fiscal year 2018 or a subsequent fiscal year, that provide a demonstration described in subparagraph (D) to the Secretary"; and

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

"(D) DEMONSTRATION DESCRIBED.—The demonstration described in this subparagraph is a demonstration, through means such as an attestation, that the hospital has not taken any action described in subsection (a)(2) of section 3010A of the Public Health Service Act, with respect to the use of any certified EHR technology.".

(ii) HARDSHIP EXEMPTION IN CASE OF DECERTIFIED EHR.—Subclause (II) of section 1886(b)(3)(B)(ix) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(ix)) is amended to read as follows:

"(II)(aa) The Secretary may, on a case-by-case basis, exempt a subsection (d) hospital from the application of subclause (I) with respect to a fiscal year if the Secretary determines, subject to annual renewal, that requiring such hospital to be a meaningful EHR user during such fiscal year would result in a significant hardship, such as in the case of a hospital in a rural area without sufficient Internet access.

"(bb) The Secretary may, on a case-by-case basis, exempt a subsection (d) hospital from the application of subclause (I) with respect to a fiscal year if the Secretary determines, subject to annual renewal, that such hospital was determined to not be a meaningful EHR user because the qualified electronic health record used by such hospital was decertified under section 3001(c)(5)(C) of the Public Health Service Act. An exemption under the previous sentence may be applied to a subsection (d) hospital only, subject to items (cc) and (dd), during the first payment year with respect to the first EHR reporting period to which such decertification applies.

"(cc) In no case shall an exemption by reason of item (bb) be for a period of less than 12 months.

"(dd) An exemption under item (bb) may be extended for a period of an additional 12 months subject to the limitation described in item (ee).

"(ee) Subject to item (cc), in no case may a hospital be granted an exemption under this subclause for more than 5 years.".

(C) DEMONSTRATION REQUIRED FOR MEANINGFUL EHR USE INCENTIVES UNDER MEDICAID.—Section 1903(t)(2) of the Social Security Act (42 U.S.C. 1396b(t)(2)) is amended by adding at the end the following: "An eligible professional shall not qualify as a Medicaid provider under this subsection, with respect to a year beginning with 2018, unless such provider demonstrates to the Secretary, through means such as an attestation, that the provider has not taken any action described in subsection (a)(2) of section 3010A of the Public Health Service Act with respect to which the provider knows or should know (as defined in section 1128A(i)(7) of the Social Security Act) about, with respect to the use of any certified EHR technology.".

(f) DEFINITIONS.—

(1) CERTIFIED EHR TECHNOLOGY.—Paragraph (1) of section 3000 of the Public Health Service Act (42 U.S.C. 300jj) is amended to read as follows:

"(1) CERTIFIED EHR TECHNOLOGY.—The term 'certified EHR technology' means a qualified electronic health record that is certified pursuant to section 3001(c)(5) as meeting the certification criteria defined in subparagraph (B) of such section that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals) including, beginning January 1, 2018, with respect to which the vendor or other entity offering such technology is in compliance with the requirements under section 3001(c)(5)(C)(i).".

(2) WIDESPREAD INTEROPERABILITY.—Section 3000 of the Public Health Service Act (42 U.S.C. 300jj) is amended by adding at the end the following new paragraph:

"(15) WIDESPREAD INTEROPERABILITY.—The term 'widespread interoperability' means that, on a nationwide basis—

"(A) health information technology is interoperable, in accordance with section 3010; and

"(B) such technology is employed by meaningful EHR users under the specified meaningful use incentive programs (as defined in section 3010A(e)) and by other clinicians and health care providers.".

(g) CONFORMING AMENDMENTS.—

(1) VOLUNTARY USE OF STANDARDS.—Section 3006 of the Public Health Service Act (42 U.S.C. 300jj–16) is amended—

(A) in subsection (a)(1), by inserting ", including an interoperability standard adopted under such section" after "section 3004".

(B) in subsection (b), by inserting ", including the interoperability standards adopted under such section" after "section 3004".

(2) HIPAA PRIVACY AND SECURITY LAW DEFINITION CORRECTION.—Section 3009(a)(2)(A) of the Public Health Service Act (42 U.S.C. 300jj–19(a)(2)(A)) is amended by striking "title IV" and inserting "title XIII".

(3) COORDINATION OF FEDERAL ACTIVITIES.—Section 13111 of the HITECH Act is amended—

(A) in subsection (a), by inserting before the period at the end the following: "(and, beginning on January 1, 2018, that are also interoperable under section 3010 of such Act, including by being in compliance with interoperability standards adopted under section 3004 of such Act)"; and

(B) in subsection (b), by inserting "(and, beginning on January 1, 2018, including an interoperability standard adopted under section 3004 of such Act)" before "the President".

(4) APPLICATION TO PRIVATE ENTITIES.—Section 13112 of the HITECH Act is amended by inserting before the period at the end the following: "(and, beginning on January 1, 2018, that are also interoperable under section 3010 of such Act, including by being in compliance with interoperability standards adopted under section 3004 of such Act)".

(5) COORDINATION WITH RECOMMENDATIONS FOR ACHIEVING WIDESPREAD EHR INTEROPERABILITY.—Section 106 of the Medicare Access and CHIP Reauthorization Act of 2015 (Public Law 114–10) is amended by striking subsection (b).".

(h) PATIENT EMPOWERMENT.—It is the sense of Congress that—

(1) patients have the right to the entirety of the health information of such patients, including such information contained in an electronic health record of such patients;

(2) such right extends to both structured and unstructured data; and

(3) to further facilitate patient ownership over health information of such patient—

(A) health care providers should not have the ability to deny a patient's request for access to the entirety of such health information of such patient; and

(B) health care providers do not need the consent of their patients to share personal health information of such patients with other covered entities, in compliance with the HIPAA privacy regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 for the purposes of supporting patient care, except in situations where consent is specifically required under such regulations, such as in cases related to the psychiatric records of the patient.

Subtitle B—Telehealth

SEC. 3021. TELEHEALTH SERVICES UNDER THE MEDICARE PROGRAM.

(a) PROVISION OF INFORMATION BY CENTERS FOR MEDICARE & MEDICAID SERVICES.—Not later than 1 year after the date of the enactment of this Act, the Administrator of the Centers for Medicare & Medicaid Services shall provide to the committees of jurisdiction of the House of Representatives and the Senate information on the following:

(1) The populations of Medicare beneficiaries, such as those who are dually eligible for the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) and the Medicaid program under title XIX of such Act (42 U.S.C. 1396 et seq.) and those with chronic conditions, whose care may be improved most in terms of quality and efficiency by the expansion, in a manner that meets or exceeds the existing in-person standard of care under the Medicare program under title XVIII of such Act, of telehealth services under section 1834(m)(4) of such Act (42 U.S.C. 1395m(m)(4)).

(2) Activities by the Center for Medicare and Medicaid Innovation which examine the use of telehealth services in models, projects, or initiatives funded through section 1115A of the Social Security Act (42 U.S.C. 1315a).

(3) The types of high volume procedures codes or diagnoses under such title XVIII which might be suitable to the furnishing of services via telehealth.

(4) Barriers that might prevent the expansion of telehealth services under section 1834(m)(4) of the Social Security Act (42 U.S.C. 1395m(m)(4)) beyond such services that are in effect as of the date of the enactment of this Act.

(b) PROVISION OF INFORMATION BY MEDPAC.—Not later than 1 year after the date of the enactment of this Act, the Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6) shall, using data from the Medicare Advantage program under part C of title XVIII of such Act (42 U.S.C. 1395w–21 et seq.), provide information to the committees of jurisdiction of the House of Representatives and the Senate that identifies—

(1) services—

(A) for which payment could not be made, as of the date of the enactment of this Act, under the fee-for-service program under parts A and B of such title by reason of any limitation imposed under section 1834(m) of such Act (42 U.S.C. 1395m(m)); and

(B) that are services that are recommended by the Commission to be included as telehealth services for which payment may be made under the fee-for-service program under parts A and B of such title; and

(2) barriers to furnishing telehealth services for which payment may be made under such title XVIII and solutions to address such barriers.

(c) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) States should collaborate, through the use of State health board compacts or other mechanisms, to create common licensure requirements services in order to facilitate multistate practices and allow for health care providers to provide such services across State lines;

(2) health care providers should be appropriately licensed in the physical location where the patient is receiving services;

(3) eligible originating sites should be expanded beyond those originating sites described in section 1834(m)(4)(C) of the Social Security Act (42 U.S.C. 1395m(m)(4)(C)); and

(4) any expansion of telehealth services under the Medicare program should—

(A) recognize that telemedicine is the delivery of safe, effective, quality health care services, by a health care provider, using technology as the mode of care delivery;

(B) meet or exceed the conditions of coverage and payment with respect to the Medicare program under title XVIII unless specifically address in subsequent statute, of such Act if the service were furnished in person, including standards of care; and

(C) involve clinically appropriate means to furnish such services.

Subtitle C—Encouraging Continuing Medical Education for Physicians

SEC. 3041. EXEMPTING FROM MANUFACTURER TRANSPARENCY REPORTING CERTAIN TRANSFERS USED FOR EDUCATIONAL PURPOSES.

(a) IN GENERAL.—Section 1128G(e)(10)(B) of the Social Security Act (42 U.S.C. 1320a–7h(e)(10)(B)) is amended—

(1) in clause (iii), by inserting ", including peer-reviewed journals, journal reprints, journal supplements, medical conference reports, and medical textbooks" after "patient use"; and

(2) by adding at the end the following new clause:

"(xiii) In the case of a covered recipient who is a physician, an indirect payment or transfer of value to the covered recipient—

"(I) for speaking at, or preparing educational materials for, an educational event for physicians or other health care professionals that does not commercially promote a covered drug, device, biological, or medical supply; or

"(II) that serves the sole purpose of providing the covered recipient with medical education, such as by providing the covered recipient with the tuition required to attend an educational event or with materials provided to physicians at an educational event.".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to transfers of value made on or after the date of the enactment of this Act.

Subtitle D—Disposable Medical Technologies

SEC. 3061. TREATMENT OF CERTAIN ITEMS AND DEVICES.

(a) IN GENERAL.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

"(r) PAYMENT FOR CERTAIN DISPOSABLE DEVICES.—

"(1) IN GENERAL.—The Secretary shall make separate payment in the amount established under paragraph (3) to a home health agency for a device described in paragraph (2) when furnished to an individual who receives home health services for which payment is made under section 1895(b).

"(2) DEVICE DESCRIBED.—For purposes of paragraph (1), a device described in this paragraph is a disposable device for which, as of January 1, 2015, there is—

"(A) a Level I Healthcare Common Procedure Coding System (HCPCS) code for which the description for a professional service includes the furnishing of such device; and

"(B) a separate Level I HCPCS code for a professional service that uses durable medical equipment instead of such device.

"(3) PAYMENT AMOUNT.—The Secretary shall establish the separate payment amount for such a device such that such amount does not exceed the payment that would be made for the HCPCS code described in paragraph (2)(A) under section 1833(t) (relating to payment for covered OPD services).".

(b) CONFORMING AMENDMENT.—Section 1861(m)(5) of the Social Security Act (42 U.S.C. 1395x(m)(5)) is amended by inserting "and devices described in section 1834(r)(2)" after "durable medical equipment".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to devices furnished on or after January 1, 2017.

Subtitle E—Local Coverage Decision Reforms

SEC. 3081. IMPROVEMENTS IN THE MEDICARE LOCAL COVERAGE DETERMINATION (LCD) PROCESS.

(a) IN GENERAL.—Section 1862(l)(5) of the Social Security Act (42 U.S.C. 1395y(l)(5)) is amended by adding at the end the following new subparagraph:

"(D) LOCAL COVERAGE DETERMINATIONS.—The Secretary shall require each medicare administrative contractor that develops a local coverage determination to make available on the website of such contractor and in the coverage database on the Medicare website, at least 45 days before the effective date of such determination, the following information:

"(i) Such determination in its entirety.

"(ii) Where and when the proposed determination was first made public.

"(iii) Hyperlinks to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.

"(iv) A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence.

"(v) An explanation of the rationale that supports such determination.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to local coverage determinations that are proposed or revised on or after the date that is 180 days after the date of the enactment of this Act.

Subtitle F—Medicare Pharmaceutical and Technology Ombudsman

SEC. 3101. MEDICARE PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN.

Section 1808(c) of the Social Security Act (42 U.S.C. 1395b–9(c)) is amended by adding at the end the following new paragraph:

"(4) PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN.—Not later than 12 months after the date of the enactment of this paragraph, the Secretary shall provide for a pharmaceutical and technology ombudsman within the Centers for Medicare & Medicaid Services who shall receive and respond to complaints, grievances, and requests that—

"(A) are from entities that manufacture pharmaceutical, biotechnology, medical device, or diagnostic products that are covered or for which coverage is being sought under this title; and

"(B) are with respect to coverage, coding, or payment under this title for such products.".

Subtitle G—Medicare Site-of-Service Price Transparency

SEC. 3121. MEDICARE SITE-OF-SERVICE PRICE TRANSPARENCY.

Section 1834 of the Social Security Act (42 U.S.C. 1395m), as amended by section 3061, is further amended by adding at the end the following new subsection:

"(s) SITE-OF-SERVICE PRICE TRANSPARENCY.—

"(1) IN GENERAL.—In order to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or to an ambulatory surgical center under this title, the Secretary shall, for 2017 and each year thereafter, make available to the public via a searchable website, with respect to an appropriate number of such items and services—

"(A) the estimated payment amount for the item or service under the outpatient department fee schedule under subsection (t) of section 1833 and the ambulatory surgical center payment system under subsection (i) of such section; and

"(B) the estimated amount of beneficiary liability applicable to the item or service.

"(2) CALCULATION OF ESTIMATED BENEFICIARY LIABILITY.—For purposes of paragraph (1)(B), the estimated amount of beneficiary liability, with respect to an item or service, is the amount for such item or service for which an individual who does not have coverage under a medicare supplemental policy certified under section 1882 or any other supplemental insurance coverage is responsible.

"(3) IMPLEMENTATION.—In carrying out this subsection, the Secretary—

"(A) shall include in the notice described in section 1804(a) a notification of the availability of the estimated amounts made available under paragraph (1); and

"(B) may utilize mechanisms in existence on the date of the enactment of this subsection, such as the portion of the website of the Centers for Medicare & Medicaid Services on which information comparing physician performance is posted (commonly referred to as the Physician Compare website), to make available such estimated amounts under such paragraph.

"(4) FUNDING.—For purposes of implementing this subsection, the Secretary shall provide for the transfer, from the Supplemental Medical Insurance Trust Fund under section 1841 to the Centers for Medicare & Medicaid Services Program Management Account, of $6,000,000 for fiscal year 2015, to remain available until expended.".

Subtitle H—Medicare Part D Patient Safety and Drug Abuse Prevention

SEC. 3141. PROGRAMS TO PREVENT PRESCRIPTION DRUG ABUSE UNDER MEDICARE PARTS C AND D.

(a) DRUG MANAGEMENT PROGRAM FOR AT-RISK BENEFICIARIES.—

(1) IN GENERAL.—Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–10(c)) is amended by adding at the end the following:

"(5) DRUG MANAGEMENT PROGRAM FOR AT-RISK BENEFICIARIES.—

"(A) AUTHORITY TO ESTABLISH.—A PDP sponsor may establish a drug management program for at-risk beneficiaries under which, subject to subparagraph (B), the PDP sponsor may, in the case of an at-risk beneficiary for prescription drug abuse who is an enrollee in a prescription drug plan of such PDP sponsor, limit such beneficiary's access to coverage for frequently abused drugs under such plan to frequently abused drugs that are prescribed for such beneficiary by one or more prescribers selected under subparagraph (D), and dispensed for such beneficiary by one or more pharmacies selected under such subparagraph.

"(B) REQUIREMENT FOR NOTICES.—

"(i) IN GENERAL.—A PDP sponsor may not limit the access of an at-risk beneficiary for prescription drug abuse to coverage for frequently abused drugs under a prescription drug plan until such sponsor—

"(I) provides to the beneficiary an initial notice described in clause (ii) and a second notice described in clause (iii); and

"(II) verifies with the providers of the beneficiary that the beneficiary is an at-risk beneficiary for prescription drug abuse.

"(ii) INITIAL NOTICE.—An initial notice described in this clause is a notice that provides to the beneficiary—

"(I) notice that the PDP sponsor has identified the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse;

"(II) information describing all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health services and other counseling services;

"(III) notice of, and information about, the right of the beneficiary to appeal such identification under subsection (h) and the option of an automatic escalation to external review;

"(IV) a request for the beneficiary to submit to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would prefer the PDP sponsor to select under subparagraph (D) in the case that the beneficiary is identified as an at-risk beneficiary for prescription drug abuse as described in clause (iii)(I);

"(V) an explanation of the meaning and consequences of the identification of the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse, including an explanation of the drug management program established by the PDP sponsor pursuant to subparagraph (A);

"(VI) clear instructions that explain how the beneficiary can contact the PDP sponsor in order to submit to the PDP sponsor the preferences described in subclause (IV) and any other communications relating to the drug management program for at-risk beneficiaries established by the PDP sponsor; and

"(VII) contact information for other organizations that can provide the beneficiary with assistance regarding such drug management program (similar to the information provided by the Secretary in other standardized notices provided to part D eligible individuals enrolled in prescription drug plans under this part).

"(iii) SECOND NOTICE.—A second notice described in this clause is a notice that provides to the beneficiary notice—

"(I) that the PDP sponsor has identified the beneficiary as an at-risk beneficiary for prescription drug abuse;

"(II) that such beneficiary is subject to the requirements of the drug management program for at-risk beneficiaries established by such PDP sponsor for such plan;

"(III) of the prescriber (or prescribers) and pharmacy (or pharmacies) selected for such individual under subparagraph (D);

"(IV) of, and information about, the beneficiary's right to appeal such identification under subsection (h) and the option of an automatic escalation to external review;

"(V) that the beneficiary can, in the case that the beneficiary has not previously submitted to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would prefer the PDP sponsor select under subparagraph (D), submit such preferences to the PDP sponsor; and

"(VI) that includes clear instructions that explain how the beneficiary can contact the PDP sponsor.

"(iv) TIMING OF NOTICES.—

"(I) IN GENERAL.—Subject to subclause (II), a second notice described in clause (iii) shall be provided to the beneficiary on a date that is not less than 60 days after an initial notice described in clause (ii) is provided to the beneficiary.

"(II) EXCEPTION.—In the case that the PDP sponsor, in conjunction with the Secretary, determines that concerns identified through rulemaking by the Secretary regarding the health or safety of the beneficiary or regarding significant drug diversion activities require the PDP sponsor to provide a second notice described in clause (iii) to the beneficiary on a date that is earlier than the date described in subclause (I), the PDP sponsor may provide such second notice on such earlier date.

"(C) AT-RISK BENEFICIARY FOR PRESCRIPTION DRUG ABUSE.—

"(i) IN GENERAL.—For purposes of this paragraph, the term 'at-risk beneficiary for prescription drug abuse' means a part D eligible individual who is not an exempted individual described in clause (ii) and—

"(I) who is identified through the use of clinical guidelines developed by the Secretary in consultation with PDP sponsors and other stakeholders described in section 3141(f)(2)(A) of the 21st Century Cures Act; or

"(II) with respect to whom the PDP sponsor of a prescription drug plan, upon enrolling such individual in such plan, received notice from the Secretary that such individual was identified under this paragraph to be an at-risk beneficiary for prescription drug abuse under the prescription drug plan in which such individual was most recently previously enrolled and such identification has not been terminated under subparagraph (F).

"(ii) EXEMPTED INDIVIDUAL DESCRIBED.—An exempted individual described in this clause is an individual who—

"(I) receives hospice care under this title;

"(II) is a resident of a long-term care facility, of an intermediate care facility for the mentally retarded, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or

"(III) the Secretary elects to treat as an exempted individual for purposes of clause (i).

"(D) SELECTION OF PRESCRIBERS AND PHARMACIES.—

"(i) IN GENERAL.—With respect to each at-risk beneficiary for prescription drug abuse enrolled in a prescription drug plan offered by such sponsor, a PDP sponsor shall, based on the preferences submitted to the PDP sponsor by the beneficiary pursuant to clauses (ii)(IV) and (iii)(V) of subparagraph (B), select—

"(I) one or more individuals who are authorized to prescribe frequently abused drugs (referred to in this paragraph as 'prescribers') who may write prescriptions for such drugs for such beneficiary; and

"(II) one or more pharmacies that may dispense such drugs to such beneficiary.

"(ii) REASONABLE ACCESS.—In making the selections under this subparagraph—

"(I) a PDP sponsor shall ensure that the beneficiary continues to have reasonable access to frequently abused drugs (as defined in subparagraph (G)), taking into account geographic location, bene-

ficiary preference, impact on costsharing, and reasonable travel time; and

"(II) a PDP sponsor shall ensure such access (including access to prescribers and pharmacies with respect to frequently abused drugs) in the case of individuals with multiple residences and in the case of natural disasters and similar emergency situations.

"(iii) BENEFICIARY PREFERENCES.—

"(I) IN GENERAL.—If an at-risk beneficiary for prescription drug abuse submits preferences for which in-network prescribers and pharmacies the beneficiary would prefer the PDP sponsor select in response to a notice under subparagraph (B), the PDP sponsor shall—

"(aa) review such preferences;

"(bb) select or change the selection of prescribers and pharmacies for the beneficiary based on such preferences; and

"(cc) inform the beneficiary of such selection or change of selection.

"(II) EXCEPTION.—In the case that the PDP sponsor determines that a change to the selection of prescriber or pharmacy under item (bb) by the PDP sponsor is contributing or would contribute to prescription drug abuse or drug diversion by the beneficiary, the PDP sponsor may change the selection of prescriber or pharmacy for the beneficiary without regard to the preferences of the beneficiary described in subclause (I).

"(iv) CONFIRMATION.—Before selecting a prescriber (or prescribers) or pharmacy (or pharmacies) under this subparagraph, a PDP sponsor must request and receive confirmation from such a prescriber or pharmacy acknowledging and accepting that the beneficiary involved is in the drug management program for at-risk beneficiaries.

"(E) TERMINATIONS AND APPEALS.—The identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph, a coverage determination made under a drug management program for at-risk beneficiaries, and the selection of prescriber or pharmacy under subparagraph (D) with respect to such individual shall be subject to reconsideration and appeal under subsection (h) and the option of an automatic escalation to external review to the extent provided by the Secretary.

"(F) TERMINATION OF IDENTIFICATION.—

"(i) IN GENERAL.—The Secretary shall develop standards for the termination of identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph. Under such standards such identification shall terminate as of the earlier of—

"(I) the date the individual demonstrates that the individual is no longer likely, in the absence of the restrictions under this paragraph, to be an at-risk beneficiary for prescription drug abuse described in subparagraph (C)(i); and

"(II) the end of such maximum period of identification as the Secretary may specify.

"(ii) RULE OF CONSTRUCTION.—Nothing in clause (i) shall be construed as preventing a plan from identifying an individual as an at-risk beneficiary for prescription drug abuse under subparagraph (C)(i) after such termination on the basis of additional information on drug use occurring after the date of notice of such termination.

"(G) FREQUENTLY ABUSED DRUG.—For purposes of this subsection, the term 'frequently abused drug' means a drug that is a controlled substance that the Secretary determines to be frequently abused or diverted.

"(H) DATA DISCLOSURE.—In the case of an at-risk beneficiary for prescription drug abuse whose access to coverage for frequently abused drugs under a prescription drug plan has been limited by a PDP sponsor under this paragraph, such PDP sponsor shall disclose data, including any necessary individually identifiable health information, in a form and manner specified by the Secretary, about the decision to impose such limitations and the limitations imposed by the sponsor under this part.

"(I) EDUCATION.—The Secretary shall provide education to enrollees in prescription drug plans of PDP sponsors and providers regarding the drug management program for at-risk beneficiaries described in this paragraph, including education—

"(i) provided by medicare administrative contractors through the improper payment outreach and education program described in section 1874A(h); and

"(ii) through current education efforts (such as State health insurance assistance programs described in subsection (a)(1)(A) of section 119 of the Medicare Improvements for Patients and Providers Act of 2008 (42 U.S.C. 1395b–3 note)) and materials directed toward such enrollees.

"(J) APPLICATION UNDER MA–PD PLANS.—Pursuant to section 1860D—21(c)(1), the provisions of this paragraph apply under part D to MA organizations offering MA–PD plans to MA eligible individuals in the same manner as such provisions apply under this part to a PDP sponsor offering a prescription drug plan to a part D eligible individual.".

(2) INFORMATION FOR CONSUMERS.—Section 1860D–4(a)(1)(B) of the Social Security Act (42 U.S.C. 1395w–104(a)(1)(B)) is amended by adding at the end the following:

"(v) The drug management program for at-risk beneficiaries under subsection (c)(5).".

(b) UTILIZATION MANAGEMENT PROGRAMS.—Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)), as amended by subsection (a)(1), is further amended—

(1) in paragraph (1), by inserting after subparagraph (D) the following new subparagraph:

"(E) A utilization management tool to prevent drug abuse (as described in paragraph (6)(A)).''; and

(2) by adding at the end the following new paragraph:

"(6) UTILIZATION MANAGEMENT TOOL TO PREVENT DRUG ABUSE.—

"(A) IN GENERAL.—A tool described in this paragraph is any of the following:

"(i) A utilization tool designed to prevent the abuse of frequently abused drugs by individuals and to prevent the diversion of such drugs at pharmacies.

"(ii) Retrospective utilization review to identify—

"(I) individuals that receive frequently abused drugs at a frequency or in amounts that are not clinically appropriate; and

"(II) providers of services or suppliers that may facilitate the abuse or diversion of frequently abused drugs by beneficiaries.

"(iii) Consultation with the contractor described in subparagraph (B) to verify if an individual enrolling in a prescription drug plan offered by a PDP sponsor has been previously identified by another PDP sponsor as an individual described in clause (ii)(I).

"(B) REPORTING.—A PDP sponsor offering a prescription drug plan (and an MA organization offering an MA–PD plan) in a State shall submit to the Secretary and the Medicare drug integrity contractor with which the Secretary has entered into a contract under section 1893 with respect to such State a report, on a monthly basis, containing information on—

"(i) any provider of services or supplier described in subparagraph (A)(ii)(II) that is identified by such plan sponsor (or organization) during the 30-day period before such report is submitted; and

"(ii) the name and prescription records of individuals described in paragraph (5)(C).".

(c) EXPANDING ACTIVITIES OF MEDICARE DRUG INTEGRITY CONTRACTORS (MEDICS).—

(1) IN GENERAL.—Section 1893 of the Social Security Act (42 U.S.C. 1395ddd) is amended by adding at the end the following new subsection:

"(j) EXPANDING ACTIVITIES OF MEDICARE DRUG INTEGRITY CONTRACTORS (MEDICS).—

"(1) ACCESS TO INFORMATION.—Under contracts entered into under this section with Medicare drug integrity contractors (including any successor entity to a Medicare drug integrity contractor), the Secretary shall authorize such contractors to directly accept prescription and necessary medical records from entities such as pharmacies, prescription drug plans, MA–PD plans, and physicians with respect to an individual in order for such contractors to provide information relevant to the determination of whether such individual is an at-risk beneficiary for prescription drug abuse, as defined in section 1860D–4(c)(5)(C).

"(2) REQUIREMENT FOR ACKNOWLEDGMENT OF REFERRALS.—If a PDP sponsor or MA organization refers information to a contractor described in paragraph (1) in order for such contractor to assist in the determination described in such paragraph, the contractor shall—

"(A) acknowledge to the sponsor or organization receipt of the referral; and

"(B) in the case that any PDP sponsor or MA organization contacts the contractor requesting to know the determination by the contractor of whether or not an individual has been determined to be an individual described such paragraph, shall inform such sponsor or organization of such determination on a date that is not later than 15 days after the date on which the sponsor or organization contacts the contractor.

"(3) MAKING DATA AVAILABLE TO OTHER ENTITIES.—

"(A) IN GENERAL.—For purposes of carrying out this subsection, subject to subparagraph (B), the Secretary shall authorize MEDICs to respond to requests for information from PDP sponsors and MA organizations, State prescription drug monitoring programs, and other entities delegated by such sponsors or organizations using available programs and systems in the effort to prevent fraud, waste, and abuse.

"(B) HIPAA COMPLIANT INFORMATION ONLY.—Information may only be disclosed by a MEDIC under subparagraph (A) if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).".

(2) OIG STUDY AND REPORT ON EFFECTIVENESS OF MEDICS.—

(A) STUDY.—The Inspector General of the Department of Health and Human Services shall conduct a study on the effectiveness of Medicare drug integrity contractors with which the Secretary of Health and Human Services has entered into a contract under section 1893 of the Social Security Act (42 U.S.C. 1395ddd) in identifying, combating, and preventing fraud under the Medicare program, including under the authority provided under section 1893(j) of the Social Security Act, added by paragraph (1).

(B) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Inspector General shall submit to Congress a report on the study conducted under subparagraph (A). Such report shall include such recommendations for improvements in the effectiveness of such contractors as the Inspector General determines appropriate.

(d) TREATMENT OF CERTAIN COMPLAINTS FOR PURPOSES OF QUALITY OR PERFORMANCE ASSESSMENT.—Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152) is amended by adding at the end the following new subsection:

"(d) TREATMENT OF CERTAIN COMPLAINTS FOR PURPOSES OF QUALITY OR PERFORMANCE ASSESSMENT.—In conducting a quality or performance assessment of a PDP sponsor, the Secretary shall develop or utilize existing screening methods for reviewing and considering complaints that are received from enrollees in a prescription drug plan offered by such PDP sponsor and that are complaints regarding the lack of access by the individual to prescription drugs due to a drug management program for at-risk beneficiaries.".

(e) SENSE OF CONGRESS REGARDING USE OF TECHNOLOGY TOOLS TO COMBAT FRAUD.—It is the sense of Congress that MA organizations and PDP sponsors should consider using e-prescribing and other health information technology tools to support combating fraud under MA–PD plans and prescription drug plans under parts C and D of the Medicare program.

(f) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by this section shall apply to prescription drug plans (and MA–PD plans) for plan years beginning more than 1 year after the date of the enactment of this Act.

(2) STAKEHOLDER MEETINGS PRIOR TO EFFECTIVE DATE.—

(A) IN GENERAL.—Not later than January 1, 2016, the Secretary of Health and Human Services shall convene stakeholders, including individuals entitled to benefits under part A of title XVIII of the Social Security Act or enrolled under part B of such title of such Act, advocacy groups representing such individuals, physicians, pharmacists, and other clinicians, retail pharmacies, plan sponsors, entities delegated by plan sponsors, and biopharmaceutical manufacturers for input regarding the topics described in subparagraph (B).

(B) TOPICS DESCRIBED.—The topics described in this subparagraph are the topics of—

(i) the impact on cost-sharing and ensuring accessibility to prescription drugs for enrollees in prescription drug plans of PDP sponsors, and enrollees in MA–PD plans, who are at-risk beneficiaries for prescription drug abuse (as defined in subparagraph (C) of paragraph (5) of section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)));

(ii) the use of an expedited appeals process under which such an enrollee may appeal an identification of such enrollee as an at-risk bene-

ficiary for prescription drug abuse under such paragraph (similar to the processes established under the Medicare Advantage program under part C of title XVIII of the Social Security Act that allow an automatic escalation to external review of claims submitted under such part);

(iii) the types of enrollees that should be treated as exempted individuals, as described in subparagraph (C)(ii) of such paragraph;

(iv) the manner in which terms and definitions in such paragraph should be applied, such as the use of clinical appropriateness in determining whether an enrollee is an at-risk beneficiary for prescription drug abuse as defined in subparagraph (C) of such paragraph;

(v) the information to be included in the notices described in subparagraph (B) of such paragraph and the standardization of such notices; and

(vi) with respect to a PDP sponsor (or Medicare Advantage organization) that establishes a drug management program for at-risk beneficiaries under such paragraph, the responsibilities of such PDP sponsor (or organization) with respect to the implementation of such program.

(g) RULEMAKING.—The Secretary of Health and Human Services shall promulgate regulations based on the input gathered pursuant to subsection (f)(2)(A).

TITLE IV—MEDICAID, MEDICARE, AND OTHER REFORMS

Subtitle A—Medicaid and Medicare Reforms

SEC. 4001. LIMITING FEDERAL MEDICAID REIMBURSEMENT TO STATES FOR DURABLE MEDICAL EQUIPMENT (DME) TO MEDICARE PAYMENT RATES.

(a) MEDICAID REIMBURSEMENT.—

(1) IN GENERAL.—Section 1903(i) of the Social Security Act (42 U.S.C. 1396b(i)) is amended—

(A) in paragraph (25), by striking "or" at the end;

(B) in paragraph (26), by striking the period at the end and inserting "; or"; and

(C) by inserting after paragraph (26) the following new paragraph:

"(27) with respect to any amounts expended by the State on the basis of a fee schedule for items described in section 1861(n), as determined in the aggregate with respect to each class of such items as defined by the Secretary, in excess of the aggregate amount, if any, that would be paid for such items within such class on a fee-for-service basis under the program under part B of title XVIII, including, as applicable, under a competitive acquisition program under section 1847 in an area of the State.".

(2) EFFECTIVE DATE.—The amendments made by this subsection shall be effective with respect to payments for items furnished on or after January 1, 2020.

(b) MEDICARE OMBUDSMAN.—Section 1808(c) of the Social Security Act (42 U.S.C. 1395b(c)), as amended by section 3101, is further amended by adding at the end the following new paragraph:

"(5) MONITORING DME REIMBURSEMENT UNDER MEDICAID.—The ombudsmen under each of paragraphs (1) and (4) shall evaluate the impact of the competitive acquisition program under section 1847, including as applied under section 1903(i)(27), on beneficiary health status and health outcomes.".

SEC. 4002. MEDICARE PAYMENT INCENTIVE FOR THE TRANSITION FROM TRADITIONAL X-RAY IMAGING TO DIGITAL RADIOGRAPHY AND OTHER MEDICARE IMAGING PAYMENT PROVISION.

(a) PHYSICIAN FEE SCHEDULE.—

(1) PAYMENT INCENTIVE FOR TRANSITION.—

(A) IN GENERAL.—Section 1848(b) of the Social Security Act (42 U.S.C. 1395w–4(b)) is amended by adding at the end the following new paragraph:

"(9) SPECIAL RULE TO INCENTIVIZE TRANSITION FROM TRADITIONAL X-RAY IMAGING TO DIGITAL RADIOGRAPHY.—

"(A) LIMITATION ON PAYMENT FOR FILM X-RAY IMAGING SERVICES.—In the case of imaging services that are X rays taken using film and that are furnished during 2017 or a subsequent year, the payment amount for the technical component (including the technical component portion of a global fee) of such services that would otherwise be determined under this section

(without application of this paragraph and before application of any other adjustment under this section) for such year shall be reduced by 20 percent.

"(B) PHASED-IN LIMITATION ON PAYMENT FOR COMPUTED RADIOGRAPHY IMAGING SERVICES.—In the case of imaging services that are X rays taken using computed radiography technology—

"(i) in the case of such services furnished during 2018, 2019, 2020, 2021, or 2022 the payment amount for the technical component (including the technical component portion of a global fee) of such services that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this section) for such year shall be reduced by 7 percent; and

"(ii) in the case of such services furnished during 2023 or a subsequent year, the payment amount for the technical component (including the technical component portion of a global fee) of such services that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this section) for such year shall be reduced by 10 percent.

"(C) COMPUTED RADIOGRAPHY TECHNOLOGY DEFINED.—For purposes of this paragraph, the term 'computed radiography technology' means cassette-based imaging which utilizes an imaging plate to create the image involved.

"(D) IMPLEMENTATION.—In order to implement this paragraph, the Secretary shall adopt appropriate mechanisms which may include use of modifiers.".

(B) EXEMPTION FROM BUDGET NEUTRALITY.—Section 1848(c)(2)(B)(v) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)(B)(v)) is amended by adding at the end the following new subclause:

"(X) REDUCED EXPENDITURES ATTRIBUTABLE TO INCENTIVES TO TRANSITION TO DIGITAL RADIOGRAPHY.—Effective for fee schedules established beginning with 2017, reduced expenditures attributable to subparagraph (A) of subsection (b)(9) and effective for fee schedules established beginning with 2018, reduced expenditures attributable to subparagraph (B) of such subsection.".

(2) ELIMINATION OF APPLICATION OF MULTIPLE PROCEDURE PAYMENT REDUCTION.—Section 1848(b)(4) of the Social Security Act (42 U.S.C. 1395w–4(b)(4)) is amended by adding at the end the following new subparagraph:

"(E) ELIMINATION OF APPLICATION OF MULTIPLE PROCEDURE PAYMENT REDUCTION.—

"(i) IN GENERAL.—Not later than January 1, 2016, the Secretary shall not apply a multiple procedure payment reduction policy to the professional component of imaging services furnished in any subsequent year that is prior to a year in which the Secretary conducts and publishes, as part of the Medicare Physician Fee Schedule Proposed Rule for a year, the empirical analysis described in clause (ii).

"(ii) EMPIRICAL ANALYSIS DESCRIBED.—The empirical analysis described in this clause is an analysis of the Resource-Based Relative Value Scale (commonly known as the 'RBRVS') Data Manager information that is used to determine what, if any, efficiencies exist within the professional component of imaging services when two or more studies are performed on the same patient on the same day. Such empirical analysis shall include—

"(I) work sheets and other information detailing which physician work activities performed given the typical vignettes were assigned reduction percentages of 0, 25, 50, 75 and 100 percent;

"(II) a discussion of the clinical aspects that informed the assignment of the reduction percentages described in subclause (I);

"(III) an explanation of how the percentage reductions for pre-, intra-, and post-service work were determined and calculated; and

"(IV) a demonstration that the Centers for Medicare & Medicaid Services has consulted with practicing radiologists to gain knowledge of how radiologists interpret studies of multiple body parts on the same individual on the same day.".

(b) PAYMENT INCENTIVE FOR TRANSITION UNDER HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM.—Section 1833(t)(16) of the Social Security Act (42 U.S.C. 1395(t)(16)) is amended by adding at the end the following new subparagraph:

"(F) PAYMENT INCENTIVE FOR THE TRANSITION FROM TRADITIONAL X-RAY IMAGING TO DIGITAL RADIOGRAPHY.—Notwithstanding the previous provisions of this subsection:

"(i) LIMITATION ON PAYMENT FOR FILM X-RAY IMAGING SERVICES.—In the case of imaging services that are X rays taken using film and that are furnished during 2017 or a subsequent year, the payment amount for the technical component (including the technical component portion of a global fee) of such services that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 20 percent.

"(ii) PHASED-IN LIMITATION ON PAYMENT FOR COMPUTED RADIOGRAPHY IMAGING SERVICES.—In the case of imaging services that are X rays taken using computed radiography technology (as defined in section 1848(b)(9)(C))—

"(I) in the case of such services furnished during 2018, 2019, 2020, 2021, or 2022 the payment amount for the technical component (including the technical component portion of a global fee) of such services that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 7 percent; and

"(II) in the case of such services furnished during 2023 or a subsequent year, the payment amount for the technical component (including the technical component portion of a global fee) of such services that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 10 percent.

"(iii) APPLICATION WITHOUT REGARD TO BUDGET NEUTRALITY.—The reductions made under this paragraph—

"(I) shall not be considered an adjustment under paragraph (2)(E); and

"(II) shall not be implemented in a budget neutral manner.".

SEC. 4003. IMPLEMENTATION OF OFFICE OF INSPECTOR GENERAL RECOMMENDATION TO DELAY CERTAIN MEDICARE PRESCRIPTION DRUG PLAN PREPAYMENTS.

Section 1860D–15(d) of the Social Security Act (42 U.S.C. 1395w–115(d)) is amended by adding at the end the following:

"(5) TIMING OF PAYMENTS.—With respect to monthly reinsurance payment amounts under this section to a PDP sponsor for months in a year (beginning with 2020), such payment amounts for a month shall be made on the first business day occurring on or after the following date for that month:

"(A) For the month of January, January 2nd.

"(B) For the month of February, February 5th.

"(C) For the month of March, March 10th.

"(D) For the month of April, April 15th.

"(E) For the month of May, May 20th.

"(F) For the month of June, June 25th.

"(G) For the month of July and each succeeding month (other than December) in a year, the first day of the next month.

"(H) For the month of December, December 24th.".

Subtitle B—Cures Innovation Fund

SEC. 4041. CURES INNOVATION FUND.

(a) ESTABLISHMENT.—There is hereby established in the Treasury of the United States a fund to be known as the Cures Innovation Fund (in this section referred to as the "Fund").

(b) APPROPRIATIONS.—There is hereby appropriated to the Fund, out of any funds in the Treasury not otherwise appropriated, $110,000,000 for each of fiscal years 2016 through 2020.

(c) EXPENDITURES.—Amounts in the Fund shall be available, as provided by appropriation Acts, for making expenditures for carrying out the following:

(1) Section 229A of the Public Health Service Act, as added by section 1123 (relating to data on natural history of diseases).

(2) Part E of title II of the Public Health Service Act, as added by section 1141 (relating to Council for 21st Century Cures).

(3) Section 2001 and the amendments made by such section (relating to development and use of patient experience data to enhance structured risk-benefit assessment framework).

(4) Section 2021 and the amendments made by such section (relating to qualification of drug development tools).

(5) Section 2062 and the amendments made by such section (relating to utilizing evidence from clinical experience).

(6) Section 2161 (relating to grants for studying the process of continuous drug manufacturing).

(d) SUPPLEMENT, NOT SUPPLANT; PROHIBITION AGAINST TRANSFER.—Funds appropriated by subsection (b)—

(1) shall be used to supplement, not supplant, amounts otherwise made available to the National Institutes of Health and the Food and Drug Administration; and

(2) notwithstanding any transfer authority in any appropriation Act, shall not be used for any purpose other than the expenditures listed in subsection (c).

Subtitle C—Other Reforms

SEC. 4061. SPR DRAWDOWN.

(a) DRAWDOWN AND SALE.—Notwithstanding section 161 of the Energy Policy and Conservation Act (42 U.S.C. 6241), the Secretary of Energy shall draw down and sell 8,000,000 barrels of crude oil from the Strategic Petroleum Reserve during each of the fiscal years 2018 through 2025, except as provided in subsection (b). Amounts received for a sale under this subsection shall be deposited in the general fund of the Treasury during the fiscal year in which the sale occurs.

(b) EMERGENCY PROTECTION.—The Secretary shall not draw down and sell crude oil under this section in amounts that would result in a Strategic Petroleum Reserve that contains an inventory of petroleum products representing less than 90 days of emergency reserves, based on the average daily level of net imports of crude oil and petroleum products in the previous calendar year.

(c) PROCEEDS.—Proceeds from a sale under this section shall be deposited into the general fund of the Treasury of the United States.

Subtitle D—Miscellaneous

SEC. 4081. LYME DISEASE AND OTHER TICK-BORNE DISEASES.

(a) IN GENERAL.—Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following new part:

"PART W—LYME DISEASE AND OTHER TICK-BORNE DISEASES

"SEC. 399OO. RESEARCH.

"(a) IN GENERAL.—The Secretary shall conduct or support epidemiological, basic, translational, and clinical research regarding Lyme disease and other tick-borne diseases.

"(b) BIENNIAL REPORTS.—The Secretary shall ensure that each biennial report under section 403 includes information on actions undertaken by the National Institutes of Health to carry out subsection (a) with respect to Lyme disease and other tick-borne diseases, including an assessment of the progress made in improving the outcomes of Lyme disease and such other tick-borne diseases.

"SEC. 399OO–1. WORKING GROUP.

"(a) ESTABLISHMENT.—The Secretary shall establish a permanent working group, to be known as the Interagency Lyme and Tick-Borne Disease Working Group (in this section and section 399OO–2 referred to as the 'Working Group'), to review all efforts within the Department of Health and Human Services concerning Lyme disease and other tick-borne diseases to ensure interagency coordination, minimize overlap, and examine research priorities.

"(b) RESPONSIBILITIES.—The Working Group shall—

"(1) not later than 24 months after the date of enactment of this part, and every 24 months thereafter, develop or update a summary of—

"(A) ongoing Lyme disease and other tick-borne disease research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, duration of illness, intervention, and access to services and supports for individuals with Lyme disease or other tick-borne diseases;

"(B) advances made pursuant to such research;

"(C) the engagement of the Department of Health and Human Services with persons that participate at the public meetings required by paragraph (5); and

"(D) the comments received by the Working Group at such public meetings and the Secretary's response to such comments;

"(2) ensure that a broad spectrum of scientific viewpoints is represented in each such summary;

"(3) monitor Federal activities with respect to Lyme disease and other tick-borne diseases;

"(4) make recommendations to the Secretary regarding any appropriate changes to such activities; and

"(5) ensure public input by holding annual public meetings that address scientific advances, research questions, surveillance activities, and emerging strains in species of pathogenic organisms.

"(c) MEMBERSHIP.—

"(1) IN GENERAL.—The Working Group shall be composed of a total of 14 members as follows:

"(A) FEDERAL MEMBERS.—Seven Federal members, consisting of one or more representatives of each of—

"(i) the Office of the Assistant Secretary for Health;

"(ii) the Food and Drug Administration;

"(iii) the Centers for Disease Control and Prevention;

"(iv) the National Institutes of Health; and

"(v) such other agencies and offices of the Department of Health and Human Services as the Secretary determines appropriate.

"(B) NON-FEDERAL PUBLIC MEMBERS.—Seven non-Federal public members, consisting of representatives of the following categories:

"(i) Physicians and other medical providers with experience in diagnosing and treating Lyme disease and other tick-borne diseases.

"(ii) Scientists or researchers with expertise.

"(iii) Patients and their family members.

"(iv) Nonprofit organizations that advocate for patients with respect to Lyme disease and other tick-borne diseases.

"(v) Other individuals whose expertise is determined by the Secretary to be beneficial to the functioning of the Working Group.

"(2) APPOINTMENT.—The members of the Working Group shall be appointed by the Secretary, except that of the non-Federal public members under paragraph (1)(B)—

"(A) one shall be appointed by the Speaker of the House of Representatives; and

"(B) one shall be appointed by the majority leader of the Senate.

"(3) DIVERSITY OF SCIENTIFIC PERSPECTIVES.—In making appointments under paragraph (2), the Secretary, the Speaker of the House of Representatives, and the majority leader of the Senate shall ensure that the non-Federal public members of the Working Group represent a diversity of scientific perspectives.

"(4) TERMS.—The non-Federal public members of the Working Group shall each be appointed to serve a 4-year term and may be reappointed at the end of such term.

"(d) MEETINGS.—The Working Group shall meet as often as necessary, as determined by the Secretary, but not less than twice each year.

"(e) APPLICABILITY OF FACA.—The Working Group shall be treated as an advisory committee subject to the Federal Advisory Committee Act.

"(f) REPORTING.—Not later than 24 months after the date of enactment of this part, and every 24 months thereafter, the Working Group—

"(1) shall submit a report on its activities, including an up-to-date summary under subsection (b)(1) and any recommendations under subsection (b)(4), to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor and Pensions of the Senate;

"(2) shall make each such report publicly available on the website of the Department of Health and Human Services; and

"(3) shall allow any member of the Working Group to include in any such report minority views.

"SEC. 399OO–2. STRATEGIC PLAN.

"Not later than 3 years after the date of enactment of this section, and every 5 years thereafter, the Secretary shall submit to the Congress a strategic plan, informed by the most recent summary under section 399OO–1(b)(1), for the conduct and support of Lyme disease and tick-borne disease research, including—

"(1) proposed budgetary requirements;

"(2) a plan for improving outcomes of Lyme disease and other tick-borne diseases, including progress related to chronic or persistent symptoms and chronic or persistent infection and co-infections;

"(3) a plan for improving diagnosis, treatment, and prevention;

"(4) appropriate benchmarks to measure progress on achieving the improvements described in paragraphs (2) and (3); and

"(5) a plan to disseminate each summary under section 399OO–1(b)(1) and other relevant information developed by the Working Group to the public, including health care providers, public health departments, and other relevant medical groups.".

(b) NO ADDITIONAL AUTHORIZATION OF APPROPRIATIONS.—No additional funds are authorized to be appropriated for the purpose of carrying out this section and the amendment made by this section, and this section and such amendment shall be carried out using amounts otherwise available for such purpose.

PURPOSE AND SUMMARY

For decades, our nation's commitment to the discovery, development, and delivery of new treatments and cures has made the United States the biomedical innovation capital of the world, bringing life-saving and life-improving drugs and devices to patients. It is clear that the discovery, development, and delivery process is a cycle. Information captured and analyzed at the "end" of the process—the delivery phase—can be used for new discovery and development of better treatments. The purpose of this legislation is to foster this cycle to help bring more cures and treatments to patients and strengthen the innovation ecosystem in the United States.

BACKGROUND AND NEED FOR LEGISLATION

For over a year, the Energy and Commerce Committee has engaged in a public conversation with patients, innovators, providers, regulators, and researchers about how to move advances in science and medicine into new therapies. The fight to treat and cure disease is an urgent, nonpartisan, national priority. With 10,000 known diseases, 7,000 of which are rare, and treatments for only 500 of them, it is clear that there is much work to do. Disease management costs billions of dollars, and its personal costs are much higher, causing pain and heartbreak during the battle and with each loss of life. The United States has been at the forefront of medical innovation, developing many promising treatments and cures. Nonetheless, improvement in the battle with disease and furthering the nation's leadership position in health care innovation is possible.

The yearlong 21st Century Cures listening session explored the complete cycle of cures—from the discovery of clues in basic science, to the development of new treatments, to the delivery of those cures, and back again to further discovery.

As explained in the section by section below, this legislation contains a number of policies to accelerate the cycle and help find cures and treatments for the thousands of diseases, particularly rare and serious disease.

HEARINGS

The Subcommittee on Health held a hearing entitled "The President's Council of Advisors on Science and Technology (PCAST) Re-

port on Drug Innovation" on May 20, 2014. The Subcommittee received testimony from:

- Gary Neil, M.D., Global Head of Research and Development, Medgenics;
- Sara Radcliffe, Executive Vice President of Health Section, Biotechnology Industry Organization;
- Frank J. Sasinowski, Director, Hyman, Phelps & McNamara, PC;
- Jeff Allen, Executive Director, Friends of Cancer Research; and
- Sean Tunis, M.D., Founder and Chief Executive Officer, Center for Medical Technology Policy.

The Subcommittee on Health held a hearing entitled "Examining the Role of Incentives in Advancing Treatments and Cures for Patients" on June 11, 2014. The Subcommittee received testimony from:

- Kenneth Davis, President and CEO, Mt. Sinai Health System;
- Marc Boutin, Executive Vice President and Chief Operating Officer, National Health Council;
- Alexis Borisy, Partner, Third Rock Ventures;
- Mike Carusi, General Partner, Advanced Technology Ventures;
- Fred Ledley, Professor, Natural & Applied Sciences and Management Director, Center for Integration of Science and Industry, Bentley University;
- C. Scott Hemphill, Professor of Law, Columbia Law School; and
- Steven Miller, Senior Vice President and Chief Medical Officer, Express Scripts Holding Company.

The Subcommittee on Health held a hearing entitled "Modernizing Clinical Trials" on July 9, 2014. The Subcommittee received testimony from:

- Roy S. Herbst, M.D., Ph.D., Chief of Medical Oncology, Yale Cancer Center;
- Sundeep Khosla, M.D., Director, Center for Clinical and Translational Science, Mayo Clinic;
- Jay P. Siegel, M.D., Chief Biotechnology Office and Head, Scientific Strategy and Policy, Johnson & Johnson;
- William V. Murray, President and CEO, Medical Device Innovation Consortium;
- Robert J. Meyer, M.D., Director, Virginia Center for Translational and Regulatory Sciences, University of Virginia School of Medicine;
- Paula Brown Stafford, M.P.H., President, Clinical Development, Quintiles; and
- Aaron S. Kesselheim, M.D., J.D., M.P.H, Assistant Professor of Medicine at Harvard Medical School.

The Subcommittee on Health held a hearing entitled "Incorporating the Patient Perspective" on July 11, 2014. The Subcommittee received testimony from:

- Janet Woodcock, M.D, Director, Center for Drug Evaluation and Research, Food and Drug Administration;
- Richard F. Pops, Chairman and CEO, Alkermes;

- Robert J. Beall, Ph.D., President and CEO, Cystic Fibrosis Foundation;
- Pat Furlong, Founding President and CEO, Parent Project Muscular Dystrophy;
- Leonard Lichtenfeld, M.D., Deputy Chief Medical Officer, American Cancer Society; and
- Marshall Summar, M.D., Director, Scientific Advisory Committee, National Organization for Rare Disorders.

The Subcommittee on Health held a hearing entitled "Technology for 21st Century Cures" on July 17, 2014. The Subcommittee received testimony from:

- Robert Jarrin, Senior Director, Government Affairs, Qualcomm Incorporated;
- Paul Misener, Vice President, Global Public Policy, Amazon;
- Jonathan Niloff, Chief Medical Officer and Vice President, McKesson Connected Care and Analytics, McKesson Corporation;
- Dan Riskin, Founder, Health Fidelity; and
- Dave Vockell, Chief Executive Officer, LyfeChannel.

The Subcommittee on Health held a hearing entitled "Examining Barriers to Ongoing Evidence Development and Communication" on July 22, 2014. The Subcommittee received testimony from:

- Mary Grealy, President, Healthcare Leadership Council;
- Michael A. Mussallem, Chairman and CEO, Edwards Lifesciences;
- Gregory Schimizzi, M.D., Cofounder, Carolina Arthritis Associates, on behalf of the Alliance for Specialty Medicine;
- Josh Rising, M.D., M.P.H., Director, Medical Devices, The Pew Charitable Trusts; and
- Louis Jacques, Senior Vice President and Chief Clinical Officer, ADVI.

The Subcommittee on Health held a hearing entitled "Examining the Regulation of Laboratory Developed Tests" on September 9, 2014. The Subcommittee received testimony from:

- Jeffrey Shuren, M.D., J.D., Director, Center for Devices and Radiological Health, Food and Drug Administration;
- Christopher Newton-Cheh, M.D., Assistant Professor of Medicine, Harvard Medical School, Massachusetts General Hospital;
- Andrew Fish, Executive Director, AdvaMed Diagnostics;
- Alan Mertz, President, American Clinical Laboratory Association;
- Charles Sawyers, M.D., Immediate-Past President, American Association for Cancer Research; and
- Kathleen Wilsey, Ph.D., Co-Founder, Coalition for 21st Century Medicine.

The Subcommittee on Health held a hearing entitled "Examining Ways to Combat Antibiotic Resistance and Foster New Drug Development" on September 19, 2014. The Subcommittee received testimony from:

- Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration;
- Kenneth J. Hillan, Chief Executive Officer, Achaogen, Inc.;

- Barbara E. Murray, President, Infectious Diseases Society of America;
- Kevin Outterson, Professor of Law, Boston University School of Law;
- Adrian Thomas, Vice President, Global Market Access and Public Health, Janssen Global Services, LLC;
- Allan Coukell, Director, Medical Programs, Pew Health Group, The Pew Charitable Trusts; and
- John H. Powers, Assistant Clinical Professor of Medicine, George Washington University School of Medicine.

The Subcommittee on Health held a hearing to review H.R. 6, 21st Century Cures Act, on April 30, 2015. The Subcommittee received testimony from:

- Kathy Hudson, Deputy Director for Science, Outreach, and Policy, National Institutes of Health;
- Janet Woodcock, M.D., Director of the Center for Drug Evaluation and Research, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; and
- Jeff Shuren, M.D., J.D., Director of the Center for Devices and Radiological Health, Center for Devices and Radiological Health, U.S. Food and Drug Administration.

COMMITTEE CONSIDERATION

On May 14, 2015, the Subcommittee on Health met in open markup session and forwarded H.R. 6 to the full Committee, as amended, by a voice vote. On May 19, 2015, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 6 reported to the House, as amended, by a recorded vote of 51 yeas and 0 nays.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the recorded votes on the motion to report legislation and amendments thereto. A motion by Mr. Upton to order H.R. 6 reported to the House, with amendment, was agreed to by a recorded vote of 51 ayes and 0 nays. The following reflects the recorded votes taken during the Committee consideration:

COMMITTEE ON ENERGY AND COMMERCE -- 114TH CONGRESS
ROLL CALL VOTE # 16

BILL: H.R. 6, the "21st Century Cures Act of 2015"

AMENDMENT: A motion by Mr. Upton to order H.R. 6 favorably reported to the House, as amended. (Final Passage)

DISPOSITION: AGREED TO, by a roll call vote of 51 yeas and 0 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton	X			Mr. Pallone	X		
Mr. Barton	X			Mr. Rush	X		
Mr. Whitfield	X			Ms. Eshoo	X		
Mr. Shimkus	X			Mr. Engel	X		
Mr. Pitts	X			Mr. Green	X		
Mr. Walden	X			Ms. DeGette	X		
Mr. Murphy	X			Ms. Capps			
Mr. Burgess	X			Mr. Doyle	X		
Mrs. Blackburn	X			Ms. Schakowsky	X		
Mr. Scalise				Mr. Butterfield	X		
Mr. Latta	X			Ms. Matsui	X		
Mrs. McMorris Rodgers				Ms. Castor	X		
Mr. Harper	X			Mr. Sarbanes	X		
Mr. Lance	X			Mr. McNerney	X		
Mr. Guthrie	X			Mr. Welch	X		
Mr. Olson	X			Mr. Lujan	X		
Mr. McKinley	X			Mr. Tonko	X		
Mr. Pompeo	X			Mr. Yarmuth	X		
Mr. Kinzinger	X			Ms. Clarke	X		
Mr. Griffith	X			Mr. Loebsack	X		
Mr. Bilirakis	X			Mr. Schrader	X		
Mr. Johnson	X			Mr. Kennedy	X		
Mr. Long	X			Mr. Cardenas	X		
Mrs. Ellmers	X						
Mr. Bucshon	X						
Mr. Flores	X						
Mrs. Brooks	X						
Mr. Mullin	X						
Mr. Hudson	X						
Mr. Collins	X						
Mr. Cramer	X						

05/21/2015

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee the Committee held hearings and made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The goal of this legislation is to help accelerate the discovery, development, and delivery of promising new treatments and cures for patients and strengthen the innovation ecosystem in the United States.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 6, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that H.R. 6 contains no earmarks, limited tax benefits, or limited tariff benefits.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 23, 2015.

Hon. FRED UPTON,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 6, the 21st Century Cures Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Tom Bradley and Chad Chirico.

Sincerely,

KEITH HALL, *Director.*

Enclosure.

H.R. 6—21st Century Cures Act

Summary: H.R. 6 would authorize appropriations for the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and other agencies within the Department of Health and Human Services (HHS) for programs aimed at promoting the discovery and development of drugs and other technologies that prevent, diagnose, and treat disease or to support activities authorized by the legislation. The bill also would make related changes to those agencies' programs.

In addition, H.R. 6 contains provisions that would:

- Grant additional periods of exclusivity for certain brand-name drugs approved for a new indication that treats a rare disease or condition;
- Require Medicare to make an additional payment to hospitals when Medicare beneficiaries use certain antimicrobial drugs during the course of their hospital stay;
- Direct the sale of 8 million barrels of oil from the Strategic Petroleum Reserve (SPR) in each of the fiscal years 2018 through 2025;
- Delay monthly reinsurance payments to stand-alone prescription drug plans in Medicare Part D by shifting payments between certain fiscal years; and
- Limit federal Medicaid reimbursement to states for durable medical equipment (DME).

CBO estimates that implementing the legislation would cost $106.4 billion over the 2016–2020 period, assuming the appropriation of the authorized and necessary amounts.

CBO estimates that enacting H.R. 6 would reduce direct spending, on net, by $11.9 billion over the 2016–2025 period. (Of that amount, CBO estimates that off-budget costs for the U.S. Postal Service would total $6 million over the 2016–2025 period.) Pay-as-you-go procedures apply because enacting the legislation would affect direct spending. Enacting H.R. 6 would not affect revenues.

H.R. 6 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). However, because the bill would delay entry into the market of some generic drugs and limit Medicaid payments to states for DME, the bill could increase state Medicaid costs by $2.6 billion over the 2016–2025 period, CBO estimates. States have flexibility in that program to adjust their financial and programmatic responsibilities, so those costs would not result from an intergovernmental mandate.

The bill would impose private-sector mandates, as defined in UMRA, on drug manufacturers. CBO estimates that the aggregate cost of the mandates would fall below the annual threshold established in UMRA ($154 million in 2015, adjusted annually for inflation) in each of the first five years that the mandates are in effect.

Estimated cost to the Federal Government: The estimated budgetary effects of H.R. 6 are shown in Table 1. The effects of the legislation fall primarily within budget functions 270 (energy), 550 (health) and 570 (Medicare).

Basis of estimate: For this estimate, CBO assumes that H.R. 6 will be enacted near the start of fiscal year 2016 and that authorized amounts will be appropriated each year. Outlay estimates are based on historical spending patterns for affected programs.

TABLE 1. BUDGETARY EFFECTS OF H.R. 6

	By fiscal year, in millions of dollars—						
	2016	2017	2018	2019	2020	2016–2020	2016–2025
CHANGES IN SPENDING SUBJECT TO APPROPRIATION							
Department of Health and Human Services							
National Institutes of Health							
Authorization Level	33,811	35,331	36,851	2,000	2,000	109,993	n.a.
Estimated Outlays	8,576	27,473	33,679	26,687	8,625	105,040	n.a.
Food and Drug Administration [a]							
Estimated Authorization Level	194	223	240	256	257	1,171	n.a.
Estimated Outlays	59	127	178	234	274	872	n.a.
Centers for Disease Control and Prevention							
Estimated Authorization Level	17	6	6	6	6	41	n.a.
Estimated Outlays	6	10	7	6	6	35	n.a.
Other HHS Programs [b]							
Estimated Authorization Level	112	104	106	109	111	543	n.a.
Estimated Outlays	35	82	97	104	109	427	n.a.
Other Departments and Agencies							
Estimated Authorization Level	1	*	4	6	9	21	n.a.
Estimated Outlays	1	*	4	6	9	21	n.a.
Subtotal							
Estimated Authorization Level	34,135	35,665	37,207	2,378	2,384	111,768	n.a.
Estimated Outlays	8,677	27,692	33,964	27,037	9,024	106,395	n.a.
CHANGES IN DIRECT SPENDING [c]							
Estimated Budget Authority	1	−12	−571	−532	−4,005	−5,119	−11,888
Estimated Outlays	1	−12	−571	−532	−4,005	−5,119	−11,888

Notes: * = less than $500,000; n.a. = not applicable; HHS = Health and Human Services.

Numbers may not add up to totals because of rounding.

[a] Amounts include authorizations of appropriations of $110 million for each of fiscal years 2016 through 2020 from the Cures Innovation Fund established in title IV of the bill. Estimated outlays from the Cures Innovation Fund are also reported here, assuming appropriation action consistent with the bill.

[b] H.R. 6 would provide authorizations of appropriations of $10 million for each of fiscal years 2016 through 2023 for the Council for 21st Century Cures.

[c] In addition, CBO estimates that enacting H.R. 6 would increase off-budget costs for the U.S. Postal Service by $6 million over the 2016–2025 period.

Spending subject to appropriation: H.R. 6 would authorize funding and modify programs within HHS that support medical research, oversee the development and marketing approval for drugs, and monitor the use of drugs in the United States. The legislation also would change the regulatory framework surrounding medical devices and oversight of technology by FDA. As shown in Table 2, CBO estimates that implementing H.R. 6 would cost $106.4 billion over the 2016–2020 period, assuming appropriation of the authorized and estimated amounts. Of that amount, $105.5 billion would be spent from amounts specifically authorized by H.R. 6. CBO estimated other authorizations based on information from NIH, FDA, Centers for Disease Control and Prevention (CDC), and other government agencies.

Assuming appropriation action consistent with the bill, CBO estimates that over the 2016–2020 period:

- Provisions implemented by NIH would cost $105.0 billion;
- Provisions administered by FDA would cost $872 million;
- Provisions administered by CDC would cost $35 million;
- Provisions affecting discretionary spending by other HHS programs would cost $427 million; and
- Provisions affecting discretionary spending by other Departments and agencies would cost $21 million.

TABLE 2. ESTIMATED AUTHORIZATIONS OF APPROPRIATIONS IN H.R. 6

	By fiscal year, in millions of dollars—					
	2016	2017	2018	2019	2020	2016–2020
CHANGES IN SPENDING SUBJECT TO APPROPRIATION [a]						
Title 1—Discovery						
NIH Reauthorization						
Authorization Level	31,811	33,331	34,851	0	0	99,993
Estimated Outlays	8,190	25,750	31,781	24,735	6,645	97,100
NIH Innovation Fund						
Authorization Level	2,000	2,000	2,000	2,000	2,000	10,000
Estimated Outlays	386	1,723	1,897	1,952	1,980	7,939
Other Provisions [b]						
Estimated Authorization Level	21	22	22	21	21	107
Estimated Outlays	7	17	19	20	21	84
Subtotal, Title I						
Estimated Authorization Level	33,832	35,353	36,873	2,021	2,021	110,100
Estimated Outlays	8,583	27,490	33,698	26,707	8,646	105,124
Title II—Development						
Development and Approval of Prescription Drugs and Biologics						
Estimated Authorization Level	51	55	66	69	73	315
Estimated Outlays	22	45	62	69	73	270
Development and Regulation of Medical Devices and Technology						
Estimated Authorizations Level	44	58	65	82	82	331
Estimated Outlays	31	51	61	75	80	299
Subtotal, Title II						
Estimated Authorization Level	95	113	131	151	155	646
Estimated Outlays	52	96	123	145	153	569
Title III—Delivery						
Health Information Technology and Other Provisions						
Estimated Authorization Level	12	2	2	2	2	19
Estimated Outlays	6	4	3	3	2	18
Title IV—Medicaid, Medicare, and Other Reforms						
Cures Innovation Fund [c]						
Authorization Level	110	110	110	110	110	550
Estimated Outlays	11	36	58	94	129	327
SPR Drawdown						
Estimated Authorization Level	0	0	2	2	2	6
Estimated Outlays	0	0	2	2	2	6
Lyme Disease and Other Tick-borne Diseases						
Estimated Authorization Level	86	87	90	92	94	448
Estimated Outlays	25	67	81	87	92	351
Subtotal, Title IV						
Estimated Authorization Level	193	197	202	204	206	1,004
Estimated Outlays	36	102	141	182	223	684
Total						
Estimated Authorization Level	34,135	35,665	37,207	2,378	2,384	111,768
Estimated Outlays	8,677	27,692	33,964	27,037	9,024	106,395

Notes: NIH = National Institutes of Health; SPR = Strategic Petroleum Reserve.
Numbers may not add up to totals because of rounding.
[a] Estimated outlays for specified authorizations of appropriations in H.R. 6 are shown for the title in which the authorization of appropriation is identified in the bill, assuming appropriation action is consistent with the bill.
[b] Includes authorizations of appropriations of $10 million for each of fiscal years 2016 through 2023 for the Council for 21st Century Cures.
[c] Reflects estimated outlays from the Cures Innovation Fund, including any amounts disbursed by the Fund for activities that also are associated with separate authorizations identified in titles I and II of the bill.

Title I—Discovery. Title I would reauthorize NIH, make several programmatic changes to the agency's research and loan repayment programs, and authorize other initiatives aimed at promoting medical research. CBO estimates that implementing title I would cost $105.1 billion over the 2016–2020 period, assuming the availability of appropriated funds.

NIH Reauthorization. Section 1001 would authorize the appropriation of almost $100 billion over the next three years for NIH. The authority for research programs at NIH that are subject to future appropriations expired at the end of fiscal year 2009. Since then, however, the Congress has appropriated an average of about $30 billion annually to continue operating those programs across all areas of research at NIH. CBO estimates that reauthorizing NIH would cost $97.1 billion over the 2016–2020 period.

NIH Innovation Fund. Section 1002 would direct the Secretary of HHS to establish an "NIH Innovation Fund" in the U.S. Treasury to support biomedical research. The bill would authorize the appropriation of $2 billion from that fund for each of fiscal years 2016 through 2020. CBO estimates that spending from the NIH Innovation Fund would total $7.9 billion over the 2016–2020 period.

Other Provisions. Other provisions of title I would aim to promote medical research and accelerate the availability of new therapies. CBO estimates that implementing those provisions of title I would cost $84 million over the 2016–2020 period. That amount includes:

- $45 million for the Council for 21st Century Cures, a public-private partnership intended to help accelerate the discovery, development, and delivery of treatments for patients in the United States. (The bill would authorize the appropriation of $10 million for each of fiscal years 2016 through 2023 for such activities.); [1]
- $21 million for CDC to develop a surveillance system for neurological diseases. (The bill would authorize the appropriation of $5 million for each of fiscal years 2016 through 2020 for such activities.)
- $12 million for the Secretary of HHS to participate in public-private partnerships and award grants to facilitate the collection, analysis, and availability of data on diseases. (The bill would authorize the appropriation of $5 million for each of fiscal years 2016 through 2020 for such activities.); [1] and
- $6 million for FDA to establish a pilot program to create a research sharing system (in coordination with NIH) that would give third parties direct access to data generated from clinical trials funded exclusively by the federal government and to assist NIH with standardizing certain information in the registry data bank involving eligibility for clinical trials.

Title II—Development. Title II of H.R. 6 would modify FDA's approach to regulating prescription drugs, biologicals, medical devices, and health-related technology. It also would make changes to certain surveillance activities by the CDC relating to antimicrobials and to CDC's vaccine-related activities. CBO's estimates reflect the expected number of personnel and investment in information technology required to implement the bill based on information provided by the affected agency. (Provisions in title II primarily affect regulatory activities by FDA.) We estimate that implementing Title II would cost $569 million over the 2016–2020 period, assuming the appropriation of the necessary amounts. As discussed below, Title

[1] The legislation also would authorize the appropriation of additional funds for such purposes from the Cures Innovation Fund established in title IV of the bill. See discussion of spending by the Cures Innovation Fund later in the cost estimate.

II would affect two regulatory areas: 1) prescription drugs and biologics and 2) medical devices and health-related technology.

Development and Approval of Prescription Drugs and Biologics. Title II of H.R. 6 contains several provisions that would modify FDA's regulatory framework for overseeing the development and approval process of drugs and biologics. The title also would establish a grant program for institutions of higher education and nonprofit organizations to study improvements in the process of continuous manufacturing and other production-related techniques. Finally, this title would make changes to CDC's administrative procedures involving antibiotics and vaccines. Taken together, CBO estimates that implementing provisions relating to drugs and biologics in title II would cost $270 million over the 2016–2020 period. That amount includes:

- $33 million to establish a process to qualify or validate certain drug development tools, such as biomarkers, for use in certain applications. That funding would also allow FDA to enter into cooperative agreements and to award grants to assist the agency with the review of such qualification submissions. (The bill would authorize the appropriation of $10 million for each of fiscal years 2016 through 2020 for such activities.);[1]
- $33 million to identify and publish a list of interpretive criteria for tests that characterize the susceptibility of particular bacteria, fungi, or other microorganisms to drugs;
- $31 million to facilitate approval for certain antibacterial and antifungal drugs used by a limited population of patients;
- $25 million to issue and update guidance to industry, including documents that would assist sponsors in the development of precision drugs and biologics, provide guidelines on responsible communication of certain types of information, and clarify agency procedures regarding its review of combination drug products;
- $21 million to administer a new grant program to study continuous drug manufacturing and production-related technologies. (The bill would authorize the appropriation of $5 million each of fiscal years 2016 through 2020 for that program.);[1]
- $21 million to implement a program that would aim to provide incentives to drug companies to develop new indications for drugs and biologics that target rare diseases and conditions and to extend the voucher program for rare pediatric diseases through December 31, 2018;
- $20 million to develop a regulatory structure that would allow the use of new protocols for statistical modeling and trial designs to support marketing applications for drug and biological products;
- $18 million to devise a plan with sponsors of drug and biological products eligible for accelerated approval to agree on certain details of the design of clinical studies in a manner that would expedite approval of such products;
- $14 million, which reflects the costs for a range of federal programs generated by a provision that would extend exclusivities for certain brand-name drugs. (See discussion of the effect of that provision on mandatory costs for federal health programs below.);

- $14 million to establish a "streamlined data review program" that would allow sponsors to submit qualified summaries of clinical data to support the approval or licensure of new indications under certain circumstances;
- $14 million to conduct pilot demonstrations that would expand the use of FDA's existing surveillance program (that allows the agency to query electronic data systems and proactively evaluate safety issues with medical products) to also capture additional evidence of clinical experiences associated with marketed drug products. (The bill would authorize the appropriation of $3 million for each of fiscal years 2016 through 2020 for such activities.); [1]
- $13 million for CDC to monitor and track usage of antibiotic and antifungal drugs; and
- $14 million for miscellaneous provisions of title II that would affect discretionary spending by various federal agencies, primarily FDA, CDC, and the Government Accountability Office.

Development and Regulation of Medical Devices and Technology. Title II of the bill also contains provisions that would modify the regulatory framework surrounding medical devices and oversight of technology by FDA. Assuming appropriation of the necessary amounts, CBO estimates that implementing those provisions would cost $299 million over the 2016–2020 period, primarily for FDA's personnel-related expenses. That amount includes:

- $158 million to establish a program to provide expedited review for certain devices that represent breakthrough technologies where no approved alternatives exist and that technology offers significant advantages over existing alternatives;
- $68 million to establish a new accreditation program for third parties to expedite the approval process for certain devices, review and recognize national and international standards, and develop and update several guidances and regulations;
- $68 million to implement a new framework for the regulation of medical software based on a new definition of health software, and exempting such software from most regulation; and
- $4 million for FDA's Center for Devices and Radiological Health to issue final guidance regarding its review of combination products within 18 months after the date of enactment of H.R. 6, and to update that guidance regularly.

Title III—Delivery. CBO estimates that implementing title III would cost $18 million over the 2016–2020 period, assuming appropriation of the necessary funds. That amount reflects:

- $10 million for contracts with organizations that develop standards to make recommendations for new interoperability standards for electronic health records. (The bill would authorize the appropriation of $10 million in 2016 for such activities.);
- $5 million for the Office of the National Coordinator of Health Information Technology to administer the adoption of those interoperability standards and to publish reports on interoperability;

- $2 million for the Centers for Medicare and Medicaid Services (CMS) and the Medicare Payment Advisory Commission to provide information to the Congress on the use and limitations of telehealth services; and
- $1 million for the Secretary of HHS to establish a Medicare pharmaceutical and technology ombudsman within CMS.

Title III also contains provisions that would affect direct spending. Those provisions are discussed in the direct spending section below.

Title IV—Medicaid, Medicare, and Other Reforms. H.R. 6 would create a fund to pay for new initiatives and administrative costs associated with regulatory requirements established by the bill. It would also direct the Department of Energy (DOE) to sell 64 million barrels of oil from the SPR, and would expand research activities on Lyme disease and other tick-borne diseases. CBO estimates that implementing the provisions in title IV would cost $684 million over the 2016–2020 period, assuming appropriation of the necessary funds. (Title IV also contains provisions that would affect direct spending.)

Cures Innovation Fund. Section 4041 would direct the Secretary of HHS to establish a "Cures Innovation Fund" in the U.S. Treasury. The legislation would authorize the appropriation of $110 million a year from the fund for fiscal years 2016 through 2020. Such authorizations would be in addition to any amounts made available from other authorizations of appropriations identified specifically in titles I and II for the following activities:

- Participating in public-private partnerships and awarding grants that foster the collection, analysis, and availability of data on the natural history of disease;
- Supporting initiatives of the Council for 21st Century Cures;
- Creating a regulatory framework at FDA that incorporates information about patients' experiences with a specific condition or disease, including the risks and benefits of new drug treatments;
- Establishing a process to qualify or validate certain drug development tools, such as biomarkers, for use in certain applications and allowing FDA to enter into cooperative agreements and to award grants to assist the agency with reviewing such qualification submissions;
- Establishing a regulatory framework at FDA to allow information from clinical experiences to support the approval or licensure of a new indication for a drug or biologic, or to fulfill requirements for post-approval study; and
- Administering a new FDA grant program that promotes the study of continuous drug manufacturing and other production-related technologies.

CBO estimates that spending from the Cures Innovation Fund would total $327 million over the 2016–2020 period, assuming appropriation of the authorized amounts.

SPR Drawdown. The bill would direct the DOE to sell 64 million barrels of oil from the SPR, subject to certain conditions. Based on information from DOE, CBO estimates that the transaction costs associated with selling oil from the SPR would average about 21 cents per barrel. Thus, assuming the appropriation of the necessary

amounts, CBO estimates that implementing the sales would cost $6 million over the 2016–2020 period. That estimate includes the incremental cost of power, storage, labor, and various other logistical expenses. According to DOE, selling a total of 64 million barrels from the SPR—which would reduce the current inventory by roughly 9 percent—would not require any decommissioning activities or expenses. (See discussion of the effect of the provision on mandatory costs in the direct spending section of the cost estimate.)

Lyme Disease and Other Tick-borne Diseases. Section 4081 would amend the Public Health Service Act to require the Secretary of HHS to conduct or support research on Lyme disease and other tick-borne diseases. Currently, several federal agencies fund research on tick-borne diseases including NIH and CDC. The bill also would require the Secretary to establish a permanent interagency working group on Lyme disease and other tick-borne diseases and to periodically submit to the Congress a strategic plan for conducting and supporting research in that area. Based on a 2011 study by the Institute of Medicine that reported the average annual funding level for Lyme disease and other tick-borne diseases totaled almost $90 million, CBO estimates that implementing section 4081 would cost $351 million over the 2016–2020 period.

Direct spending: Several provisions in H.R. 6 would affect direct spending. Taken together, CBO estimates that enacting H.R. 6 would reduce on-budget direct spending, on net, by about $11.9 billion over the 2016–2025 period (see Table 3); off-budget costs for the U.S. Postal Service would increase by $6 million over the same period.

TABLE 3. ESTIMATED CHANGES IN ON-BUDGET MANDATORY COSTS FOR H.R. 6

	By fiscal year, in millions of dollars—											
	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2016–2020	2016–2025
CHANGES IN ON-BUDGET DIRECT SPENDING [a]												
Title II—Development												
Encouraging the Development and Use of New Antimicrobial Drugs	0	0	49	60	63	66	71	72	73	81	172	535
Extension of Exclusivity Periods for Certain Drugs Approved for a New Indication for a Rare Disease or Condition	0	0	14	47	84	114	142	147	149	172	145	869
Subtotal, Title II	0	0	63	107	147	180	213	219	222	253	317	1,404
Title III—Delivery												
Treatment of Certain Items and Devices	0	−4	−8	−11	−15	−17	−23	−27	−30	−37	−38	−172
Medicare Site-of-service Price Transparency	1	5	0	0	0	0	0	0	0	0	6	6
Programs to Prevent Prescription Drug Abuse under Medicare Parts C and D	0	−8	−10	−11	−12	−13	−15	−15	−15	−16	−41	−115
Subtotal, Title III	1	−7	−18	−22	−27	−30	−38	−42	−45	−53	−73	−281
Title IV—Medicaid, Medicare, and Other Reforms												
Limiting Federal Medicaid Reimbursement to States for DME	0	0	0	0	−274	−391	−417	−444	−473	−504	−274	−2,503
Medicare Payment for X-rays and Other Imaging Services	0	−5	−16	−17	−17	−18	−19	−18	−17	−18	−55	−145
Delay Certain Payments to Medicare Prescription Drug Plans	0	0	0	0	−3,184	−301	−4,139	−708	3,786	−417	−3,184	−4,963
SPR Drawdown	0	0	−600	−600	−650	−650	−700	−700	−750	−750	−1,850	−5,400
Subtotal, Title IV	0	−5	−616	−617	−4,125	−1,360	−5,275	−1,870	2,546	−1,689	−5,363	−13,011
Total, Changes in On-budget Direct Spending [b]	−11	−12	−571	−532	−4,005	−1,210	−5,100	−1,693	2,723	−1,489	−5,119	11,888

Notes: DME = durable medical equipment; SPR = Strategic Petroleum Reserve.

Numbers may not add up to totals because of rounding.

[a] Budget authority equals outlays for all direct spending provisions. Medicare provisions include interactions with Medicare Advantage payments, the effect on Medicare Part A and Part B premiums, and TRICARE.

[b] CBO estimates that enacting H.R. 6 also would increase off-budget costs for the U.S. Postal Service by $6 million over the 2016–2025 period.

Title II—Development. Title II of the bill would require Medicare to make additional payments to hospitals for using qualifying antimicrobial drugs. It also would extend exclusivity periods for certain drugs approved for a new indication that pertains to treating a rare disease or condition. CBO estimates that implementing such provisions would increase on-budget direct spending for mandatory health programs by $1.4 billion over the 2016–2025 period.[2]

Encouraging the Development and Use of New Antimicrobial Drugs. The bill would require Medicare to make an additional payment to hospitals when Medicare beneficiaries use certain new antimicrobial drugs during the course of their hospital stay. To qualify for the additional payment, a drug would have to meet certain criteria, including: the drug must be approved to treat certain infections for which existing antibiotics are not sufficient and the drug must receive approval for use or for a new indication on or after December 1, 2014. A qualifying drug would be eligible for the additional payment for a period of five years. Each year, the Secretary would establish payment rates for eligible drugs based on payment rates under Part B of Medicare, subject to the pro rata reduction, if any, that the Secretary estimates is needed to limit total payments for such drugs to 0.03 percent of expected Medicare spending for hospital inpatient services. Based on information about drugs currently in the development pipeline that would be likely to satisfy the specified criteria and data from the CDC on rates of antibiotic-resistant infection, CBO estimates that enacting that provision would increase direct spending by about $535 million over the 2016–2025 period.

Extension of Exclusivity Periods for Certain Drugs Approved for a New Indication for a Rare Disease or Condition. Section 2151 of the bill would authorize the FDA to extend exclusivity periods for certain brand-name drugs already on the market by six months if, after enactment of the bill, the drug is approved for a new indication that pertains to treating a rare disease or condition. Such extensions could delay the timing of market entry by lower-priced generic drugs or biosimilars. In addition, the provision would add six months of exclusivity to the patents of select drugs; such provision only would apply to certain designated drugs previously approved under the Federal Food, Drug, and Cosmetic Act (FDCA) and not to biologics previously licensed under the Public Health Service Act.

In order to be eligible for the six month exclusivity period, a drug manufacturer would have to demonstrate safety and efficacy for treatment of a rare disease or condition for which the drug had not been previously approved. CBO expects that approval for the new indication would hinge on successfully completing new clinical trials. While many manufacturers could benefit over the next 10 years from such an extension of exclusivity, CBO expects that only certain drugs that meet all of the following criteria likely would receive one. First, a drug must have the potential to treat a rare disease or condition for which it was not originally approved. Second,

[2] Extending exclusivity periods for certain drugs would affect off-budget spending by the U.S. Postal Service (USPS) for health insurance premiums for its workers and retirees who are covered under the Federal Employees Health Benefits program. CBO estimates that the bill would increase USPS costs (which are classified as off-budget) by $6 million over the 2016–2025 period.

the expected value of returns from undertaking the additional research to obtain approval for the new indication must offset the costs. And finally, sufficient time must be available for the manufacturer to conduct the necessary trials, prepare a marketing application, undergo regulatory review, and obtain approval before facing generic competition.

CBO estimates that about 15 percent of the share of brand-name sales for drugs previously approved under the FDCA that are expected to first experience generic competition before 2025 would have such competition delayed by 6 months under this provision. By delaying the timing of market entry of lower priced generics or biosimilars, CBO expects the provision would increase the drug-related costs of federal health programs (both mandatory and discretionary programs) that pay for prescription drugs and biological products. CBO estimates that the provision would increase on-budget spending on prescription drugs by mandatory health programs by $869 million over the 2016–2025 period. Beyond 2025, the potential for the legislation to delay the entry of generic drugs or biosimilars is greater and the federal budgetary effect would increase in later years.

Title III—Delivery. Title III of the bill also contains provisions that would affect direct spending for Medicare. CBO estimates that enacting those provisions would reduce direct spending, on net, by $281 million over the 2016–2025 period.

Treatment of Certain Items and Devices. Under current law, Medicare beneficiaries may receive negative pressure wound therapy (NPWT), which uses a vacuum pump and special dressings to promote wound healing. NPWTs are available using either a durable pump or a disposable pump that can be used at home. If a home health agency (HHA) furnishes a beneficiary with NPWT using a durable form of the device, Medicare makes a payment to the HHA for the visit and to a DME supplier for the NPWT. If the HHA uses a disposable NPWT, Medicare does not make an additional payment and the HHA absorbs the cost of the NPWT. H.R. 6 would establish a new add-on payment to HHAs when they furnish disposable NPWT; that payment would be lower than the payment for durable NPWT. CBO estimates that there would be some switching from durable NPWT to disposable NPWT and thus this provision would save about $172 million over the 2016–2025 period.

Medicare Site-of-service Price Transparency. H.R. 6 would require CMS to create a new database and website that would enable beneficiaries to compare the estimated Medicare payment and cost-sharing amounts for items and services provided in hospital outpatient departments and ambulatory surgical centers. The bill would appropriate $6 million for this purpose and CBO estimates that all of the funding would be spent by the end of fiscal year 2017.

Programs to Prevent Prescription Drug Abuse under Medicare Parts C and D. The bill would permit private drug plans that administer the Medicare Part D prescription drug benefit to establish a program to limit the number of physicians and pharmacies allowed to prescribe and dispense certain drugs to enrollees identified as being at high risk for prescription drug abuse. Under H.R. 6, plans that implement such a program would use clinical guidelines established by the Secretary of HHS to target certain bene-

ficiaries who use controlled substances the Secretary determines are frequently abused or diverted. For example, restrictions might be placed on beneficiaries suspected of abusing or reselling certain controlled substances, but not placed on beneficiaries with cancer or other conditions for which those drugs are considered appropriate. Based on information from HHS and other stakeholders, CBO estimates that enacting that provision would reduce direct spending by $115 million over the 2016–2025 period.

Title IV—Medicaid, Medicare, and Other Reforms. Title IV of the bill contains provisions that would reduce direct spending. CBO estimates that enacting those provisions would reduce direct spending by $13.0 billion over the 2016–2025 period.

Limiting Federal Medicaid Reimbursement to States for DME. Under current law, states have broad flexibility to set coverage and payment policies in their Medicaid programs. Generally, the federal government reimburses states for a portion of the amount they spend on Medicaid. Section 4001 would limit the amount of spending by states to purchase DME that is eligible for federal reimbursement to the amount that would be paid by the Medicare program. Twelve states have adopted similar policies as of 2014. CBO estimates that enacting DME payment limits in the remaining states beginning January 2020 would reduce direct spending for Medicaid by approximately $2.5 billion over the 2016–2025 period.

Medicare Payments for X-rays and Other Imaging Services. The legislation would reduce Medicare's payment rates under the physician fee schedule for x-ray and other imaging services that do not use digital imaging technology, beginning in 2017. Payment rates for imaging services that use film would be reduced by 20 percent. The reduction for imaging services that use computed radiography would be 7 percent in 2018 through 2022, then 10 percent in 2023 and subsequent years. Based on a review of Medicare claims, CBO estimates that about 1 percent of current spending for imaging services paid under the physician fee schedule would be subject to the reductions in 2017. CBO expects that implementation of the payment reductions would spur adoption of digital technology, and that less than 0.2 percent of spending would be subject to those reductions by 2025. This provision would reduce direct spending about $145 million over the 2016–2025 period, CBO estimates.

Delay Certain Payments to Medicare Prescription Drug Plans. Under current law, most Medicare payments to Part D plans (including capitated payments and reinsurance payments for beneficiaries whose spending exceeds the threshold for the catastrophic portion of the prescription drug benefit) are made on either the first day of the month or the last day of the preceding month (when the first day is a weekend or holiday). Beginning in calendar year 2020, the legislation would delay monthly reinsurance payments to stand-alone prescription drug plans in Medicare Part D. Starting with a payment shift from 2020 to 2021, the provision would shift spending between fiscal years and would shift an estimated $5.0 billion from fiscal year 2025 to fiscal year 2026.[3]

[3] For example, $3.2 billion would be shifted from fiscal year 2020 to 2021, thereby reducing direct spending in 2020 by that amount. For 2021, that $3.2 billion would be shifted into 2021, but $3.5 billion would be shifted into 2022. As a result, the net change in spending in 2021 would amount to $0.3 billion. By 2025, $4.5 billion would be shifted in (from 2024) and almost $5.0 billion would be shifted out (to 2026); the net effect in 2025 would amount to 0.4 billion.

SPR Drawdown. Section 4061 would direct the DOE to sell 8 million barrels of oil from the SPR in each of the fiscal years 2018 through 2025, subject to certain conditions. Under this bill, the proceeds from such sales would be deposited in the general fund of the Treasury by the end of each fiscal year and could not be spent to purchase oil for the reserve. CBO estimates that enacting that provision would increase offsetting receipts (which are certain collections that are treated as reductions in direct spending) by $5.4 billion over the 2016–2025 period.

The estimated receipts reflect CBO's March 2015 projection of oil prices, adjusted for the technical characteristics of the oil being sold from the SPR (those adjusted prices range from about $75 to $96 per barrel over the sales period). Based on information from the Energy Information Administration, CBO estimates that the volume of crude oil in the SPR after these sales would exceed an amount equivalent to a 90-day supply of net imports crude oil and petroleum products, as required by the bill.

Pay-As-You-Go considerations: The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. The net changes in outlays that are subject to those pay-as-you-go procedures are shown in the table below. Only on-budget changes to outlays are subject to pay-as-you-go rules. Enacting H.R. 6 would not affect revenues.

CBO ESTIMATE OF PAY-AS-YOU-GO EFFECTS FOR H.R. 6, AS ORDERED REPORTED BY THE HOUSE COMMITTEE ON ENERGY AND COMMERCE ON MAY 21, 2015

	By fiscal year, in millions of dollars—												
	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2015–2020	2015–2025
NET DECREASE IN THE ON–BUDGET DEFICIT													
Total Changes	0	1	−12	−571	−532	−4,005	−1,210	−5,100	−1,693	2,723	−1,489	−5,119	−11,888
Less:													
Adjustment for Timing Shift[a] ...	0	0	0	0	0	0	0	0	0	0	−4,963	0	−4,963
Statutory Pay-As-You-Go Impact	0	1	−12	−571	−532	−4,005	−1,210	−5,100	−1,693	2,723	3,474	−5,119	−6,925

Source: Congressional Budget Office.

[a] Section 4 of the Statutory Pay-As-You-Go Act of 2010 provides for adjustments related to certain shifts in the timing of spending or revenues. The provision in H.R. 6 that would delay certain payments to Medicare prescription drug plans would create such a timing shift. That provision would shift payments in each year beginning with 2020. The adjustment for timing shifts under pay-as-you-go procedures is only applied to the spending that is shifted from 2025 to 2026.

Increase in long term direct spending: None.

Estimated impact on state, local, and tribal governments: H.R. 6 contains no intergovernmental mandates as defined in UMRA. The bill would delay entry into the market of some generic drugs resulting in an increase of state Medicaid spending for prescription drugs of $50 million over the 2016–2025 period. In addition, the bill would limit the amount that is eligible for federal matching payments to states for DME in Medicaid to the amount that Medicare would pay. That limitation could increase state Medicaid costs by about $2.5 billion over the 2016–2025 period. However, because states have flexibility in Medicaid to adjust their financial and programmatic responsibilities, including the ability to reduce the amounts they would pay vendors for DME, those costs would not result from an intergovernmental mandate.

Estimated impact to the private sector: H.R. 6 would impose private-sector mandates, as defined in UMRA, on drug manufacturers.

CBO estimates that the aggregate cost of the mandates would fall below the annual threshold established in UMRA ($154 million in 2015, adjusted annually for inflation) in each of the first five years that the mandates are in effect.

The bill would impose a mandate on manufacturers of generic drugs and biosimilars by extending by six months the periods of marketing exclusivity for products that receive a new indication for the treatment of a rare disease. Granting drugs additional marketing exclusivity would delay the entry of lower-priced versions of products in those markets. The cost of the mandate for manufacturers of generic products and biosimilars would be the annual net loss of income resulting from the delay, which could be significant depending on the drugs granted an extension. However, based on information about the sales of drugs that could be affected in the first five years that the mandate is in effect, CBO estimates that the cost of the mandate would amount to about $50 million or less in each of those years.

The bill would impose two additional mandates, and CBO estimates that the cost of each of those mandates would be small. The bill would require manufacturers of investigational drugs to make public their policy for reviewing and responding to requests for access to those drugs under compassionate use policies. The bill would allow manufacturers to comply with the mandate by posting a general policy applicable to all its investigational drugs. The bill also would require manufacturers of antimicrobial drugs to submit an application to FDA for changes to the product's label sooner than they would need to under current law. The bill would require that labels for all antimicrobial drugs include a reference to an FDA website which would contain the updated criteria for determining the effectiveness of such drugs. The mandate would result in savings to the affected manufacturers in later years because they would not need to change a product's label each time those criteria are updated.

Estimate prepared by: Federal Costs: National Institutes of Health—Ellen Werble; Food and Drug Administration—Julia Christensen, Anna Cook, and Ellen Werble; Centers for Disease Control and Prevention—Rebecca Yip; Health Information Technology—Zoë Williams; Medicaid—Daniel Hoople; Medicare—Lori Housman, Kevin McNellis, Jamease Miles, Andrea Noda, Lara Robillard, and Rebecca Yip; Strategic Petroleum Reserve—Kathy Gramp. Impact on State, Local, and Tribal Governments: J'nell Blanco Suchy. Impact on the Private Sector: Amy Petz.

Estimate approved by: Holly Harvey, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 6 establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the

Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 6 specifically directs to be completed 3 rule makings within the meaning of 5 U.S.C. 551.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

TITLE I—DISCOVERY

Section 1001. National Institutes of Health reauthorization

Section 1001 would reauthorize the National Institutes of Health (NIH) for three years: Fiscal Year (FY) 2016, $31,811,000,000; FY 2017, $33,331,000,000; and FY 2018, $34,851,000,000. The NIH authorization expired at the end of FY 2009.

Section 1002. NIH Innovation Fund

This section would establish an innovation fund at NIH for five years, FY 2016 through FY 2020, to support biomedical research through the funding of basic, translation, and clinical research. The Innovation Fund is meant to spur scientific innovation and discovery by providing an additional, supplementary funding stream to NIH. These funds will go toward high-risk high reward research and research performed by early stage investigators, among other initiatives. This section establishes an Accelerating Advancement Program at NIH that would allow for dollar for dollar matching from the Office of the Director for institutes and centers seeking funding from the Innovation Fund.

NIH also is encouraged to support research into effective treatments for areas of unmet medical needs. These areas include, but are not limited to, biomarkers, precision medicine, infectious diseases, and antibiotics. The infectious diseases studied should include the pathogens listed as qualifying pathogens by the FDA: Acinetobacter species, Aspergillus species, Burkholderia cepacia complex, Campylobacter species, Candida species, Clostridium difficile, Enterobacteriaceae, Enterococcus species, Mycobacterium tuberculosis complex, Neisseria gonorrhoeae, Neisseria meningitidis, Non-tuberculous mycobacteria species, Pseudomonas species, Staphylococcus aureus, Streptococcus agalactiae, Streptococcus pneumoniae, Streptococcus pyogenes, Vibrio cholera, Coccidioides species, Crytococcus species, and Helicobacter pylori.

These also should include those pathogens listed by FDA in the future.

The Committee also recognizes that several tropical diseases have been identified in the United States over the last decade, including West Nile virus, Chagas disease, cysticerosis, and toxocariasis. While NIH currently supports tropical medicine research centers located in endemic areas outside the U.S., similar support is necessary in parts of the U.S. that are emerging as highly endemic as well, such as the Gulf Coast and Southwest regions. Considering the urgent need for diagnostics and vaccines, the Committee expects NIH to consider tropical diseases endemic to the U.S. to be "unmet medical needs in the United States" for purposes of identifying strategic focus areas for the Innovation Fund, in addition to the tropical diseases listed as eligible for the priority review voucher program established in the Food and Drug Administration Amendments Act of 2007.

Section 1021. NIH research strategic plan

Section 1021 directs NIH to create a scientifically based five-year strategic plan to support research priorities determined by NIH. The plan would be used by the Director of NIH to identify research opportunities and strategic focus areas in which the resources of the national research institutes and national centers can best contribute to the goal of expanding knowledge of human health in the U.S. The plan also would contain overarching and trans-NIH Mission Priority Focus Areas that have the goal of preventing or eliminating the burden of a disease or condition. NIH would have to update the plan every five years. The strategic plan also would ensure that NIH prioritizes maintaining the biomedical workforce of the future.

Currently, individual institutes and centers compile their own strategic plans. NIH as a whole does not have an overarching strategic plan to inform decisions on where to focus research efforts. At this time, no plan shows how inter-institute research is occurring or coordinated. With increased funding, taxpayers should understand the overarching vision of NIH and the priorities it is setting.

Section 1022. Increasing accountability at the National Institutes of Health

This section would provide the Director of NIH with increased authority and address duplication in Federal biomedical research. Under this section, the Director of NIH would have the authority to appoint directors of the national research institutes, excluding the Director of the National Cancer Institute, as well as the directors of the national centers for five-year terms. There would be no limit on the number of terms a director may serve. If the office of a director of a national research institute or national center is vacant before the end of a five-year term, the Director of NIH could appoint a new director for a five year term starting at the date of appointment. Currently, the Director of NIH makes recommendations to the Secretary of Health and Human Services (HHS), and the Secretary makes the final decision on the appointment of the directors.

Section 1022 also would increase accountability by including a review of all "R-series" grants by directors of the national research

institutes or national centers. Directors would have to consider the NIH strategic plan when awarding these grants and whether other agencies are funding programs or projects to accomplish the same goal.

This section would instruct the Institute of Medicine (IOM) to conduct a report on duplication in Federal biomedical research.

This section, in conjunction with the strategic plan, is intended to increase accountability and ownership of decision-making and prioritization at NIH.

Section 1023. Reducing administrative burdens of researchers

This section would help reduce the administrative burden on researchers funded by NIH by implementing findings from various sources. The Scientific Management Review Board, the National Academy of Sciences, and the 2007 and 2012 Faculty Burden Surveys conducted by the Federal Demonstration Partnership have examined this issue extensively. Administrative burden takes time away from researchers focusing on their scientific pursuits.

Section 1024. Exemption for the National Institutes of Health from the Paper Work Reduction Act requirements

This section would exempt the NIH from the Paperwork Reduction Act (PRA) requirements surrounding proposed information collection. Currently, two rounds of public comment and Office of Management and Budget (OMB) approval are required for each proposed information collection. The complete review and approval process takes between six and nine months. The PRA was designed to maximize the utility of information collected by the Federal government. However, this review is burdensome on NIH investigators and delays important research efforts.

Section 1025. NIH travel

This section would set forth a sense of Congress to reiterate the importance of scientific conferences and meetings to the mission of NIH.

Section 1026. Other transactions authority

This section would provide the National Center for Advancing Translational Science (NCATS) at NIH with more flexibility on the use of Other Transaction Authority (OTA) so that it can operate like the Defense Advanced Research Projects Agency (DARPA).

Section 1027. NCATS phase IIB restriction

This section would remove a restriction NCATS' conduct of, or grants for, phase II and III clinical trials.

Section 1028. High-risk, high-reward research

This section would support research that pursues innovative approaches to major challenges in biomedical research that involve inherent high risk, but has the potential to lead to breakthroughs.

Robert Lefkowitz, the 2012 Nobel Prize winner for Chemistry said:

> There's a current problem in biomedical research. The emphasis is on doing things which are not risky. To have a grant proposal funded, you have to propose something

> and then present what is called preliminary data, which is basically evidence that you've already done what you're proposing to do. If there's any risk involved, then your proposal won't be funded. So the entire system tends to encourage not particularly creative research, relatively descriptive and incremental changes which are incremental advances which you are certain to make but not change things very much.

According to the most recent budget congressional justification, NIH states:

> Since the High-Risk High-Reward program tests new ways of supporting innovation, NIH commissioned a rigorous external evaluation of the most mature of these initiatives, the Pioneer Awards. Comparison of research from Pioneer Awards, R01s (NIH's most common project-based grant mechanism), and research funded by the Howard Hughes Medical Institute (HHMI) showed that the Pioneer program has been successful in attracting and supporting research that is more innovative and has greater impact than R01s, and it is comparable to HHMI-supported research.

The language would build on actions already occurring at NIH and require each institute, as appropriate, to fund high risk, high impact science. The NIH Director would establish the percentage of funding an individual institute will be required to spend in this area. Institute Directors in collaboration with the NIH Director would establish programs to accomplish this goal. This language does not state what funding mechanism must be used to accomplish this goal. While NIH's Pioneer and Innovator Awards would be logical types of programs, this section would provide NIH with flexibility to accomplish the goal. The NIH Director would be given the authority to establish the percentage of funding because not all Institute Directors have embraced funding this type of research.

Section 1029. Sense of Congress on increased inclusion of underrepresented communities in clinical trials

Over the past twenty-five years, there have been national efforts in the U.S. to increase the representation of minorities in clinical trials. Although current participation rates do not fully represent the overall population of minorities in the U.S., some progress has been made. This section would set forth a sense of Congress to reiterate the importance of increasing the representation of underrepresented communities in clinical trials. This would help ensure that adequate information is available to assess the safety and effectiveness of drugs in all populations.

Section 1041. Improvement of loan repayment programs of National Institutes of Health

The NIH loan repayment programs help attract and retain early career health professionals by assisting in their repayment of debt associated with medical education and training. NIH wants to encourage outstanding health professionals to pursue careers in biomedical, behavioral, social and clinical research. Since 1998, the NIH Loan Repayment Programs have encouraged promising re-

searchers and scientists to pursue research careers by repaying up to $35,000 of their qualified student loan debt each year if they commit at least two years to conducting qualified research.

Participation in the NIH Loan Repayment Programs has had a major impact on the careers of thousands of research scientists. Participants in the NIH Loan Repayment Programs stay in research longer, apply for and receive more research grants, and become independent investigators more frequently than their colleagues who do not receive loan repayment program funding.

This section would increase the loan repayment cap from $35,000 to $50,000 for the loan repayment programs administered at NIH.

Section 1042. Report

The bulk of the money received by NIH goes to researchers who are esteemed in their fields—but there are concerns that this may limit funding for early or mid-career scientists who may have innovative and potentially transformational ideas. A study for the National Bureau of Economic Research from 2005 examined the age at which over 2,000 Nobel Prize winners and other notable scientists in the 20th century came up with the idea that led to their breakthrough. Most were between thirty-five and thirty-nine. Yet the median age of first-time recipients of R01 grants, the most common and sought-after form of NIH funding, is forty-two, while the median age of all recipients is fifty-two. More people over sixty-five are funded with research grants than those under age thirty-five.

The most innovative thinking frequently comes from younger scientists. NIH is aware of the disparity; NIH Director Francis S. Collins has spoken out about not investing in young scientists and taken steps to target younger researchers. As a result, the average age of first-time grant recipients has stopped rising, but the problem still exists, and NIH can do more.

The language in this section would require NIH to submit a report to Congress within eighteen months of enactment on the actions taken by NIH to attract, retain, and develop emerging scientists.

Section 1061. Capstone Award

The reasons for the age increase of NIH grantees are diverse and complicated. There are not enough faculty positions for the number of graduates with PhDs. When mandatory retirement at age 65 was removed from academia, the number of scientists remaining on the faculty after age sixty-five and even after age seventy dramatically increased. Since so few openings in academia become available, individuals often pursue multiple postdoctoral fellowships. This increases the age at which they start applying for R01 or R01-equivalent grants higher and higher. The current structure actually encourages individuals to get multiple postdoctoral fellowships. Another reason academic institutions encourage multiple postdoctoral fellowships is because postdoctoral fellows cost academic centers and labs less.

The language would create a new "Capstone Award" at NIH. The award could be used to facilitate the transition or conclusion of research programs for senior investigators. This award would allow researchers a new funding mechanism should senior researchers choose to transition their research to pursue other opportunities.

Once a researcher receives a capstone award, he or she may not receive another grant from NIH. The Howard Hughes Medical Institute created a similar program, which has seen significant success.

Section 1081. National Pediatric Research Network

The National Pediatric Research Network Act of 2013 passed as part of the PREEMIE Reauthorization Act and became law on November 27, 2013.

The bill amended the Public Health Service Act to authorize the Director of NIH to establish a National Pediatric Research Network.

It authorized the Director of NIH, in part, to make awards for not more than twenty pediatric research consortia, disseminate scientific findings, and meet requirements prescribed by the Director.

This provision would amend the law to require NIH to establish new pediatric research consortia, and clarify that the Office of the Director can work with any other research institutes or centers to implement the National Pediatric Research Network Act.

Section 1082. Global pediatric clinical study network sense of Congress

Clinical trials are one of the most challenging, resource intensive, and time consuming components of medical product development. Clinical trials for pediatric products prove even more challenging due to limited populations and a limited infrastructure. According to the discussion paper, *Developing a Clinical Trials Infrastructure*, by Paul Eisenberg, Amgen, Inc.; Petra Kaufmann, National Institute of Neurological Disorders and Stroke; Ellen Sigal, Friends of Cancer Research; and Janet Woodcock, U.S. Food and Drug Administration, "clinical trials in the United States have become too expensive, difficult to enroll, inefficient to implement, and ineffective to support the development of new medical products using modern evidentiary standards." The cost and time associated with clinical trials are symptoms of dysfunction within the clinical trial system and infrastructure. Establishing a pediatric clinical study network would create a mechanism to facilitate clinical trials for pediatrics in a more efficient and cost effective way.

This sense of Congress encourages NIH and FDA to work with external stakeholders to build on the success of the Enro-EMA pediatric network to establish a larger and stronger infrastructure to facilitate more pediatric research in order to increase the number of medical products for pediatric populations.

Section 1083. Appropriate age groupings in clinical research

This section would ensure appropriate age groups are included in research studies involving human subjects.

Section 1101. Sharing of data generated through NIH-funded research

There is an increasing expectation from the scientific community and the public that data generated with Federal funds, particularly scientific data, should be shared to enhance transparency in Federal research spending, improve the return on investment in research, and help enhance the quality of research. In particular, the

President has directed Federal agencies to ensure that peer-reviewed publications and digital scientific data resulting from Federally funded scientific research are accessible to the public, the scientific community, and industry.

NIH has long-standing policies that expect data to be shared, such as the 2003 Data Sharing Policy and the 2014 Genomic Data Sharing Policy, as well as specific program policies in place at NIH Institutes and Centers. The NIH Director has explicit statutory authority (section 217 of the HHS Omnibus Appropriations Act of 2009) to require NIH-funded investigators to make their final, peer-reviewed manuscripts publicly available through submission to PubMed Central.

NIH promotes data sharing among awardees in a number of ways. For example, consistent with the Final NIH Statement on Sharing Research Data (Data Sharing Policy) issued in 2003, NIH generally expects applicants to address data sharing in their applications. Through the applicants' submission of data sharing plans, which are incorporated into the terms and conditions of grant awards, sharing consistent with those plans becomes a requirement.

This section would make explicit in statute that the Director has the authority to require researchers to share data that results from NIH funded research.

Section 1102. Standardization of data in clinical trial registry data bank on eligibility for clinical trials

This section would enhance patient searches for ongoing trials by requiring NIH to standardize certain patient inclusion and exclusion information across all trials housed in ClinicalTrials.gov.

The Committee recognizes the important role ClinicalTrials.gov can and does play in helping to facilitate patient matching with ongoing clinical trials. While the current database does afford opportunities for patients and providers to identify such trials, the process is cumbersome and can be difficult to navigate.

During hearings that preceded the legislative process of 21st Century Cures, various patient advocates and other stakeholders noted that increased standardization of data elements across the various trials would help ease the time and effort required to search the database. Such standardization would serve as a foundation upon which health information technology developers might develop applications that facilitate searches from a physician's office through platforms such as electronic health records. Such innovation would help support patients in search of treatment who have run out of FDA-approved treatment options.

The Committee agrees that increased standardization would be of immense benefit to those seeking to search ClinicalTrials.gov, but recognizes that too much standardization could result in valuable data being excluded.

Section 1121. Clinical trial data system

This section would create a pilot third-party scientific research sharing system for trials solely funded by the agencies of HHS in order to allow the use and analysis of de-identified data beyond each individual research project.

Currently, the U.S. is the world leader in medical and scientific research. The Committee commends NIH for its leadership and as supports increased funding through the 21st Century Cures legislation. However, the Committee recognizes that the data generated from such research can play a role in the development of future cures well beyond the conclusion of the specific project being funded.

The NIH has taken steps to increase access to participant-level data from clinical trials. For example, a National Institute of Allergy and Infectious Diseases program provided de-identified participant level information from a network of clinical trials studying autoimmune disorders. Additionally, the National Institute of Mental Health is establishing a common informatics platform for exchanging data from clinical trials of novel interventions for the treatment of mental illness. The creation of the clinical trial data system would build upon those efforts.

The creation of a database designed to store data originating from HHS funded research projects for use and analysis beyond the initial research project holds much promise for the future research. Consider the implications of granting researchers access to de-identified, patient-specific clinical trial data in order to identify ways to improve subsequent trials and reduce the potential for bad outcomes, such as adverse events or even death. Or, consider the potential that research projects in one area could help inform successful solutions in others. The Committee is also cognizant of the paramount importance of protecting patient privacy and confidential commercial information and is confident that these benefits can be obtained while simultaneously protecting these important concerns.

The Committee finds that the creation of a clinical trial database for the purposes of sharing HHS funded data with researchers to support the development of new cures for patients in need allows the Federal government to maximize the benefit of such data and support our global authority in the area of new medical product development.

Section 1122. National neurological diseases surveillance system

Currently, there is limited infrastructure to advance data collection regarding neurological diseases. This lack of data has hindered research and understanding of neurological diseases and new disease targets.

Section 1122 would require the Centers for Disease Control and Prevention (CDC) to set up a surveillance system for neurological diseases like Parkinson's and MS. Other diseases could include Alzheimer's disease among others. The neurological disease surveillance system would enhance and expand the infrastructure and activities to track the epidemiology of neurological diseases. This system will help foster the collection of information on neurological diseases, such as demographics, risk factors, diagnosis, progression markers, and other relevant information.

This provision would authorize $5 million for FY 2016 to FY 2020 for the activities authorized in section 1122. Recognizing the scope of this program will be governed by the availability of resources, the CDC should include multiple sclerosis and Parkinson's disease, and others as practicable.

Section 1123. Data on natural history of diseases

Section 1123 would add section 229A to Part A of title II of the Public Health Service Act, authorizing the Secretary to participate in public-private partnerships and award grants to patient advocacy organizations or other organizations to establish or facilitate the collection, maintenance, analysis, and interpretation of data regarding the natural history of diseases, with a particular focus on rare diseases. Such data would be made publicly available to help facilitate and expedite medical product development programs.

Section 1124. Accessing, sharing, and using health data for research purposes

Section 1124 would make several clarifications and revisions to the regulations implementing the Health Insurance Portability and Accountability Act (HIPAA).

First, it would permit, but not require, covered entities to use protected health information for research purposes by including research within the definition of health care operations. The Committee intends for the covered entity to be able to elect for an activity meeting the requirements of this section to constitute health care operations, for the purposes of compliance with HIPAA, even if it constitutes research under other applicable law. The Committee also intends that this bill creates no changes with respect to the handling of information protected under the Uniform Trade Secrets Act or other commercial or financial information that is privileged or confidential.

Further, section 1124 would permit covered entities to provide access to data for research purposes in the same controlled ways as they currently do for public health activities. In addition, it would permit remote access to protected health information maintained by a covered entity or by a business associate and/or cloud provider on behalf of a covered entity. However, a researcher authorized to access such information may not copy or otherwise retain the protected health information after the approved activities are concluded. The covered entity and the researcher must maintain appropriate privacy and security safeguards.

Finally, section 1124 would clarify the permissibility of authorization for future research use and disclosure of an individual's protected health information under controlled conditions

Section 1141. Council for 21st Century Cures

This section would establish a public-private partnership in the U.S. to accelerate the discovery, development, and delivery of innovative cures, treatments, and preventive measures for patients. This public-private partnership would bring together regulators, academia, patients, providers and others to review and recommend improvements to help accelerate cures and treatments.

TITLE II—DEVELOPMENT

Section 2001. Development and use of patient experience data to enhance structured risk-benefit framework

Section 2001 would amend section 505 of the Federal Food, Drug and Cosmetic Act (FFDCA), requiring the Secretary, in the context of the new drug review process, to implement a structured frame-

work to facilitate the incorporation of patient experiences in the consideration of a drug's benefits and risks. Within two years of the date of enactment of this bill, the Secretary would be required to establish processes under which an entity seeking to develop patient experience data, such as data relating to the impact of a disease or a therapy on patients' lives could submit research concepts, proposed guidance documents, completed data, and summaries and analyses of such data, among other things. Further, within three years of enactment and after convening workshops to obtain input, the Secretary would be required to publish draft guidance on, among other things, methodological considerations and approaches for the collection of patient experience data, including patient-reported outcomes. Final guidance would be published after a public meeting is convened and not later than one year after the comment period for the draft guidance closes.

Section 2021. Qualification of drug development tools

The Committee believes that collaboratively improving the development and qualification of drug development tools, including biomarkers, is critical and that biomedical research consortia and other outside entities can play an important role throughout the process.

Section 2021 would add section 507 to the FFDCA, codifying a structured framework for the submission, review, and qualification of biomarkers and other drug development tools for specific contexts of use that, if qualified, can be relied on by any person for such purposes. The Secretary may consult with outside experts and consider their recommendations throughout the review of a qualification package submitted under this framework.

In addition, section 2021 would require the Secretary to make public information related to each submission, all drug development tools qualified, and all surrogate endpoints that were the basis of approval or licensure of a drug or biological product, while maintaining the protections currently in place for confidential commercial or trade secret information contained in an application submitted outside this legislation's public qualification process and under section 505 of the FFDCA or section 351 of the Public Health Service Act.

The Secretary, in consultation with biomedical research consortia and other interested parties, through a collaborative public process, is required under section 2021 to issue draft guidance on the implementation of section 507 no later than two years after enactment. The development of this guidance is to be informed by the Secretary's publication of a taxonomy for the classification of biomarkers, which is required to be published in draft form no later than one year after enactment.

Section 2022. Accelerated approval development plan

Section 2022 would amend section 506 of the FFDCA to enable the sponsor of a drug that the Secretary determines may be eligible for accelerated approval (i.e., a drug that the Secretary determines could meet all of the statutory and regulatory criteria for approval pursuant section 506(c)) to request voluntarily that the Secretary agree to an accelerated approval development plan, including the surrogate endpoint to be assessed; the design of the study that will

utilize the surrogate endpoint; and the magnitude of the effect of the surrogate endpoint that would be sufficient to form the primary basis of a claim that the drug is effective. The Secretary may require the sponsor to modify or terminate such plan if additional data or information indicates the plan as originally agreed upon is no longer sufficient to demonstrate the safety and effectiveness of the drug, or the drug is no longer eligible for accelerated approval under section 506(c). Prior to the effective date of the modification or termination, the sponsor shall be granted a meeting to discuss the Secretary's basis for the modification or termination.

Section 2041. Precision medicine guidance and other programs of Food and Drug Administration

Section 2041 would require the Secretary to issue and periodically update guidance defining the term "precision drug or biological product" and assisting sponsors in their development. Further, section 2041 would add section 592 to the FFDCA authorizing the Secretary, in the case of a drug or biological product for the treatment of a serious or life-threatening disease or condition designated under section 526 as a drug for a rare disease or condition, to rely upon data or information previously submitted by the sponsor for a different drug or biological product that incorporates or utilizes the same or similar underlying approach. This provision does not permit FDA or any applicant to rely upon data or information of another sponsor unless the applicant has provided the agency with an effective contractual right of reference permitting such reliance.

Section 2061. Broader application of Bayesian statistics and adaptive trial designs

Section 2061 would require FDA to hold a public meeting and issue guidance documents that would assist sponsors in incorporating adaptive designs and Bayesian statistical modeling into their proposed clinical protocols and applications for new drugs and biological products.

Section 2062. Utilizing evidence from clinical experience

Section 2062 would amend the FFDCA by adding section 505F, which would require the Secretary to establish a program to evaluate the potential use of evidence from clinical experience to help support the approval of a new indication for a drug approved under section 505(b) and to help support or satisfy post-approval study requirements. Such program shall be implemented no later than two years after enactment. In parallel, FDA would identify and execute pilot demonstrations to extend existing use of the Sentinel System to, among other things, support these efforts. The Committee does not intend for anything in this section to be construed as prohibiting the Secretary from using evidence from clinical experience for purposes not specified in this section or in any way altering the standards of evidence required by the FFDCA or the PHS Act, or the Secretary's authority to require post-approval studies or clinical trials. Furthermore, the Committee believes that FDA's current safety surveillance activities using Sentinel are exempt under existing law, and that no inference should be drawn that the activi-

ties set forth in the provision, or similar activities, are not exempt under existing law.

Section 2063. Streamlined data review program

Section 2063 would amend the FFDCA by adding section 505H, which would require the Secretary to establish a program authorizing the holder of an approved application to submit a summary of clinical data intended to support the approval or licensure of the drug for a new indication for the treatment of cancer or other types of indications as determined appropriate by the Secretary. The Committee believes that this program should enable FDA to make approval decisions for certain supplemental applications based on such qualified data summaries. In implementing the program, the Secretary is required to post on the FDA website and update annually the number of applications reviewed under the program, the average time for completion of reviews, and the number of applications for which FDA made use of full data sets in addition to the qualified data summary. Further, FDA is required to issue final guidance on implementing the program within two years of enactment, including the process for expanding the types of indications to be considered.

Section 2081. Sense of Congress

Section 2081 reaffirms the Committee's belief that FDA should continue to expedite the approval of drugs designated as breakthrough therapies as early as possible in the clinical development process, provided that the Secretary determines that an application for a drug meets the required evidentiary standards of safety and effectiveness under the FFDCA.

Section 2082. Expanded access policy

Section 2083. Finalizing draft guidance on expanded access

Expanded access programs provide a pathway for patients to gain access to investigational new drugs that have not been approved by the FDA. However, some patients encounter challenges navigating that. There are also scientific challenges regarding how adverse events experienced by patients should be used during FDA's review of a drug for safety and efficacy.

Section 2082 would require certain manufacturers or distributors of an investigational drug to make publicly available, such as through a manufacturer's or distributor's web site, basic information on their expanded access policy. Such policy may apply generally to all of such manufacturer's or distributor's investigational drugs. The provision would not require such companies to offer a drug through an expanded access program or serve as a right to an expanded access program.

Section 2083 would require the FDA to expedite guidance providing clarity to sponsors seeking drug approval regarding the consideration during the drug review process of adverse events experienced by patients receiving a drug through an expanded access program.

Section 2101. Facilitating dissemination of health care economic information

Section 2101 would amend section 502(a) of the FFDCA to clarify the scope of health care economic information drug manufacturers can permissibly disseminate to payors, formulary committees, or other similar entities.

Section 2102. Facilitating responsible communication of scientific and medical developments

Section 2102 would require the Secretary to issue draft guidance, no later than eighteen months from the date of enactment, to clarify how drug and device manufacturers can permissibly disseminate truthful and non-misleading scientific and medical information about a drug or device that is not included in the approved labeling for the product.

Section 2121. Approval of certain drugs for use in a limited population of patients

Section 2122. Susceptibility test interpretive criteria for microorganisms

Section 2123. Encouraging the development and use of antimicrobial drugs

This section would build off of the progress Congress made with the passage of the GAIN Act as a part of the Food and Drug Safety and Innovation Act (FDASIA) in 2012 by facilitating the development of new antibacterial or antifungal drugs through a new FDA approval pathway and creating economic incentives for new drug development.

The Committee believes that antibiotic resistance remains a real and material public threat to the U.S. The unique nature of resistance means that every antimicrobial drug currently on the market is susceptible to drug resistance. The development of new and important treatments for patients with unmet medical needs therefore needs to continue if we are to stay ahead of the pace of antimicrobial resistance. The Committee thinks such development can benefit from regulatory improvements and increased Federal investments. Furthermore, the Committee recognizes that the prudent and appropriate use of antimicrobial drugs can help to prevent the development of resistance and maintain the effectiveness of these drugs.

The Committee supports a limited population approval pathway that would allow the FDA, in partnership with developers, to develop a regulatory process that takes into account the nature of the product and the population of patients it is intended to treat as a means of reducing the time and investment needed to approve such drugs.

In order for such a pathway to function appropriately, choosing such an approach over the traditional development pathway must be voluntary for both the sponsor and Agency. In addition, pursuit of approval for a limited population of patients under this pathway, with its commensurate requirements, should only begin upon completion of a formal written agreement between the sponsor and FDA.

Products approved under this pathway are intended for use in limited populations of patients with infections for which there are few or no satisfactory treatment options available, most likely infections caused by multi-drug resistant organisms. The new tools that will be available to the Agency include labeling requirements that stipulate that the words "Limited Population" be placed in a prominent manner and adjacent to the brand name on the product labeling. This branding element will assist in alerting the healthcare community about the additional uncertainty and risk associated with these products as a result of their streamlined development program. It also will assist FDA, CDC, and professional groups by educating healthcare providers that the risk-benefit profile for these drugs is different than for antimicrobial products approved under a traditional pathway and that these products should be used judiciously and only for patients with serious or life-threatening infections where other suitable, alternative therapies are not available.

Section 2122 provides a streamlined mechanism for the incorporation of updated susceptibility interpretive criteria ('breakpoints') in antimicrobial susceptibility testing (AST) devices, and in their labeling. It does this by establishing an efficient and transparent process for FDA recognition of susceptibility test interpretive criteria, while maintaining FDA's rigorous review standards. AST devices use breakpoints to identify whether a pathogen is susceptible (likely to respond), intermediate, or resistant (not likely to respond) to the tested antimicrobial drugs. These breakpoints change over time because of the evolving nature of antimicrobial resistance. Given the urgent public health crisis caused by antimicrobial resistance, and the need to support the prudent and appropriate use of antimicrobial drugs, the Committee believes that AST devices must provide information based on up-to-date breakpoints for the wide range of pathogens seen in clinical practice, while directing healthcare providers to the labeling of antimicrobial drugs for information about their approved uses.

The Committee also has put forward a new economic incentive through Medicare-payment policy for antimicrobial drugs developed to treat highly-resistant infections. In combination, the Committee intends that such efforts support the development of new and life-saving antibiotic treatments.

Section 2141. Timely review of vaccines by the Advisory Committee on Immunization Practices

In addition to the challenging development environment for vaccines, vaccine manufacturers have an additional step in the development process; the Advisory Committee on Immunization Practices (ACIP) Recommendation process, which takes place following FDA licensure. ACIP working groups "carefully review data available on the vaccine in order to make recommendations to ACIP" and the 15 voting members of ACIP vote on their working groups recommendations before forwarding them to the CDC's Director for approval.[1]

[1] *http://www.cdc.gov/vaccines/hcp/patient-ed/conservations/downloads/vacsafe-acip-color-office.pdf.*

The Committee believes the working groups should have enough time to review the data and information to make an informed recommendation to ACIP, and that ACIP vote on such recommendations in a timely way to ensure patient access to these lifesaving vaccines. Under this section, ACIP would have to provide a decision or update the working groups' status at each scheduled meeting so manufacturers will be able to plan for vaccine distribution. If the Advisory Committee does not make recommendations regarding a vaccine at the first regularly scheduled meeting after licensure, the sponsor can request that the Advisory Committee make such recommendations on an expedited basis.

Section 2142. Review of processes and consistency of ACIP recommendations

This section would require the Director of the CDC to conduct a review of the process used by ACIP in order to evaluate ACIP's consistency in formulating and issuing recommendations pertaining to vaccines. Following such review, the CDC Director shall publish a report on the results of the review, including recommendations on improving the consistency of process.

Section 2143. Meetings between CDC and vaccine developers

Currently, there is no formalized process for stakeholders to meet with CDC to understand the process for developing vaccines. This section would create and formalize processes for the making of vaccination scheduling recommendations by ACIP, for CDC review of ACIP recommendations, and for meetings between CDC and vaccine developers. These meetings will provide companies investing in vaccines more certainty and understanding when establishing investment and development plans.

Section 2151. Extension of exclusivity periods for a drug approved for a new indication for a rare disease or condition

Despite the success of the Orphan Drug Act in bringing drugs to market to patients facing diseases with smaller patient populations, most of the thirty million patients suffering from 7,000 rare diseases still have no treatment options. Ninety-five percent of rare diseases have no FDA-approved treatment.

Section 2151 would incentivize the repurposing of major market drugs for rare diseases—advancing safe and effective treatments and cures to patients facing these rare diseases. The provision would provide a one-time, six month extension of certain exclusivity periods and patent protection for an already-approved drug if the drug's sponsor obtains approval of a new indication for the drug for a rare disease or condition.

Section 2152. Reauthorization of rare pediatric disease priority review voucher incentive program

This section would reauthorize the rare pediatric disease priority review voucher (PRV) program through December 31, 2018. The rare pediatric disease PRV program was established in FDASIA in order to encourage companies to invest in rare pediatric diseases. There are many challenges associated with pediatric drug development and even greater hurdles for rare pediatric diseases with small patient populations. The ability to sell such priority review

vouchers was intended to provide an incentive to foster drug development for rare pediatric diseases.

This section also would broaden the definition of a rare pediatric disease to ensure that pediatric oncology drugs and treatments for sickle cell disease are eligible for designation. The original legislation intended for these products to be included; but FDA found that it could not interpret the statutory language to include them. The draft guidance that FDA released on November 17, 2014, entitled "Rare Pediatric Disease Priority Review Vouchers," interpreted the definition of rare pediatric disease to mean greater than 50 percent of the affected population with the rare disease in the U.S. is aged 0 through 18 years. While many drugs have qualified for this program under this interpretation, including some drugs for pediatric cancers, this section broadens the definition to include more drugs for pediatric rare diseases, including drugs for a broader range of pediatric cancers and sickle cell disease.

Finally, this provision requires the U.S. Government Accounting Office to complete a report evaluating the effectiveness of the program for encouraging drug development for rare pediatric diseases.

Section 2161. Grants for studying the process of continuous drug manufacturing

This section would allow FDA to award grants to higher education and non-profit organizations to study and recommend improvements to the process of continuous manufacturing (and other similar innovative monitoring and control techniques) of drugs and biologics.

The Committee believes that continuous manufacturing advancements will make drug development less expensive and manufacturing more flexible, and improve the quality of drugs.

Section 2162. Re-exportation among members of the European Economic Area

Under current law, U.S. companies and manufacturers are limited in their ability to re-export controlled substances products within the European Economic Area. Section 2162 would allow U.S. pharmaceutical companies to re-export controlled substances similar to foreign pharmaceutical manufacturers, providing a level-playing field regarding controlled substances exports.

Section 2181. Enhancing combination products review

Combination products are often at the cutting edge of innovation as they combine drugs, devices, and/or biological products. Section 2181 requires FDA to issue a final guidance document describing the role of all agency centers when reviewing a combination product

Section 2201. Priority review for breakthrough devices

Section 2201 would add section 515B to the FFDCA, which would require the Secretary to establish a program to provide priority review for qualifying medical devices.

Under this section, a sponsor would be able to request designation at any time prior to the submission of an application under section 515(c), a petition for classification under section 513(f)(2), or a notification under section 510(k). No later than sixty days

after the receipt of such a request, the Secretary shall determine whether the device qualifies based on criteria set forth in this section. For purposes of expediting the development and review of qualifying devices, this section would require the Secretary to take a number of actions, including the assignment of senior agency personnel to oversee the process.

The Committee believes that this section is intended to encourage the Secretary and provide the Secretary with sufficient authorities to apply efficient and flexible approaches to expedite the development of, and prioritize the agency's review of, devices that represent breakthrough technologies.

Section 2221. Third-party quality system assessment

Section 2221 would amend the FFDCA by adding section 524B. Section 524B would require the Secretary to establish a third-party quality system assessment program to accredit persons to assess whether a requestor's quality system, including its design controls, can reasonably assure the safety and effectiveness of certain devices. This section would allow companies to make specified changes to devices or device manufacturing processes without prior FDA approval or clearance if their quality system has been assessed by an accredited person and deemed certified by the Secretary as being capable of evaluating such specified changes and ensuring the safety and effectiveness of the devices subject to such changes.

A certification deemed accepted by the Secretary under proposed section 524B may be revoked upon a determination that the requestor's quality system no longer meets the certification criteria specified in the final guidance with respect to in-scope devices. As a result, any device-related changes made to an in-scope device subsequent to such a determination are subject to the applicable submission requirements. Any device that incorporates device-related changes implemented subsequent to the determination would be considered unapproved or uncleared, and thus may not serve as a legally marketed predicate until the Secretary has approved or cleared the changed device for marketing.

Section 2222. Valid scientific evidence

Section 2222 would amend section 513(a)(3)(B) of the FFDCA to clarify that the Secretary, in the context of reviewing device submissions, may rely on registry data, studies published in peer-reviewed journals, and data collected in countries other than the U.S.

Section 2223. Training and oversight in least-burdensome appropriate means concept

Section 2223 would amend section 513 of the FFDCA and require that each FDA employee involved in the review of premarket device submissions under section 515 or section 510(k) receive training on the "least burdensome" concept, which has been in statute since 1997. Further, FDA would be required to update its guidance and have an audit by the FDA ombudsman conducted on such training.

Section 2224. Recognition of standards

Section 2224 would amend section 514(c) of the FFDCA to establish a process by which any person can request that the Secretary recognize all or part of an appropriate standard relating to devices that has been established by a nationally or internationally recognized standard setting organization. This section would require the Secretary, within sixty days of receiving such a request, to make a determination and issue a response in writing that explains the Secretary's rationale for such determination, including the scientific, technical, regulatory, or other basis, and to make such response publicly available as the Secretary determines appropriate. Further, section 2224 would require the Secretary to provide training on the use of such standards in device reviews and to issue guidance identifying principles for recognizing standards.

Section 2225. Easing regulatory burden with respect to certain Class I and Class II devices

Section 2225 would amend section 510(l) and (m) of the FFDCA to provide a process for the Secretary to identify, through publication in the Federal Register, certain types of class I and II devices the Secretary determines no longer require reports under section 510(k) to provide reasonable assurance of safety and effectiveness.

Section 2226. Advisory committee process

Section 2226 would amend section 513(b) of the FFDCA to enable the more active participation of the person whose device is specifically the subject of the panel review. It would provide the sponsor the opportunity to make recommendations on the expertise needed among voting members of the panel and codify the Secretary's existing practice for giving due consideration to such recommendations. Further, the Secretary would be required to provide adequate time for initial presentations by the person whose device is specifically the subject of the classification panel review. The provisions in section 2226 apply only to panel meetings where a specific device is the subject, not panel meetings where an entire device type is the subject.

For purposes of 513(b)(5)(B) and 513(b)(6)(A) and (B), as amended by section 2226, a device that is specifically the subject of review of a classification panel means a device that is the subject a premarket approval application, premarket notification (510(k)), de novo classification request, humanitarian device exemption application, or investigational device exemption application, or such other type of premarket submission as the Secretary in its sole discretion may specify, and which was referred to the panel for review.

Section 2227. Humanitarian device exemption application

Section 2227 would amend section 520(m) of the FFDCA to provide the Secretary with the authority to apply the humanitarian device exemption to diseases and conditions that affect up to 8,000 individuals in the U.S.

Section 2228. CLIA waiver study design guidance for in vitro diagnostics

Section 2228 would require the Secretary to publish draft guidance within one year of enactment on the appropriate use of com-

parable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The Secretary would be required to finalize such guidance no later than one year after the comment period closes.

Section 2241. Health software

Section 2242. Applicability and inapplicability of regulation

Section 2243. Exclusion from definition of device

Technological innovation around health software and wireless platforms such as smartphones hold great promise for the health care system. However, there are concerns related to the current regulatory approach for health technologies. Sections 2241, 2242, and 2243 would support further development in this field by updating the regulatory laws around software and creating clarity for developers and reviewers alike.

The Committee believes that regulatory discretion is an important tool for FDA to keep up with the pace of innovation.

The Committee believes that the ability to bring certainty and clarity to developers of software products will encourage further innovation in the health care sector. Software and hardware products are unique platforms and distinct enough from each other to warrant review of the ways in which software is approved by FDA to ensure such innovation in this sector continues long into the future.

Further, the Committee believes that software-provided health-related information, in and of itself, is not a threat to the health and welfare of the public. As such, it should not on its own warrant FDA regulation. Save for those products designed to replace the judgment of a clinician, the Committee believes that the Federal government should take a cautious approach to regulation. The Committee believes that the clarity for developers that these provisions provide will support continued health information technology development in the health care sector for decades to come.

Section 2261. Protection of human subjects in research; applicability of rules

Section 2261 would require the Secretary to harmonize differences between the HHS Human Subject Regulations and the FDA Human Subject Regulations to simplify and facilitate researchers' compliance with applicable regulations for the protection of human subjects in research. Specifically, the Secretary would be required to make such modifications as may be necessary to reduce regulatory duplication and unnecessary delays, to modernize such provisions in the context of multisite and cooperative research projects, and to incorporate local considerations, community values, and mechanisms to protect vulnerable populations. Further, the Secretary would be required to issue such regulations and guidance and take such other actions as may be necessary to implement this section and help facilitate the broader use of single, central, or lead institutional review boards.

This provision seeks to reduce regulatory duplication and delays for clinical trials by harmonizing the clinical trial rules imposed by

HHS's Office of Human Research Protection (OHRP) and FDA, to the extent possible and consistent with other statutory provisions.

Section 2262. Use of non-local institutional review boards for review of investigational device exemptions and human device exemptions

Section 2262 would amend section 520 of the FFDCA to remove the requirement to use local institutional review boards (IRB) for clinical testing of medical devices and the use of approved humanitarian use devices. By permitting the use of a central IRB in multisite studies, when appropriate, such research can be facilitated and costs may be reduced, while still protecting the rights, safety, and welfare of study subjects. The ability to have non-local IRB review for approved humanitarian use devices should improve accessibility to these devices in facilities without an associated IRB, such as outpatient surgical clinics or small hospitals.

Section 2263. Alteration or waiver of informed consent for clinical investigations

Section 2263 would amend sections 520(g)(3) and 505(i)(4) of the FFDCA to specify that informed consent is not required for clinical testing of devices and drugs that pose no more than minimal risk to the human subjects and includes appropriate safeguards as prescribed by the Secretary to protect the rights, safety, and welfare of the participants.

This provision will enable the FDA to further harmonize its regulations with the current Federal Policy for the Protection of Human Subjects (the Common Rule), by allowing a waiver of informed consent to conduct minimal-risk research under certain conditions, and in the absence of an emergency or serious or life-threatening risk to subjects, consistent with the Common Rule.

Section 2281. Silvio O. Conte Senior Biomedical Research Service

This section would enable FDA to hire more efficiently and ensure that the agency has the staff required to ensure they keep up with the pace of innovation. One of the biggest challenges that FDA faces is hiring qualified and competitive individuals, and this provision enables the Agency to attract scientists that are designated as "outstanding in their field of biomedical research, clinical research evaluation, and biomedical product assessment." Increasing the number of scientists in the biomedical research service will ensure that FDA can utilize the service to hire and retain experts in the biomedical field.

Section 2282. Enabling FDA scientific engagement

This section expresses congressional support for eliminating barriers that prevent agency staff from attending scientific conferences and meetings. Allowing staff travel for their continued training and education will help the agency keep pace with the latest scientific developments. Such travel has been discouraged due to the resource intensive approval processes, which has negatively affected FDA's ability to review applications with the latest scientific knowledge.

Section 2283. Reagan-Udall Foundation for the Food and Drug Administration

The changes to the Reagan Udall Foundation (RUF) statute relate to issues of internal Foundation governance and management to ensure that RUF has access to the expertise and human capital it needs to fulfill its statutory mission of advancing FDA's scientific priorities. The section would clarify the ability of the RUF Board of Directors to expand the Board's size and add to the Board members of FDA Advisory Committees. It also would leave the matter of compensation for the RUF Executive Director to the discretion of the Board, as is the case with the Foundation for the NIH. These changes would help ensure that RUF has, both on its Board and in its senior management, persons who have the experience and skills to collaborate effectively with FDA in identifying and advancing RUF's core mission areas and who can be effective in locating the public and private resources needed to achieve those shared goals.

RUF's purpose is to assist FDA in fulfilling its mission. Ensuring staff are educated and informed of what outside groups are doing and of the latest scientific innovation is essential to achieving that purpose.

Section 2284. Collection of certain voluntary information exempted from Paperwork Reduction Act

This section would exempt FDA from the PRA with respect to the collection from patients, industry, academia, and other stakeholders of voluntary information such as through voluntary surveys and questionnaires. This would enable FDA to more easily and efficiently receive patient input. The PRA has increased administrative burden at FDA, drained resources, and prohibited FDA from communicating effectively and efficiently with outside parties. Removing these burdens from FDA should enable the agency to utilize these resources for other important work.

Section 2285. Hiring authority for scientific, technical, and professional personnel

The Committee finds that, in order to have a modern and efficient regulatory system, FDA needs to have scientists trained and educated in the latest science and medical research. During the Subcommittee on Health hearing on H.R. 6, Janet Woodcock, M.D., Director of the Center for Drug Evaluation and Research at FDA, noted that hiring is a problem across FDA:

> The science right now is exploding; the new products are extremely innovative. That is wonderful, but we need to have some good scientists who can go toe-to-toe with the best in industry, and industry can afford the best scientists . . . we have extreme difficulty hiring senior people who have worked outside the government.[2]

This provision would enable FDA to hire more efficiently by giving the agency broad and flexible new authority to recruit and retain the staff required to ensure that the agency keeps up with the

[2] *http://docs.house.gov/neetings/IF/IF14/20150430/103400/HHRG-1140IF14-Transcript020150430-U23.pdf.*

pace of innovation. It also includes the ability to offer salaries competitive with those in the private sector and in academia. This authority is essential for FDA be able to hire in an effective manner and to avoid existing inefficient processes.

Section 2301. Exempting from sequestration certain user fees

Section 2301 would permanently exempt the following FDA user fees from sequestration: fees for medical devices, prescription drugs, generics drugs, biosimilars, animal drugs, and generic animal drugs. This provision would provide certainty regarding access to FDA user fees and provide funding for drug and device review and other critical agency functions.

TITLE III—DELIVERY

Section 3001. Ensuring interoperability

As evidenced by statements from numerous 21st Century Cures roundtable participants, the ability to share research and clinical data is a cornerstone of our drive for new cures. The Office of the National Coordinator (ONC) for Health Information Technology has led the charge, but recently has identified barriers to nationwide interoperability of health technology. Section 3001 would refocus national efforts on making systems interoperable and holding individuals responsible for blocking or otherwise inhibiting the flow of patient information throughout our healthcare system.

Section 3021. Telehealth service under the Medicare program

The Energy and Commerce Bipartisan Telemedicine Member Working Group has been working to find a solution that has plagued Congress and our health system for decades: how to adopt new technologies into our delivery system in ways that promote greater quality care and fiscal integrity. Section 3021 would support the efforts of the working group by requiring specific actions of government bodies identified as critical to developing a long-term solution to this problem.

The Committee believes that continuing efforts to identify and adopt solutions that promote increased utilization of telemedicine services and technologies in the Medicare program is beneficial for Medicare beneficiaries. The Committee therefore will continue its efforts and those of the Bipartisan Working Group to effectuate such change.

Section 3041. Exempting from manufacturer transparency reporting certain transfers used for educational purposes

Section 3041 would amend section 1128G(e)(10)(B) of the Social Security Act to exempt certain transfers of value from reporting requirements that providers have noted had a chilling effect on their engagement in important continuing medical education activities.

Section 3061. Treatment of certain items and devices

Today, seniors who receive their care in a home setting are not able to access certain services afforded others because of the nature of the durable medical equipment (DME) payment system. This section would ensure that those seniors receiving care in the home setting are not denied access to certain treatments that would oth-

erwise be available to them based simply on the location in which they seek care.

Section 3081. Improvements in the Medicare local coverage determination (LCD) process

The local coverage determination (LCD) process is an important means by which seniors can access treatments that would not otherwise be covered by Medicare due to the length of time it takes for the national process to conclude its work. However, improvements are needed. Section 3081 would increase transparency around the LCD process and begin the process of bringing greater accountability to the actions of those contracting with the Centers for Medicare and Medicaid Services to manage the operation of the Medicare program.

Section 3101. Medicare pharmaceutical and technology ombudsman

This section would create a new technology ombudsman within Medicare to address problems relating to coverage of new and life-saving technologies.

Section 3121. Medicare site-of-service price transparency

The Medicare benefit currently pays varying rates for the same services depending on where they are delivered. As a result, seniors' out of pocket costs can be higher or lower for a given procedure based upon where the service is provided. This section would give seniors the ability to shop among certain sites of service for certain services so that they can identify the most cost-effective treatments. The Committee believes this is an important step in supporting seniors who wish to shop for the best value at the best cost.

Section 3141. Programs to prevent prescription drug abuse under Medicare parts C and D

This section would allow prescription drug plans in Medicare Part D to develop a safe prescribing and dispensing program for beneficiaries that are prescribed a high volume of controlled substances.

TITLE IV—MEDICAID, MEDICARE, AND OTHER REFORMS

Section 4001. Limiting Federal Medicaid reimbursement to States for durable medical equipment (DME) to Medicare payment rates

Modeled after the policy in the President's FY 2016 budget and previous budget proposals from the Administration, this section would limit Federal matching funds for Medicaid payments for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to Medicare fee schedule rates, and where applicable, the market-based rates paid by Medicare under its competitive bidding program (CBP). The Federal upper payment limit established by this policy is not specific to payment for an individual DMEPOS claim, but would apply in the aggregate to classes of DMEPOS, as defined by the Secretary.

This policy would take effect beginning January 1, 2020. The provision also directs the Medicare Ombudsman established by this

legislation to evaluate the impact of this limit on Federal matching funds on beneficiary health status and outcomes. This policy should not be construed as limiting a State from covering or continuing to cover DME items that are not listed on the Medicare fee schedule. Rather, this policy establishes a Federal upper limit for DME in Medicaid to the applicable Medicare rate.

Section 4002. Medicare payment incentive for the transition from traditional x-ray imaging to digital radiography and other Medicare imaging payment provision

Consistent with the Committee's goals of improving patient care and encouraging the adoption of innovative medical technologies, this section would implement differential Medicare reimbursement for film x-ray and computed radiography (CR) to incentivize the transition to digital radiography (DR). This policy would encourage providers' transition to modern digital technologies and improve patient safety and care as providers transition away from older technology, which may produce less detailed images, thus requiring another image to be taken which exposes patients to the negative clinical effects of additional scans. Additionally, as a matter of basic fairness and transparency, this policy would eliminate application of the multiple procedure payment reduction unless the Secretary conducts and publishes empirical analysis within the Medicare Physician Fee Schedule Proposed Rule in the prior year.

Section 4003. Implementation of Office of Inspector General recommendations to delay certain Medicare prescription drug plan prepayments

Section 4003 would delay monthly reinsurance prepayments for prescription drug plans, beginning in January 2020. This policy implements an Office of Inspector General recommendation to adjust the timing of Medicare's prepayments to Medicare Advantage organizations to better reflect when payments are made to providers, as is currently the policy in the Federal Employees Health Benefits Program. However, this policy only applies to the reinsurance portion of the payment.

Section 4041. Cures Innovation Fund

This section would establish a $110 million annual fund from FY 2016 through FY 2020 for research, regulatory modernization, and other activities authorized by the 21st Century Cures Act, including activities of FDA.

Section 4061. SPR drawdown

This section would direct the Department of Energy to draw down and sell crude oil from the Strategic Petroleum Reserve (SPR).

Section 4081. Lyme disease and other tick-borne diseases

This section would help to accelerate improved methods for prevention, diagnosis, and treatment of Lyme disease. It would establish a working group to prepare a report that would summarize Federal research efforts related to Lyme disease and other tick-borne diseases. Informed by the report prepared by the working

group, the Secretary would develop a strategic plan to improve health outcomes.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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TITLE II—ADMINISTRATION AND MISCELLANEOUS PROVISIONS

PART A—ADMINISTRATION

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SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH *AND BIOMEDICAL PRODUCT ASSESSMENT* SERVICE

SEC. 228. (a)(1) There shall be in the Public Health Service a [Silvio O. Conte Senior Biomedical Research Service, not to exceed 500 members] *Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service (in this section referred to as the "Service"), the purpose of which is to recruit and retain competitive and qualified scientific and technical experts outstanding in the field of biomedical research, clinical research evaluation, and biomedical product assessment.*

[(2) The authority established in paragraph (1) regarding the number of members in the Silvio O. Conte Senior Biomedical Research Service is in addition to any authority established regarding the number of members in the commissioned Regular Corps, in the Reserve Corps, and in the Senior Executive Service. Such paragraph may not be construed to require that the number of members in the commissioned Regular Corps, in the Reserve Corps, or in the Senior Executive Service be reduced to offset the number of members serving in the Silvio O. Conte Senior Biomedical Research Service (in this section referred to as the "Service").]

(2) The authority established in paragraph (1) may not be construed to require the Secretary to reduce the number of employees serving under any other employment system in order to offset the number of members serving in the Service.

(b) The Service shall be appointed by the Secretary without regard to the provisions of title 5, United States Code, regarding appointment, and shall consist of individuals outstanding in the field of biomedical research [or clinical research evaluation], *clinical research evaluation or biomedical product assessment.* No individual may be appointed to the Service unless such individual (1) has earned a doctoral level degree in biomedicine or a related field, *or a master's level degree in engineering, bioinformatics, or a related or emerging field,* and (2) meets the qualification standards pre-

scribed by the Office of Personnel Management for appointment to a position at GS–15 of the General Schedule. Notwithstanding any previous applicability to an individual who is a member of the Service, the provisions of subchapter I of chapter 35 (relating to retention preference), chapter 43 (relating to performance appraisal and performance actions), chapter 51 (relating to classification), subchapter III of chapter 53 (relating to General Schedule pay rates), and chapter 75 (relating to adverse actions) of title 5, United States Code, shall not apply to any member of the Service.

(c) The Secretary shall develop a performance appraisal system designed to—

(1) provide for the systematic appraisal of the performance of members, and

(2) encourage excellence in performance by members.

(d)(1) The Secretary shall determine, subject to the provisions of this subsection, the pay of members of the Service.

(2) The pay of a member of the Service shall not be less than the minimum rate payable for GS–15 of the General Schedule **[**and shall not exceed the rate payable for level I of the Executive Schedule unless approved by the President under section 5377(d)(2) of title 5, United States Code**]** *and shall not exceed the rate payable for the President*.

[(e) The Secretary may, upon the request of a member who—

[(1) performed service in the employ of an institution of higher education immediately prior to his appointment as a member of the Service, and

[(2) retains the right to continue to make contributions to the retirement system of such institution,

contribute an amount not to exceed 10 percent per annum of the member's basic pay to such institution's retirement system on behalf of such member. A member who requests that such contribution be made shall not be covered by, or earn service credit under, any retirement system established for employees of the United States under title 5, United States Code, but such service shall be creditable for determining years of service under section 6303(a) of such title.**]**

[(f)**]** *(e)* Subject to the following sentence, the Secretary may, notwithstanding the provisions of title 5, United States Code, regarding appointment, appoint an individual who is separated from the Service involuntarily and without cause to a position in the competitive civil service at GS–15 of the General Schedule, and such appointment shall be a career appointment. In the case of such an individual who immediately prior to his appointment to the Service was not a career appointee in the civil service or the Senior Executive Service, such appointment shall be in the excepted civil service and may not exceed a period of 2 years.

[(g)**]** *(f)* The Secretary shall promulgate such rules and regulations, not inconsistent with this section, as may be necessary for the efficient administration of the Service.

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SEC. 229A. DATA ON NATURAL HISTORY OF DISEASES.

(a) IN GENERAL.—The Secretary may, for the purposes described in subsection (b)—

(1) participate in public-private partnerships engaged in one or more activities specified in subsection (c); and

(2) award grants to patient advocacy groups or other organizations determined appropriate by the Secretary.

(b) PURPOSES DESCRIBED.—The purposes described in this subsection are to establish or facilitate the collection, maintenance, analysis, and interpretation of data regarding the natural history of diseases, with a particular focus on rare diseases.

(c) ACTIVITIES OF PUBLIC-PRIVATE PARTNERSHIPS.—The activities of public-private partnerships in which the Secretary may participate for purposes of this section include—

(1) cooperating with other entities that sponsor or maintain disease registries, including disease registries and disease registry platforms for rare diseases;

(2) developing or enhancing a secure information technology system that—

(A) has the capacity to support data needs across a wide range of disease studies;

(B) is easily modified as knowledge is gained during such studies; and

(C) is capable of handling increasing amounts of data as more studies are carried out; and

(3) providing advice to clinical researchers, patient advocacy groups, and other entities with respect to—

(A) the design and conduct of disease studies;

(B) the modification of any such ongoing studies; and

(C) addressing associated patient privacy issues.

(d) AVAILABILITY OF DATA ON NATURAL HISTORY OF DISEASES.—Data relating to the natural history of diseases obtained, aggregated, or otherwise maintained by a public-private partnership in which the Secretary participates under subsection (a) shall be made available, consistent with otherwise applicable Federal and State privacy laws, to the public (including patient advocacy groups, researchers, and drug developers) to help to facilitate and expedite medical product development programs.

(e) CONFIDENTIALITY.—Notwithstanding subsection (d), nothing in this section authorizes the disclosure of any information that is a trade secret or commercial or financial information that is privileged or confidential and subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2016 through 2020.

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PART E—COUNCIL FOR 21ST CENTURY CURES

SEC. 281. ESTABLISHMENT.

A nonprofit corporation to be known as the Council for 21st Century Cures (referred to in this part as the "Council") shall be established in accordance with this section. The Council shall be a public-private partnership headed by an Executive Director (referred to in this part as the "Executive Director"), appointed by the members

of the Board of Directors. The Council shall not be an agency or instrumentality of the United States Government.

SEC. 281A. PURPOSE.

The purpose of the Council is to accelerate the discovery, development, and delivery in the United States of innovative cures, treatments, and preventive measures for patients.

SEC. 281B. DUTIES.

For the purpose described in section 281A, the Council shall—

(1) foster collaboration and coordination among the entities that comprise the Council, including academia, government agencies, industry, health care payors and providers, patient advocates, and others engaged in the cycle of discovery, development, and delivery of life-saving and health-enhancing innovative interventions;

(2) undertake communication and dissemination activities;

(3) publish information on the activities funded under section 281D;

(4) establish a strategic agenda for accelerating the discovery, development, and delivery in the United States of innovative cures, treatments, and preventive measures for patients;

(5) identify gaps and opportunities within and across the discovery, development, and delivery cycle;

(6) develop and propose recommendations based on the gaps and opportunities so identified;

(7) facilitate the interoperability of the components of the discovery, development, and delivery cycle;

(8) propose recommendations that will facilitate precompetitive collaboration;

(9) identify opportunities to work with, but not duplicate the efforts of, nonprofit organizations and other public-private partnerships; and

(10) identify opportunities for collaboration with organizations operating outside of the United States, such as the Innovative Medicines Initiative of the European Union.

SEC. 281C. ORGANIZATION; ADMINISTRATION.

(a) BOARD OF DIRECTORS.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—The Council shall have a Board of Directors (in this part referred to as the "Board of Directors"), which shall be composed of the ex officio members under subparagraph (B) and the appointed members under subparagraph (C). All members of the Board shall be voting members.

(B) EX OFFICIO MEMBERS.—The ex officio members of the Board shall be the following individuals or their designees:

(i) The Director of the National Institutes of Health.

(ii) The Commissioner of Food and Drugs.

(iii) The Administrator of the Centers for Medicare & Medicaid Services.

(iv) The heads of five other Federal agencies deemed by the Secretary to be engaged in biomedical research and development.

(C) APPOINTED MEMBERS.—The appointed members of the Board shall consist of 17 individuals, of whom—

(i) 8 shall be appointed by the Comptroller General of the United States from a list of nominations submitted by leading trade associations—

(I) 4 of whom shall be representatives of the biopharmaceutical industry;

(II) 2 of whom shall be representatives of the medical device industry; and

(III) 2 of whom shall be representatives of the information and digital technology industry; and

(ii) 9 shall be appointed by the Comptroller General of the United States, after soliciting nominations—

(I) 2 of whom shall be representatives of academic researchers;

(II) 3 of whom shall be representatives of patients;

(III) 2 of whom shall be representatives of health care providers; and

(IV) 2 of whom shall be representatives of health care plans and insurers.

(D) CHAIR.—The Chair of the Board shall be selected by the members of the Board by majority vote from among the members of the Board.

(2) TERMS AND VACANCIES.—

(A) IN GENERAL.—The term of office of each member of the Board appointed under paragraph (1)(C) shall be 5 years.

(B) VACANCY.—Any vacancy in the membership of the Board—

(i) shall not affect the power of the remaining members to execute the duties of the Board; and

(ii) shall be filled by appointment by the appointed members described in paragraph (1)(C) by majority vote.

(C) PARTIAL TERM.—If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed under subparagraph (B) to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(3) RESPONSIBILITIES.—Not later than 90 days after the date on which the Council is incorporated and its Board of Directors is fully constituted, the Board of Directors shall establish bylaws and policies for the Council that—

(A) are published in the Federal Register and available for public comment;

(B) establish policies for the selection and, as applicable, appointment of—

(i) the officers, employees, agents, and contractors of the Council; and

(ii) the members of any committees of the Council;

(C) establish policies, including ethical standards, for the conduct of programs and other activities under section 281D; and

(D) establish specific duties of the Executive Director.

(4) MEETINGS.—

(A) IN GENERAL.—The Board of Directors shall—

(i) meet on a quarterly basis; and

(ii) submit to Congress, and make publicly available, the minutes of such meetings.

(B) AGENDA.—The Board of Directors shall, not later than 3 months after the incorporation of the Council—

(i) issue an agenda (in this part referred to as the "agenda") outlining how the Council will achieve the purpose described in section 281A; and

(ii) annually thereafter, in consultation with the Executive Director, review and update such agenda.

(b) APPOINTMENT AND INCORPORATION.—Not later than 6 months after the date of enactment of the 21st Century Cures Act—

(1) the Comptroller General of the United States shall appoint the appointed members of the Board of Directors under subsection (a)(1)(C); and

(2) the ex officio members of the Board of Directors under subsection (a)(1)(B) shall serve as incorporators and shall take whatever actions are necessary to incorporate the Council.

(c) NONPROFIT STATUS.—In carrying out this part, the Board of Directors shall establish such policies and bylaws, and the Executive Director shall carry out such activities, as may be necessary to ensure that the Council maintains status as an organization that—

(1) is described in subsection (c)(3) of section 501 of the Internal Revenue Code of 1986; and

(2) is, under subsection (a) of such section, exempt from taxation.

(d) EXECUTIVE DIRECTOR.—The Executive Director shall—

(1) be the chief executive officer of the Council; and

(2) subject to the oversight of the Board of Directors, be responsible for the day-to-day management of the Council.

SEC. 281D. OPERATIONAL ACTIVITIES AND ASSISTANCE.

(a) IN GENERAL.—The Council shall establish a sufficient operational infrastructure to fulfill the duties specified in section 281B.

(b) PRIVATE SECTOR MATCHING FUNDS.—The Council may accept financial or in-kind support from participating entities or private foundations or organizations when such support is deemed appropriate.

SEC. 281E. TERMINATION; REPORT.

(a) IN GENERAL.—The Council shall terminate on September 30, 2023.

(b) REPORT.—Not later than one year after the date on which the Council is established and each year thereafter, the Executive Director shall submit to the appropriate congressional committees a report on the performance of the Council. In preparing such report, the Council shall consult with a nongovernmental consultant with appropriate expertise.

SEC. 281F. FUNDING.

For the each of fiscal years 2016 through 2023, there is authorized to be appropriated $10,000,000 to the Council for purposes of carrying out the duties of the Council under this part.

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

PART A—RESEARCH AND INVESTIGATION

* * * * * * *

HEALTH CONFERENCES AND HEALTH EDUCATION INFORMATION

SEC. 310. (a) A conference of the health authorities in and among the several States shall be called annually by the Secretary. Whenever in his opinion the interests of the public health would be promoted by a conference, the Secretary may invite as many of such health authorities and officials of other State or local public or private agencies, institutions, or organizations to confer as he deems necessary or proper. Upon the application of health authorities of five or more States it shall be the duty of the Secretary to call a conference of all State health authorities joining in the request. Each State represented at any conference shall be entitled to a single vote. Whenever at any such conference matters relating to mental health are to be discussed, the mental health authorities of the respective States shall be invited to attend.

(b) From time to time the Secretary shall issue information related to public health, in the form of publications or otherwise, for the use of the public, and shall publish weekly reports of health conditions in the United States and other countries and other pertinent health information for the use of persons and institutions concerned with health services.

(c)(1) In this subsection, the term "vaccine developer" means a nongovernmental entity engaged in—

(A)(i) the development of a vaccine with the intent to pursue licensing of the vaccine by the Food and Drug Administration; or

(ii) the production of a vaccine licensed by the Food and Drug Administration; and

(B) vaccine research.

(2)(A) Upon the submission of a written request for a meeting by a vaccine developer, that includes a justification for the meeting, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall convene a meeting of representatives of the vaccine developer and experts from the Centers for Disease Control and Prevention in immunization programs, epidemiology, and other relevant areas at which the Director (or the Director's designee), for the purpose of informing the vaccine developer's understanding of public health needs and priorities, shall provide the perspectives of the Centers for Disease Control and Prevention and other relevant Federal agencies regarding—

(i) public health needs, epidemiology, and implementation considerations with regard to a vaccine developer's potential vaccine profile; and

(ii) potential implications of such perspectives for the vaccine developer's vaccine research and development planning.

(B) In addition to the representatives specified in subparagraph (A), the Secretary may, with the agreement of the vaccine developer requesting a meeting under such subparagraph, include in such meeting representatives of—

(i) the Food and Drug Administration; and

(ii) the National Vaccine Program.

(C) The Secretary shall convene a meeting requested under subparagraph (A) not later than 120 days after receipt of the request for the meeting.

(3)(A) Upon the submission of a written request by a vaccine developer, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall provide to the vaccine developer any age-based or other demographically assessed disease epidemiological analyses or data that—

(i) are specified in the request;

(ii) have been published;

(iii) have been performed by or are in the possession of the Centers;

(iv) are not a trade secret or commercial or financial information that is privileged or confidential and subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code; and

(v) do not contain individually identifiable information.

(B) The Secretary shall provide analyses requested by a vaccine manufacturer under subparagraph (A) not later than 120 calendar days after receipt of the request for the analyses.

(4) The Secretary shall promptly notify a vaccine developer if—

(A) the Secretary becomes aware of any change to information that was—

(i) shared by the Secretary with the vaccine developer during a meeting under paragraph (2); or

(ii) provided by the Secretary to the vaccine developer in one or more analyses under paragraph (3); and

(B) the change to such information may have implications for the vaccine developer's vaccine research and development.

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PART B—FEDERAL-STATE COOPERATION

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SEC. 317U. MONITORING ANTIBACTERIAL AND ANTIFUNGAL DRUG USE AND RESISTANCE.

(a) MONITORING.—The Secretary shall use an appropriate monitoring system to monitor—

(1) the use of antibacterial and antifungal drugs, including those receiving approval or licensure for a limited population pursuant to section 505(z) of the Federal Food, Drug, and Cosmetic Act; and

(2) changes in bacterial and fungal resistance to drugs.

(b) PUBLIC AVAILABILITY OF DATA.—The Secretary shall make summaries of the data derived from monitoring under this section publicly available for the purposes of—

(1) improving the monitoring of important trends in antibacterial and antifungal resistance; and

(2) ensuring appropriate stewardship of antibacterial and antifungal drugs, including those receiving approval or licen-

sure for a limited population pursuant to section 505(z) of the Federal Food, Drug, and Cosmetic Act.

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PART F—LICENSING—BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES

Subpart 1—Biological Products

REGULATION OF BIOLOGICAL PRODUCTS

SEC. 351. (a)(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and

(B) each package of the biological product is plainly marked with—

(i) the proper name of the biological product contained in the package;

(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

(iii) the expiration date of the biological product.

(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act.

(C) The Secretary shall approve a biologics license application—

(i) on the basis of a demonstration that—

(I) the biological product that is the subject of the application is safe, pure, and potent; and

(II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and

(ii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(D) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING; RISK EVALUATION AND MITIGATION STRATEGY.—A person that submits an application for a license under this paragraph is subject to sections 505(o), 505(p), and 505–1 of the Federal Food, Drug, and Cosmetic Act.

(3) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).

(b) No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.

(c) Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establish-

ment for the propagation or manufacture and preparation of any biological product.

(d)(1) Upon a determination that a batch, lot, or other quantity of a product licensed under this section presents an imminent or substantial hazard to the public health, the Secretary shall issue an order immediately ordering the recall of such batch, lot, or other quantity of such product. An order under this paragraph shall be issued in accordance with section 554 of title 5, United States Code.

(2) Any violation of paragraph (1) shall subject the violator to a civil penalty of up to $100,000 per day of violation. The amount of a civil penalty under this paragraph shall, effective December 1 of each year beginning 1 year after the effective date of this paragraph, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest 1/10 of 1 percent. For purposes of this paragraph, the term "base quarter", as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.

(e) No person shall interfere with any officer, agent, or employee of the Service in the performance of any duty imposed upon him by this section or by regulations made by authority thereof.

(f) Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a fine not exceeding $500 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

(g) Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act (U.S.C., 1940 edition, title 21, ch. 9).

(h) A partially processed biological product which—

(1) is not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;

(2) is not intended for sale in the United States; and

(3) is intended for further manufacture into final dosage form outside the United States,

shall be subject to no restriction on the export of the product under this Act or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et. seq.) if the product is manufactured, processed, packaged, and held in conformity with current good manufacturing practice requirements or meets international manufacturing standards as certified by an international standards organization recognized by the Secretary and meets the requirements of section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)).

(i) In this section:

(1) The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(2) The term "biosimilar" or "biosimilarity", in reference to a biological product that is the subject of an application under subsection (k), means—

(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(3) The term "interchangeable" or "interchangeability", in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

(4) The term "reference product" means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).

(j)*(1)* The Federal Food, Drug, and Cosmetic Act, including the requirements under sections 505(o), 505(p), *505(z),* and 505–1 of such Act, applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act.

(2) In applying section 505(z) of the Federal Food, Drug, and Cosmetic Act to the licensure of biological products under this section—

(A) references to an antibacterial or antifungal drug that is intended to treat a serious or life-threatening infection shall be construed to refer to a biological product intended to treat a serious or life-threatening bacterial or fungal infection; and

(B) references to approval of a drug under section 505(c) of such Act shall be construed to refer to a licensure of a biological product under subsection (a) of this section.

(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—

(1) IN GENERAL.—Any person may submit an application for licensure of a biological product under this subsection.

(2) CONTENT.—

(A) IN GENERAL.—

(i) REQUIRED INFORMATION.—An application submitted under this subsection shall include information demonstrating that—

(I) the biological product is biosimilar to a reference product based upon data derived from—

(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

(bb) animal studies (including the assessment of toxicity); and

(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and po-

tency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

(ii) DETERMINATION BY SECRETARY.—The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

(iii) ADDITIONAL INFORMATION.—An application submitted under this subsection—

(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

(II) may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product.

(B) INTERCHANGEABILITY.—An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

(3) EVALUATION BY SECRETARY.—Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if—

(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

(i) is biosimilar to the reference product; or

(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(4) SAFETY STANDARDS FOR DETERMINING INTERCHANGEABILITY.—Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

(A) the biological product—

(i) is biosimilar to the reference product; and

(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

(5) GENERAL RULES.—

(A) ONE REFERENCE PRODUCT PER APPLICATION.—A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

(B) REVIEW.—An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

(C) RISK EVALUATION AND MITIGATION STRATEGIES.—The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

(6) EXCLUSIVITY FOR FIRST INTERCHANGEABLE BIOLOGICAL PRODUCT.—Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsection (l)(6) against the applicant that submitted the application for the first ap-

proved interchangeable biosimilar biological product; or

(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (l)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (l)(6).

For purposes of this paragraph, the term "final court decision" means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

(7) EXCLUSIVITY FOR REFERENCE PRODUCT.—

(A) EFFECTIVE DATE OF BIOSIMILAR APPLICATION APPROVAL.—Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

(B) FILING PERIOD.—An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

(C) FIRST LICENSURE.—Subparagraphs (A) and (B) shall not apply to a license for or approval of—

(i) a supplement for the biological product that is the reference product; or

(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

(8) GUIDANCE DOCUMENTS.—

(A) IN GENERAL.—The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

(B) PUBLIC COMMENT.—

(i) IN GENERAL.—The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

(ii) INPUT REGARDING MOST VALUABLE GUIDANCE.—The Secretary shall establish a process through which

the public may provide the Secretary with input regarding priorities for issuing guidance.

(C) NO REQUIREMENT FOR APPLICATION CONSIDERATION.—The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

(D) REQUIREMENT FOR PRODUCT CLASS-SPECIFIC GUIDANCE.—If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

(E) CERTAIN PRODUCT CLASSES.—

(i) GUIDANCE.—The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

(ii) MODIFICATION OR REVERSAL.—The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

(iii) NO EFFECT ON ABILITY TO DENY LICENSE.—Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

(l) PATENTS.—

(1) CONFIDENTIAL ACCESS TO SUBSECTION (k) APPLICATION.—

(A) APPLICATION OF PARAGRAPH.—Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the "subsection (k) applicant") and the sponsor of the application for the reference product (referred to in this subsection as the "reference product sponsor"), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

(B) IN GENERAL.—

(i) PROVISION OF CONFIDENTIAL INFORMATION.—When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the "confidential information").

(ii) RECIPIENTS OF INFORMATION.—The persons described in this clause are the following:

(I) OUTSIDE COUNSEL.—One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the "outside counsel"), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(II) IN-HOUSE COUNSEL.—One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(iii) PATENT OWNER ACCESS.—A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his or her agreement to be subject to the confidentiality provisions set forth in this paragraph, including those under clause (ii).

(C) LIMITATION ON DISCLOSURE.—No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

(D) USE OF CONFIDENTIAL INFORMATION.—Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

(E) OWNERSHIP OF CONFIDENTIAL INFORMATION.—The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

(F) EFFECT OF INFRINGEMENT ACTION.—In the event that the reference product sponsor files a patent infringement

suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy such information, it will confirm destruction in writing to the subsection (k) applicant.

(G) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed—

(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

(ii) as an agreement or admission by the subsection (k) applicant with respect to the competency, relevance, or materiality of any confidential information.

(H) EFFECT OF VIOLATION.—The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

(2) SUBSECTION (k) APPLICATION INFORMATION.—Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

(3) LIST AND DESCRIPTION OF PATENTS.—

(A) LIST BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into

the United States of the biological product that is the subject of the subsection (k) application; and

(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

(B) LIST AND DESCRIPTION BY SUBSECTION (k) APPLICANT.—Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

(C) DESCRIPTION BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

(4) PATENT RESOLUTION NEGOTIATIONS.—

(A) IN GENERAL.—After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6).

(B) FAILURE TO REACH AGREEMENT.—If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

(5) PATENT RESOLUTION IF NO AGREEMENT.—

(A) NUMBER OF PATENTS.—The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

(B) EXCHANGE OF PATENT LISTS.—

(i) IN GENERAL.—On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—

(I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and

(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

(ii) NUMBER OF PATENTS LISTED BY REFERENCE PRODUCT SPONSOR.—

(I) IN GENERAL.—Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

(II) EXCEPTION.—If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

(6) IMMEDIATE PATENT INFRINGEMENT ACTION.—

(A) ACTION IF AGREEMENT ON PATENT LIST.—If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

(B) ACTION IF NO AGREEMENT ON PATENT LIST.—If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

(C) NOTIFICATION AND PUBLICATION OF COMPLAINT.—

(i) NOTIFICATION TO SECRETARY.—Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

(ii) PUBLICATION BY SECRETARY.—The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

(7) NEWLY ISSUED OR LICENSED PATENTS.—In the case of a patent that—

(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

(8) NOTICE OF COMMERCIAL MARKETING AND PRELIMINARY INJUNCTION.—

(A) NOTICE OF COMMERCIAL MARKETING.—The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

(B) PRELIMINARY INJUNCTION.—After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

(ii) not included, as applicable, on—

(I) the list of patents described in paragraph (4); or

(II) the lists of patents described in paragraph (5)(B).

(C) REASONABLE COOPERATION.—If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

(9) LIMITATION ON DECLARATORY JUDGMENT ACTION.—

(A) SUBSECTION (k) APPLICATION PROVIDED.—If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

(B) SUBSEQUENT FAILURE TO ACT BY SUBSECTION (k) APPLICANT.—If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(C) SUBSECTION (k) APPLICATION NOT PROVIDED.—If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

(m) PEDIATRIC STUDIES.—

(1) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subsections (a), (d), (e), (f), (h), (i), (j), (k), (l), (n), and (p) of section 505A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act.

(2) MARKET EXCLUSIVITY FOR NEW BIOLOGICAL PRODUCTS.—If, prior to approval of an application that is submitted under subsection (a), the Secretary determines that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports

thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

(3) MARKET EXCLUSIVITY FOR ALREADY-MARKETED BIOLOGICAL PRODUCTS.—If the Secretary determines that information relating to the use of a licensed biological product in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

(4) EXCEPTION.—The Secretary shall not extend a period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(3) is made later than 9 months prior to the expiration of such period.

(5) RELATION TO EXCLUSIVITY FOR A BIOLOGICAL PRODUCT APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in paragraphs (2)(A), (2)(B), (3)(A), and (3)(B) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in such paragraphs shall be in addition to any extensions under section 505G.

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PART P—ADDITIONAL PROGRAMS

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SEC. 399V–6 SURVEILLANCE OF NEUROLOGICAL DISEASES.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other agencies as determined appropriate by the Secretary, shall—

(1) enhance and expand infrastructure and activities to track the epidemiology of neurological diseases, including multiple sclerosis and Parkinson's disease; and

(2) incorporate information obtained through such activities into a statistically sound, scientifically credible, integrated surveillance system, to be known as the National Neurological Diseases Surveillance System.

(b) RESEARCH.—The Secretary shall ensure that the National Neurological Diseases Surveillance System is designed in a manner that facilitates further research on neurological diseases.

(c) CONTENT.—In carrying out subsection (a), the Secretary—

(1) shall provide for the collection and storage of information on the incidence and prevalence of neurological diseases in the United States;

(2) to the extent practicable, shall provide for the collection and storage of other available information on neurological diseases, such as information concerning—

(A) demographics and other information associated or possibly associated with neurological diseases, such as age, race, ethnicity, sex, geographic location, and family history;

(B) risk factors associated or possibly associated with neurological diseases, including genetic and environmental risk factors; and

(C) diagnosis and progression markers;

(3) may provide for the collection and storage of information relevant to analysis on neurological diseases, such as information concerning—

(A) the epidemiology of the diseases;

(B) the natural history of the diseases;

(C) the prevention of the diseases;

(D) the detection, management, and treatment approaches for the diseases; and

(E) the development of outcomes measures; and

(4) may address issues identified during the consultation process under subsection (d).

(d) CONSULTATION.—In carrying out this section, the Secretary shall consult with individuals with appropriate expertise, including—

(1) epidemiologists with experience in disease surveillance or registries;

(2) representatives of national voluntary health associations that—

(A) focus on neurological diseases, including multiple sclerosis and Parkinson's disease; and

(B) have demonstrated experience in research, care, or patient services;

(3) health information technology experts or other information management specialists;

(4) clinicians with expertise in neurological diseases; and

(5) research scientists with experience conducting translational research or utilizing surveillance systems for scientific research purposes.

(e) GRANTS.—The Secretary may award grants to, or enter into contracts or cooperative agreements with, public or private nonprofit entities to carry out activities under this section.

(f) COORDINATION WITH OTHER FEDERAL, STATE, AND LOCAL AGENCIES.—Subject to subsection (h), the Secretary shall make in-

formation and analysis in the National Neurological Diseases Surveillance System available, as appropriate—

(1) to Federal departments and agencies, such as the National Institutes of Health, the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Agency for Healthcare Research and Quality, the Department of Veterans Affairs, and the Department of Defense; and

(2) to State and local agencies.

(g) PUBLIC ACCESS.—Subject to subsection (h), the Secretary shall make information and analysis in the National Neurological Diseases Surveillance System available, as appropriate, to the public, including researchers.

(h) PRIVACY.—The Secretary shall ensure that privacy and security protections applicable to the National Neurological Diseases Surveillance System are at least as stringent as the privacy and security protections under HIPAA privacy and security law (as defined in section 3009(a)(2)).

(i) REPORT.—Not later than 4 years after the date of the enactment of this section, the Secretary shall submit a report to the Congress concerning the implementation of this section. Such report shall include information on—

(1) the development and maintenance of the National Neurological Diseases Surveillance System;

(2) the type of information collected and stored in the System;

(3) the use and availability of such information, including guidelines for such use; and

(4) the use and coordination of databases that collect or maintain information on neurological diseases.

(j) DEFINITION.—In this section, the term "national voluntary health association" means a national nonprofit organization with chapters, other affiliated organizations, or networks in States throughout the United States.

(k) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $5,000,000 for each of fiscal years 2016 through 2020.

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PART W—LYME DISEASE AND OTHER TICK-BORNE DISEASES

SEC. 399OO. RESEARCH.

(a) IN GENERAL.—The Secretary shall conduct or support epidemiological, basic, translational, and clinical research regarding Lyme disease and other tick-borne diseases.

(b) BIENNIAL REPORTS.—The Secretary shall ensure that each biennial report under section 403 includes information on actions undertaken by the National Institutes of Health to carry out subsection (a) with respect to Lyme disease and other tick-borne diseases, including an assessment of the progress made in improving the outcomes of Lyme disease and such other tick-borne diseases.

SEC. 399OO–1. WORKING GROUP.

(a) ESTABLISHMENT.—The Secretary shall establish a permanent working group, to be known as the Interagency Lyme and Tick-Borne Disease Working Group (in this section and section 399OO–

2 referred to as the "Working Group"), to review all efforts within the Department of Health and Human Services concerning Lyme disease and other tick-borne diseases to ensure interagency coordination, minimize overlap, and examine research priorities.

(b) RESPONSIBILITIES.—The Working Group shall—

(1) not later than 24 months after the date of enactment of this part, and every 24 months thereafter, develop or update a summary of—

(A) ongoing Lyme disease and other tick-borne disease research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, duration of illness, intervention, and access to services and supports for individuals with Lyme disease or other tick-borne diseases;

(B) advances made pursuant to such research;

(C) the engagement of the Department of Health and Human Services with persons that participate at the public meetings required by paragraph (5); and

(D) the comments received by the Working Group at such public meetings and the Secretary's response to such comments;

(2) ensure that a broad spectrum of scientific viewpoints is represented in each such summary;

(3) monitor Federal activities with respect to Lyme disease and other tick-borne diseases;

(4) make recommendations to the Secretary regarding any appropriate changes to such activities; and

(5) ensure public input by holding annual public meetings that address scientific advances, research questions, surveillance activities, and emerging strains in species of pathogenic organisms.

(c) MEMBERSHIP.—

(1) IN GENERAL.—The Working Group shall be composed of a total of 14 members as follows:

(A) FEDERAL MEMBERS.—Seven Federal members, consisting of one or more representatives of each of—

(i) the Office of the Assistant Secretary for Health;

(ii) the Food and Drug Administration;

(iii) the Centers for Disease Control and Prevention;

(iv) the National Institutes of Health; and

(v) such other agencies and offices of the Department of Health and Human Services as the Secretary determines appropriate.

(B) NON-FEDERAL PUBLIC MEMBERS.—Seven non-Federal public members, consisting of representatives of the following categories:

(i) Physicians and other medical providers with experience in diagnosing and treating Lyme disease and other tick-borne diseases.

(ii) Scientists or researchers with expertise.

(iii) Patients and their family members.

(iv) Nonprofit organizations that advocate for patients with respect to Lyme disease and other tick-borne diseases.

(v) Other individuals whose expertise is determined by the Secretary to be beneficial to the functioning of the Working Group.

(2) APPOINTMENT.—The members of the Working Group shall be appointed by the Secretary, except that of the non-Federal public members under paragraph (1)(B)—

(A) one shall be appointed by the Speaker of the House of Representatives; and

(B) one shall be appointed by the majority leader of the Senate.

(3) DIVERSITY OF SCIENTIFIC PERSPECTIVES.—In making appointments under paragraph (2), the Secretary, the Speaker of the House of Representatives, and the majority leader of the Senate shall ensure that the non-Federal public members of the Working Group represent a diversity of scientific perspectives.

(4) TERMS.—The non-Federal public members of the Working Group shall each be appointed to serve a 4-year term and may be reappointed at the end of such term.

(d) MEETINGS.—The Working Group shall meet as often as necessary, as determined by the Secretary, but not less than twice each year.

(e) APPLICABILITY OF FACA.—The Working Group shall be treated as an advisory committee subject to the Federal Advisory Committee Act.

(f) REPORTING.—Not later than 24 months after the date of enactment of this part, and every 24 months thereafter, the Working Group—

(1) shall submit a report on its activities, including an up-to-date summary under subsection (b)(1) and any recommendations under subsection (b)(4), to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor and Pensions of the Senate;

(2) shall make each such report publicly available on the website of the Department of Health and Human Services; and

(3) shall allow any member of the Working Group to include in any such report minority views.

SEC. 399OO–2. STRATEGIC PLAN.

Not later than 3 years after the date of enactment of this section, and every 5 years thereafter, the Secretary shall submit to the Congress a strategic plan, informed by the most recent summary under section 399OO–1(b)(1), for the conduct and support of Lyme disease and tick-borne disease research, including—

(1) proposed budgetary requirements;

(2) a plan for improving outcomes of Lyme disease and other tick-borne diseases, including progress related to chronic or persistent symptoms and chronic or persistent infection and co-infections;

(3) a plan for improving diagnosis, treatment, and prevention;

(4) appropriate benchmarks to measure progress on achieving the improvements described in paragraphs (2) and (3); and

(5) a plan to disseminate each summary under section 399OO–1(b)(1) and other relevant information developed by the

Working Group to the public, including health care providers, public health departments, and other relevant medical groups.

TITLE IV—NATIONAL RESEARCH INSTITUTES

PART A—NATIONAL INSTITUTES OF HEALTH

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APPOINTMENT AND AUTHORITY OF DIRECTOR OF NIH

SEC. 402. (a) The National Institutes of Health shall be headed by the Director of NIH who shall be appointed by the President by and with the advice and consent of the Senate. The Director of NIH shall perform functions as provided under subsection (b) and as the Secretary may otherwise prescribe.

(b) In carrying out the purposes of section 301, the Secretary, acting through the Director of NIH—

(1) shall carry out this title, including being responsible for the overall direction of the National Institutes of Health and for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health;

(2) shall coordinate and oversee the operation of the national research institutes, national centers, and administrative entities within the National Institutes of Health;

(3) shall, in consultation with the heads of the national research institutes and national centers, be responsible for program coordination across the national research institutes and national centers, including conducting priority-setting reviews, to ensure that the research portfolio of the National Institutes of Health is balanced and free of unnecessary duplication, and takes advantage of collaborative, cross-cutting research;

(4) shall assemble accurate data to be used to assess research priorities, including information to better evaluate scientific opportunity, public health burdens, and progress in reducing minority and other health disparities;

[(5) shall ensure that scientifically based strategic planning is implemented in support of research priorities as determined by the agencies of the National Institutes of Health;**]**

(5) shall ensure that scientifically based strategic planning is implemented in support of research priorities as determined by the agencies of the National Institutes of Health, including through development, use, and updating of the research strategic plan under subsection (m);

(6) shall ensure that the resources of the National Institutes of Health are sufficiently allocated for research projects identified in strategic plans;

(7)(A) shall, through the Division of Program Coordination, Planning, and Strategic Initiatives—

(i) identify research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or supporting additional research that involves collaboration between 2 or more national research institutes or

national centers, or would otherwise benefit from strategic coordination and planning;

(ii) include information on such research in reports under section 403; and

(iii) in the case of such research supported with funds referred to in subparagraph (B)—

(I) require as appropriate that proposals include milestones and goals for the research;

(II) require that the proposals include timeframes for funding of the research; and

(III) ensure appropriate consideration of proposals for which the principal investigator is an individual who has not previously served as the principal investigator of research conducted or supported by the National Institutes of Health;

(B)(i) may, with respect to funds reserved under section 402A(c)(1) for the Common Fund, allocate such funds to the national research institutes and national centers for conducting and supporting research that is identified under subparagraph (A); and

(ii) shall, with respect to funds appropriated to the Common Fund pursuant to section 402A(a)(2), allocate such funds to the national research institutes and national centers for making grants for pediatric research that is identified under subparagraph (A); and

(C) may assign additional functions to the Division in support of responsibilities identified in subparagraph (A), as determined appropriate by the Director;

(8) shall, in coordination with the heads of the national research institutes and national centers, ensure that such institutes and centers—

(A) preserve an emphasis on investigator-initiated research project grants, including with respect to research involving collaboration between 2 or more such institutes or centers; and

(B) when appropriate, maximize investigator-initiated research project grants in their annual research portfolios;

(9) shall ensure that research conducted or supported by the National Institutes of Health is subject to review in accordance with section 492 and that, after such review, the research is reviewed in accordance with section 492A(a)(2) by the appropriate advisory council under section 406 before the research proposals are approved for funding;

(10) shall have authority to review and approve the establishment of all centers of excellence recommended by the national research institutes;

(11)(A) shall oversee research training for all of the national research institutes and National Research Service Awards in accordance with section 487; and

(B) may conduct and support research training—

(i) for which fellowship support is not provided under section 487; and

(ii) that does not consist of residency training of physicians or other health professionals;

(12) may, from funds appropriated under section 402A(b), reserve funds to provide for research on matters that have not received significant funding relative to other matters, to respond to new issues and scientific emergencies, and to act on research opportunities of high priority;

(13) may, subject to appropriations Acts, collect and retain registration fees obtained from third parties to defray expenses for scientific, educational, and research-related conferences;

(14) for the national research institutes and administrative entities within the National Institutes of Health—

(A) may acquire, construct, improve, repair, operate, and maintain, at the site of such institutes and entities, laboratories, and other research facilities, other facilities, equipment, and other real or personal property, and

(B) may acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed ten years;

(15) may secure resources for research conducted by or through the National Institutes of Health;

(16) may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific peer review groups and scientific program advisory committees as are needed to carry out the requirements of this title and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups;

(17) may secure for the National Institutes of Health consultation services and advice of persons from the United States or abroad;

(18) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(19) may, for purposes of study, admit and treat at facilities of the National Institutes of Health individuals not otherwise eligible for such treatment;

(20) may accept voluntary and uncompensated services;

(21) may perform such other administrative functions as the Secretary determines are needed to effectively carry out this title;

(22) may appoint physicians, dentists, and other health care professionals, subject to the provisions of title 5, United States Code, relating to appointments and classifications in the competitive service, and may compensate such professionals subject to the provisions of chapter 74 of title 38, United States Code;

(23) shall designate a contact point or office to help innovators and physicians identify sources of funding available for pediatric medical device development; [and]

(24) implement the Cures Acceleration Network described in section 480[.]*; and*

(25) shall, with respect to funds appropriated under section 402A(e) to the NIH Innovation Fund, allocate such funds to the national research institutes and national centers for conducting and supporting innovation fund initiatives identified under paragraph (3) of such section.

The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under paragraph (16). The members of such a group shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of such group. Not more than one-fourth of the members of any such group shall be officers or employees of the United States.

(c) The Director of NIH may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(d)(1) The Director of NIH may obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of service) the services of not more than 220 experts or consultants, with scientific or other professional qualifications, for the National Institutes of Health.

(2)(A) Except as provided in subparagraph (B), experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment.

(B) Expenses specified in subparagraph (A) shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

(e) The Director of NIH shall—

(1) advise the agencies of the National Institutes of Health on medical applications of research;

(2) coordinate, review, and facilitate the systematic identification and evaluation of, clinically relevant information from research conducted by or through the national research institutes;

(3) promote the effective transfer of the information described in paragraph (2) to the health care community and to entities that require such information;

(4) monitor the effectiveness of the activities described in paragraph (3); and

(5) ensure that, after January 1, 1994, all new or revised health education and promotion materials developed or funded

by the National Institutes of Health and intended for the general public are in a form that does not exceed a level of functional literacy, as defined in the National Literacy Act of 1991 (Public Law 102–73).

(f) There shall be in the National Institutes of Health an Associate Director for Prevention. The Director of NIH shall delegate to the Associate Director for Prevention the functions of the Director relating to the promotion of the disease prevention research programs of the national research institutes and the coordination of such programs among the national research institutes and between the national research institutes and other public and private entities, including elementary, secondary, and post-secondary schools. The Associate Director shall—

(1) annually review the efficacy of existing policies and techniques used by the national research institutes to disseminate the results of disease prevention and behavioral research programs; and

(2) recommend, coordinate, and oversee the modification or reconstruction of such policies and techniques to ensure maximum dissemination, using advanced technologies to the maximum extent practicable, of research results to such entities.

(h) The Secretary, acting through the Director of NIH and the Directors of the agencies of the National Institutes of Health, shall, in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research.

(i)(1)(A) The Secretary, acting through the Director of NIH, shall establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions (in this subsection referred to as the "data bank"). The activities of the data bank shall be integrated and coordinated with related activities of other agencies of the Department of Health and Human Services, and to the extent practicable, coordinated with other data banks containing similar information.

(B) The Secretary shall establish the data bank after consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention.

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. The Secretary shall disseminate such information through information systems, which shall include toll-free telephone communications, available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers.

(3) The data bank shall include the following:

(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to section 505(i) of the Federal Food, Drug, and Cosmetic Act, which provides a description of the purpose of each experimental drug, either with the consent of the protocol

sponsor, or when a trial to test effectiveness begins. Information provided shall consist of eligibility criteria for participation in the clinical trials, a description of the location of trial sites, and a point of contact for those wanting to enroll in the trial, and shall be in a form that can be readily understood by members of the public. Such information shall be forwarded to the data bank by the sponsor of the trial not later than 21 days after the approval of the protocol.

(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

(i) under a treatment investigational new drug application that has been submitted to the Secretary under section 561(c) of the Federal Food, Drug, and Cosmetic Act; or

(ii) as a Group C cancer drug (as defined by the National Cancer Institute).

The data bank may also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatments.

(4) The data bank shall not include information relating to an investigation if the sponsor has provided a detailed certification to the Secretary that disclosure of such information would substantially interfere with the timely enrollment of subjects in the investigation, unless the Secretary, after the receipt of the certification, provides the sponsor with a detailed written determination that such disclosure would not substantially interfere with such enrollment.

(5) Fees collected under section 736 of the Federal Food, Drug, and Cosmetic Act shall not be used in carrying out this subsection.

(j) EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.—

(1) DEFINITIONS; REQUIREMENT.—

(A) DEFINITIONS.—In this subsection:

(i) APPLICABLE CLINICAL TRIAL.—The term "applicable clinical trial" means an applicable device clinical trial or an applicable drug clinical trial.

(ii) APPLICABLE DEVICE CLINICAL TRIAL.—The term "applicable device clinical trial" means—

(I) a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and

(II) a pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act.

(iii) APPLICABLE DRUG CLINICAL TRIAL.—

(I) IN GENERAL.—The term "applicable drug clinical trial" means a controlled clinical investiga-

tion, other than a phase I clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act.

(II) CLINICAL INVESTIGATION.—For purposes of subclause (I), the term "clinical investigation" has the meaning given that term in section 312.3 of title 21, Code of Federal Regulations (or any successor regulation).

(III) PHASE I.—For purposes of subclause (I), the term "phase I" has the meaning given that term in section 312.21 of title 21, Code of Federal Regulations (or any successor regulation).

(iv) CLINICAL TRIAL INFORMATION.—The term "clinical trial information" means, with respect to an applicable clinical trial, those data elements that the responsible party is required to submit under paragraph (2) or under paragraph (3).

(v) COMPLETION DATE.—The term "completion date" means, with respect to an applicable clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated.

(vi) DEVICE.—The term "device" means a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

(vii) DRUG.—The term "drug" means a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act or a biological product as defined in section 351 of this Act.

(viii) ONGOING.—The term "ongoing" means, with respect to a clinical trial of a drug or a device and to a date, that—

(I) 1 or more patients is enrolled in the clinical trial; and

(II) the date is before the completion date of the clinical trial.

(ix) RESPONSIBLE PARTY.—The term "responsible party", with respect to a clinical trial of a drug or device, means—

(I) the sponsor of the clinical trial (as defined in section 50.3 of title 21, Code of Federal Regulations (or any successor regulation)); or

(II) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under this subsection for the submission of clinical trial information.

(B) REQUIREMENT.—The Secretary shall develop a mechanism by which the responsible party for each applicable clinical trial shall submit the identity and contact information of such responsible party to the Secretary at the time of submission of clinical trial information under paragraph (2).

(2) EXPANSION OF CLINICAL TRIAL REGISTRY DATA BANK WITH RESPECT TO CLINICAL TRIAL INFORMATION.—

(A) IN GENERAL.—

(i) EXPANSION OF DATA BANK.—To enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials, the Secretary, acting through the Director of NIH, shall expand, in accordance with this subsection, the clinical trials registry of the data bank described under subsection (i)(1) (referred to in this subsection as the "registry data bank"). The Director of NIH shall ensure that the registry data bank is made publicly available through the Internet.

(ii) CONTENT.—The clinical trial information required to be submitted under this paragraph for an applicable clinical trial shall include—

(I) descriptive information, including—

(aa) a brief title, intended for the lay public;

(bb) a brief summary, intended for the lay public;

(cc) the primary purpose;

(dd) the study design;

(ee) for an applicable drug clinical trial, the study phase;

(ff) study type;

(gg) the primary disease or condition being studied, or the focus of the study;

(hh) the intervention name and intervention type;

(ii) the study start date;

(jj) the expected completion date;

(kk) the target number of subjects; and

(ll) outcomes, including primary and secondary outcome measures;

(II) recruitment information, including—

(aa) eligibility criteria;

(bb) gender;

(cc) age limits;

(dd) whether the trial accepts healthy volunteers;

(ee) overall recruitment status;

(ff) individual site status; and

(gg) in the case of an applicable drug clinical trial, if the drug is not approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act, specify whether or not there is expanded access to the drug under section 561 of the Federal Food, Drug, and Cosmetic Act

for those who do not qualify for enrollment in the clinical trial and how to obtain information about such access;

(III) location and contact information, including—

(aa) the name of the sponsor;

(bb) the responsible party, by official title; and

(cc) the facility name and facility contact information (including the city, State, and zip code for each clinical trial location, or a toll-free number through which such location information may be accessed); and

(IV) administrative data (which the Secretary may make publicly available as necessary), including—

(aa) the unique protocol identification number;

(bb) other protocol identification numbers, if any; and

(cc) the Food and Drug Administration IND/IDE protocol number and the record verification date.

(iii) MODIFICATIONS.—The Secretary may by regulation modify the requirements for clinical trial information under this paragraph, if the Secretary provides a rationale for why such a modification improves and does not reduce such clinical trial information.

(B) FORMAT AND STRUCTURE.—

(i) SEARCHABLE CATEGORIES.—The Director of NIH shall ensure that the public may, in addition to keyword searching, search the entries in the registry data bank by 1 or more of the following criteria:

(I) The disease or condition being studied in the clinical trial, using Medical Subject Headers (MeSH) descriptors.

(II) The name of the intervention, including any drug or device being studied in the clinical trial.

(III) The location of the clinical trial.

(IV) The age group studied in the clinical trial, including pediatric subpopulations.

(V) The study phase of the clinical trial.

(VI) The sponsor of the clinical trial, which may be the National Institutes of Health or another Federal agency, a private industry source, or a university or other organization.

(VII) The recruitment status of the clinical trial.

(VIII) The National Clinical Trial number or other study identification for the clinical trial.

(ii) ADDITIONAL SEARCHABLE CATEGORY.—Not later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Director of NIH shall ensure that the public may search the entries of the registry data bank by

the safety issue, if any, being studied in the clinical trial as a primary or secondary outcome.

(iii) OTHER ELEMENTS.—The Director of NIH shall also ensure that the public may search the entries of the registry data bank by such other elements as the Director deems necessary on an ongoing basis.

(iv) FORMAT.—The Director of the NIH shall ensure that the registry data bank is easily used by the public, and that entries are easily compared.

(C) DATA SUBMISSION.—The responsible party for an applicable clinical trial, including an applicable drug clinical trial for a serious or life-threatening disease or condition, that is initiated after, or is ongoing on the date that is 90 days after, the date of the enactment of the Food and Drug Administration Amendments Act of 2007, shall submit to the Director of NIH for inclusion in the registry data bank the clinical trial information described in of subparagraph (A)(ii) not later than the later of—

(i) 90 days after such date of enactment;

(ii) 21 days after the first patient is enrolled in such clinical trial; or

(iii) in the case of a clinical trial that is not for a serious or life-threatening disease or condition and that is ongoing on such date of enactment, 1 year after such date of enactment.

(D) POSTING OF DATA.—

(i) APPLICABLE DRUG CLINICAL TRIAL.—The Director of NIH shall ensure that clinical trial information for an applicable drug clinical trial submitted in accordance with this paragraph is posted in the registry data bank not later than 30 days after such submission.

(ii) APPLICABLE DEVICE CLINICAL TRIAL.—The Director of NIH shall ensure that clinical trial information for an applicable device clinical trial submitted in accordance with this paragraph is posted publicly in the registry data bank—

(I) not earlier than the date of clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act, or approval under section 515 or 520(m) of such Act, as applicable, for a device that was not previously cleared or approved, and not later than 30 days after such date; or

(II) for a device that was previously cleared or approved, not later than 30 days after the clinical trial information under paragraph (3)(C) is required to be posted by the Secretary.

(3) EXPANSION OF REGISTRY DATA BANK TO INCLUDE RESULTS OF CLINICAL TRIALS.—

(A) LINKING REGISTRY DATA BANK TO EXISTING RESULTS.—

(i) IN GENERAL.—Beginning not later than 90 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, for those clinical trials that form the primary basis of an efficacy claim or are conducted after the drug involved is

approved or after the device involved is cleared or approved, the Secretary shall ensure that the registry data bank includes links to results information as described in clause (ii) for such clinical trial—

(I) not earlier than 30 days after the date of the approval of the drug involved or clearance or approval of the device involved; or

(II) not later than 30 days after the results information described in clause (ii) becomes publicly available.

(ii) REQUIRED INFORMATION.—

(I) FDA INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

(aa) If an advisory committee considered at a meeting an applicable clinical trial, any posted Food and Drug Administration summary document regarding such applicable clinical trial.

(bb) If an applicable drug clinical trial was conducted under section 505A or 505B of the Federal Food, Drug, and Cosmetic Act, a link to the posted Food and Drug Administration assessment of the results of such trial.

(cc) Food and Drug Administration public health advisories regarding the drug or device that is the subject of the applicable clinical trial, if any.

(dd) For an applicable drug clinical trial, the Food and Drug Administration action package for approval document required under section 505(l)(2) of the Federal Food, Drug, and Cosmetic Act.

(ee) For an applicable device clinical trial, in the case of a premarket application under section 515 of the Federal Food, Drug, and Cosmetic Act, the detailed summary of information respecting the safety and effectiveness of the device required under section 520(h)(1) of such Act, or, in the case of a report under section 510(k) of such Act, the section 510(k) summary of the safety and effectiveness data required under section 807.95(d) of title 21, Code of Federal Regulations (or any successor regulation).

(II) NIH INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

(aa) Medline citations to any publications focused on the results of an applicable clinical trial.

(bb) The entry for the drug that is the subject of an applicable drug clinical trial in the National Library of Medicine database of structured product labels, if available.

(iii) RESULTS FOR EXISTING DATA BANK ENTRIES.—The Secretary may include the links described in clause (ii) for data bank entries for clinical trials submitted to the data bank prior to enactment of the Food and Drug Administration Amendments Act of 2007, as available.

(B) INCLUSION OF RESULTS.—The Secretary, acting through the Director of NIH, shall—

(i) expand the registry data bank to include the results of applicable clinical trials (referred to in this subsection as the "registry and results data bank");

(ii) ensure that such results are made publicly available through the Internet;

(iii) post publicly a glossary for the lay public explaining technical terms related to the results of clinical trials; and

(iv) in consultation with experts on risk communication, provide information with the information included under subparagraph (C) in the registry and results data bank to help ensure that such information does not mislead the patients or the public.

(C) BASIC RESULTS.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall include in the registry and results data bank for each applicable clinical trial for a drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act or a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or 520(m) of such Act, the following elements:

(i) DEMOGRAPHIC AND BASELINE CHARACTERISTICS OF PATIENT SAMPLE.—A table of the demographic and baseline data collected overall and for each arm of the clinical trial to describe the patients who participated in the clinical trial, including the number of patients who dropped out of the clinical trial and the number of patients excluded from the analysis, if any.

(ii) PRIMARY AND SECONDARY OUTCOMES.—The primary and secondary outcome measures as submitted under paragraph (2)(A)(ii)(I)(ll), and a table of values for each of the primary and secondary outcome measures for each arm of the clinical trial, including the results of scientifically appropriate tests of the statistical significance of such outcome measures.

(iii) POINT OF CONTACT.—A point of contact for scientific information about the clinical trial results.

(iv) CERTAIN AGREEMENTS.—Whether there exists an agreement (other than an agreement solely to comply with applicable provisions of law protecting the privacy of participants) between the sponsor or its agent and the principal investigator (unless the sponsor is an employer of the principal investigator) that restricts in any manner the ability of the principal investigator, after the completion date of the trial, to

discuss the results of the trial at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the trial.

(D) EXPANDED REGISTRY AND RESULTS DATA BANK.—

(i) EXPANSION BY RULEMAKING.—To provide more complete results information and to enhance patient access to and understanding of the results of clinical trials, not later than 3 years after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall by regulation expand the registry and results data bank as provided under this subparagraph.

(ii) CLINICAL TRIALS.—

(I) APPROVED PRODUCTS.—The regulations under this subparagraph shall require the inclusion of the results information described in clause (iii) for—

(aa) each applicable drug clinical trial for a drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act; and

(bb) each applicable device clinical trial for a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or 520(m) of such Act.

(II) UNAPPROVED PRODUCTS.—The regulations under this subparagraph shall establish whether or not the results information described in clause (iii) shall be required for—

(aa) an applicable drug clinical trial for a drug that is not approved under section 505 of the Federal Food, Drug, and Cosmetic Act and not licensed under section 351 of this Act (whether approval or licensure was sought or not); and

(bb) an applicable device clinical trial for a device that is not cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act and not approved under section 515 or section 520(m) of such Act (whether clearance or approval was sought or not).

(iii) REQUIRED ELEMENTS.—The regulations under this subparagraph shall require, in addition to the elements described in subparagraph (C), information within each of the following categories:

(I) A summary of the clinical trial and its results that is written in non-technical, understandable language for patients, if the Secretary determines that such types of summary can be included without being misleading or promotional.

(II) A summary of the clinical trial and its results that is technical in nature, if the Secretary

determines that such types of summary can be included without being misleading or promotional.

(III) The full protocol or such information on the protocol for the trial as may be necessary to help to evaluate the results of the trial.

(IV) Such other categories as the Secretary determines appropriate.

(iv) RESULTS SUBMISSION.—The results information described in clause (iii) shall be submitted to the Director of NIH for inclusion in the registry and results data bank as provided by subparagraph (E), except that the Secretary shall by regulation determine—

(I) whether the 1-year period for submission of clinical trial information described in subparagraph (E)(i) should be increased from 1 year to a period not to exceed 18 months;

(II) whether the clinical trial information described in clause (iii) should be required to be submitted for an applicable clinical trial for which the clinical trial information described in subparagraph (C) is submitted to the registry and results data bank before the effective date of the regulations issued under this subparagraph; and

(III) in the case when the clinical trial information described in clause (iii) is required to be submitted for the applicable clinical trials described in clause (ii)(II), the date by which such clinical trial information shall be required to be submitted, taking into account—

(aa) the certification process under subparagraph (E)(iii) when approval, licensure, or clearance is sought; and

(bb) whether there should be a delay of submission when approval, licensure, or clearance will not be sought.

(v) ADDITIONAL PROVISIONS.—The regulations under this subparagraph shall also establish—

(I) a standard format for the submission of clinical trial information under this paragraph to the registry and results data bank;

(II) additional information on clinical trials and results that is written in nontechnical, understandable language for patients;

(III) considering the experience under the pilot quality control project described in paragraph (5)(C), procedures for quality control, including using representative samples, with respect to completeness and content of clinical trial information under this subsection, to help ensure that data elements are not false or misleading and are nonpromotional;

(IV) the appropriate timing and requirements for updates of clinical trial information, and whether and, if so, how such updates should be tracked;

(V) a statement to accompany the entry for an applicable clinical trial when the primary and secondary outcome measures for such clinical trial are submitted under paragraph (4)(A) after the date specified for the submission of such information in paragraph (2)(C); and

(VI) additions or modifications to the manner of reporting of the data elements established under subparagraph (C).

(vi) CONSIDERATION OF WORLD HEALTH ORGANIZATION DATA SET.—The Secretary shall consider the status of the consensus data elements set for reporting clinical trial results of the World Health Organization when issuing the regulations under this subparagraph.

(vii) PUBLIC MEETING.—The Secretary shall hold a public meeting no later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 to provide an opportunity for input from interested parties with regard to the regulations to be issued under this subparagraph.

(E) SUBMISSION OF RESULTS INFORMATION.—

(i) IN GENERAL.—Except as provided in clauses (iii), (iv), (v), and (vi) the responsible party for an applicable clinical trial that is described in clause (ii) shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraph (C) not later than 1 year, or such other period as may be provided by regulation under subparagraph (D), after the earlier of—

(I) the estimated completion date of the trial as described in paragraph (2)(A)(ii)(I)(jj)); or

(II) the actual date of completion.

(ii) CLINICAL TRIALS DESCRIBED.—An applicable clinical trial described in this clause is an applicable clinical trial subject to—

(I) paragraph (2)(C); and

(II)(aa) subparagraph (C); or

(bb) the regulations issued under subparagraph (D).

(iii) DELAYED SUBMISSION OF RESULTS WITH CERTIFICATION.—If the responsible party for an applicable clinical trial submits a certification that clause (iv) or (v) applies to such clinical trial, the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) as required under the applicable clause.

(iv) SEEKING INITIAL APPROVAL OF A DRUG OR DEVICE.—With respect to an applicable clinical trial that is completed before the drug is initially approved under section 505 of the Federal Food, Drug, and Cosmetic Act or initially licensed under section 351 of this Act, or the device is initially cleared under section 510(k) or initially approved under section 515 or

520(m) of the Federal Food, Drug, and Cosmetic Act, the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) not later than 30 days after the drug or device is approved under such section 505, licensed under such section 351, cleared under such section 510(k), or approved under such section 515 or 520(m), as applicable.

(v) SEEKING APPROVAL OF A NEW USE FOR THE DRUG OR DEVICE.—

(I) IN GENERAL.—With respect to an applicable clinical trial where the manufacturer of the drug or device is the sponsor of an applicable clinical trial, and such manufacturer has filed, or will file within 1 year, an application seeking approval under section 505 of the Federal Food, Drug, and Cosmetic Act, licensing under section 351 of this Act, or clearance under section 510(k), or approval under section 515 or 520(m), of the Federal Food, Drug, and Cosmetic Act for the use studied in such clinical trial (which use is not included in the labeling of the approved drug or device), then the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) on the earlier of the date that is 30 days after the date—

(aa) the new use of the drug or device is approved under such section 505, licensed under such section 351, cleared under such section 510(k), or approved under such section 515 or 520(m);

(bb) the Secretary issues a letter, such as a complete response letter, not approving the submission or not clearing the submission, a not approvable letter, or a not substantially equivalent letter for the new use of the drug or device under such section 505, 351, 510(k), 515, or 520(m); or

(cc) except as provided in subclause (III), the application or premarket notification under such section 505, 351, 510(k), 515, or 520(m) is withdrawn without resubmission for no less than 210 days.

(II) REQUIREMENT THAT EACH CLINICAL TRIAL IN APPLICATION BE TREATED THE SAME.—If a manufacturer makes a certification under clause (iii) that this clause applies with respect to a clinical trial, the manufacturer shall make such a certification with respect to each applicable clinical trial that is required to be submitted in an application or report for licensure, approval, or clearance (under section 351 of this Act or section 505, 510(k), 515, or 520(m) of the Federal Food, Drug,

and Cosmetic Act, as applicable) of the use studied in the clinical trial.

(III) TWO-YEAR LIMITATION.—The responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information subject to subclause (I) on the date that is 2 years after the date a certification under clause (iii) was made to the Director of NIH, if an action referred to in item (aa), (bb), or (cc) of subclause (I) has not occurred by such date.

(vi) EXTENSIONS.—The Director of NIH may provide an extension of the deadline for submission of clinical trial information under clause (i) if the responsible party for the trial submits to the Director a written request that demonstrates good cause for the extension and provides an estimate of the date on which the information will be submitted. The Director of NIH may grant more than one such extension for a clinical trial.

(F) NOTICE TO DIRECTOR OF NIH.—The Commissioner of Food and Drugs shall notify the Director of NIH when there is an action described in subparagraph (E)(iv) or item (aa), (bb), or (cc) of subparagraph (E)(v)(I) with respect to an application or a report that includes a certification required under paragraph (5)(B) of such action not later than 30 days after such action.

(G) POSTING OF DATA.—The Director of NIH shall ensure that the clinical trial information described in subparagraphs (C) and (D) for an applicable clinical trial submitted in accordance with this paragraph is posted publicly in the registry and results database not later than 30 days after such submission.

(H) WAIVERS REGARDING CERTAIN CLINICAL TRIAL RESULTS.—The Secretary may waive any applicable requirements of this paragraph for an applicable clinical trial, upon a written request from the responsible party, if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is consistent with the protection of public health, or in the interest of national security. Not later than 30 days after any part of a waiver is granted, the Secretary shall notify, in writing, the appropriate committees of Congress of the waiver and provide an explanation for why the waiver was granted.

(I) ADVERSE EVENTS.—

(i) REGULATIONS.—Not later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall by regulation determine the best method for including in the registry and results data bank appropriate results information on serious adverse and frequent adverse events for applicable clinical trials described in subparagraph (C) in a manner and form that is useful and not misleading to patients, physicians, and scientists.

(ii) DEFAULT.—If the Secretary fails to issue the regulation required by clause (i) by the date that is 24 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, clause (iii) shall take effect.

(iii) ADDITIONAL ELEMENTS.—Upon the application of clause (ii), the Secretary shall include in the registry and results data bank for applicable clinical trials described in subparagraph (C), in addition to the clinical trial information described in subparagraph (C), the following elements:

(I) SERIOUS ADVERSE EVENTS.—A table of anticipated and unanticipated serious adverse events grouped by organ system, with number and frequency of such event in each arm of the clinical trial.

(II) FREQUENT ADVERSE EVENTS.—A table of anticipated and unanticipated adverse events that are not included in the table described in subclause (I) that exceed a frequency of 5 percent within any arm of the clinical trial, grouped by organ system, with number and frequency of such event in each arm of the clinical trial.

(iv) POSTING OF OTHER INFORMATION.—In carrying out clause (iii), the Secretary shall, in consultation with experts in risk communication, post with the tables information to enhance patient understanding and to ensure such tables do not mislead patients or the lay public.

(v) RELATION TO SUBPARAGRAPH (C).—Clinical trial information included in the registry and results data bank pursuant to this subparagraph is deemed to be clinical trial information included in such data bank pursuant to subparagraph (C).

(4) ADDITIONAL SUBMISSIONS OF CLINICAL TRIAL INFORMATION.—

(A) VOLUNTARY SUBMISSIONS.—A responsible party for a clinical trial that is not an applicable clinical trial, or that is an applicable clinical trial that is not subject to paragraph (2)(C), may submit complete clinical trial information described in paragraph (2) or paragraph (3) provided the responsible party submits clinical trial information for each applicable clinical trial that is required to be submitted under section 351 or under section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act in an application or report for licensure, approval, or clearance of the drug or device for the use studied in the clinical trial.

(B) REQUIRED SUBMISSIONS.—

(i) IN GENERAL.—Notwithstanding paragraphs (2) and (3) and subparagraph (A), in any case in which the Secretary determines for a specific clinical trial described in clause (ii) that posting in the registry and results data bank of clinical trial information for such clinical trial is necessary to protect the public health—

(I) the Secretary may require by notification that such information be submitted to the Secretary in accordance with paragraphs (2) and (3) except with regard to timing of submission;

(II) unless the responsible party submits a certification under paragraph (3)(E)(iii), such information shall be submitted not later than 30 days after the date specified by the Secretary in the notification; and

(III) failure to comply with the requirements under subclauses (I) and (II) shall be treated as a violation of the corresponding requirement of such paragraphs.

(ii) CLINICAL TRIALS DESCRIBED.—A clinical trial described in this clause is—

(I) an applicable clinical trial for a drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act or for a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or section 520(m) of such Act, whose completion date is on or after the date 10 years before the date of the enactment of the Food and Drug Administration Amendments Act of 2007; or

(II) an applicable clinical trial that is described by both by paragraph (2)(C) and paragraph (3)(D)(ii)(II)).

(C) UPDATES TO CLINICAL TRIAL DATA BANK.—

(i) SUBMISSION OF UPDATES.—The responsible party for an applicable clinical trial shall submit to the Director of NIH for inclusion in the registry and results data bank updates to reflect changes to the clinical trial information submitted under paragraph (2). Such updates—

(I) shall be provided not less than once every 12 months, unless there were no changes to the clinical trial information during the preceding 12-month period;

(II) shall include identification of the dates of any such changes;

(III) not later than 30 days after the recruitment status of such clinical trial changes, shall include an update of the recruitment status; and

(IV) not later than 30 days after the completion date of the clinical trial, shall include notification to the Director that such clinical trial is complete.

(ii) PUBLIC AVAILABILITY OF UPDATES.—The Director of NIH shall make updates submitted under clause (i) publicly available in the registry data bank. Except with regard to overall recruitment status, individual site status, location, and contact information, the Director of NIH shall ensure that updates to elements required under subclauses (I) to (V) of paragraph (2)(A)(ii) do not result in the removal of any informa-

tion from the original submissions or any preceding updates, and information in such databases is presented in a manner that enables users to readily access each original element submission and to track the changes made by the updates. The Director of NIH shall provide a link from the table of primary and secondary outcomes required under paragraph (3)(C)(ii) to the tracked history required under this clause of the primary and secondary outcome measures submitted under paragraph (2)(A)(ii)(I)(ll).

(5) COORDINATION AND COMPLIANCE.—

(A) CLINICAL TRIALS SUPPORTED BY GRANTS FROM FEDERAL AGENCIES.—

(i) GRANTS FROM CERTAIN FEDERAL AGENCIES.—If an applicable clinical trial is funded in whole or in part by a grant from any agency of the Department of Health and Human Services, including the Food and Drug Administration, the National Institutes of Health, or the Agency for Healthcare Research and Quality, any grant or progress report forms required under such grant shall include a certification that the responsible party has made all required submissions to the Director of NIH under paragraphs (2) and (3).

(ii) VERIFICATION BY FEDERAL AGENCIES.—The heads of the agencies referred to in clause (i), as applicable, shall verify that the clinical trial information for each applicable clinical trial for which a grantee is the responsible party has been submitted under paragraphs (2) and (3) before releasing any remaining funding for a grant or funding for a future grant to such grantee.

(iii) NOTICE AND OPPORTUNITY TO REMEDY.—If the head of an agency referred to in clause (i), as applicable, verifies that a grantee has not submitted clinical trial information as described in clause (ii), such agency head shall provide notice to such grantee of such non-compliance and allow such grantee 30 days to correct such non-compliance and submit the required clinical trial information.

(iv) CONSULTATION WITH OTHER FEDERAL AGENCIES.—The Secretary shall—

(I) consult with other agencies that conduct research involving human subjects in accordance with any section of part 46 of title 45, Code of Federal Regulations (or any successor regulations), to determine if any such research is an applicable clinical trial; and

(II) develop with such agencies procedures comparable to those described in clauses (i), (ii), and (iii) to ensure that clinical trial information for such applicable clinical trial is submitted under paragraphs (2) and (3).

(B) CERTIFICATION TO ACCOMPANY DRUG, BIOLOGICAL PRODUCT, AND DEVICE SUBMISSIONS.—At the time of submission of an application under section 505 of the Federal Food, Drug, and Cosmetic Act, section 515 of such Act, sec-

tion 520(m) of such Act, or section 351 of this Act, or submission of a report under section 510(k) of such Act, such application or submission shall be accompanied by a certification that all applicable requirements of this subsection have been met. Where available, such certification shall include the appropriate National Clinical Trial control numbers.

(C) QUALITY CONTROL.—

(i) PILOT QUALITY CONTROL PROJECT.—Until the effective date of the regulations issued under paragraph (3)(D), the Secretary, acting through the Director of NIH and the Commissioner of Food and Drugs, shall conduct a pilot project to determine the optimal method of verification to help to ensure that the clinical trial information submitted under paragraph (3)(C) is non-promotional and is not false or misleading in any particular under subparagraph (D). The Secretary shall use the publicly available information described in paragraph (3)(A) and any other information available to the Secretary about applicable clinical trials to verify the accuracy of the clinical trial information submitted under paragraph (3)(C).

(ii) NOTICE OF COMPLIANCE.—If the Secretary determines that any clinical trial information was not submitted as required under this subsection, or was submitted but is false or misleading in any particular, the Secretary shall notify the responsible party and give such party an opportunity to remedy such noncompliance by submitting the required revised clinical trial information not later than 30 days after such notification.

(D) TRUTHFUL CLINICAL TRIAL INFORMATION.—

(i) IN GENERAL.—The clinical trial information submitted by a responsible party under this subsection shall not be false or misleading in any particular.

(ii) EFFECT.—Clause (i) shall not have the effect of—

(I) requiring clinical trial information with respect to an applicable clinical trial to include information from any source other than such clinical trial involved; or

(II) requiring clinical trial information described in paragraph (3)(D) to be submitted for purposes of paragraph (3)(C).

(E) PUBLIC NOTICES.—

(i) NOTICE OF VIOLATIONS.—If the responsible party for an applicable clinical trial fails to submit clinical trial information for such clinical trial as required under paragraphs (2) or (3), the Director of NIH shall include in the registry and results data bank entry for such clinical trial a notice—

(I) that the responsible party is not in compliance with this Act by—

(aa) failing to submit required clinical trial information; or

(bb) submitting false or misleading clinical trial information;

(II) of the penalties imposed for the violation, if any; and

(III) whether the responsible party has corrected the clinical trial information in the registry and results data bank.

(ii) NOTICE OF FAILURE TO SUBMIT PRIMARY AND SECONDARY OUTCOMES.—If the responsible party for an applicable clinical trial fails to submit the primary and secondary outcomes as required under section 2(A)(ii)(I)(ll), the Director of NIH shall include in the registry and results data bank entry for such clinical trial a notice that the responsible party is not in compliance by failing to register the primary and secondary outcomes in accordance with this act, and that the primary and secondary outcomes were not publicly disclosed in the database before conducting the clinical trial.

(iii) FAILURE TO SUBMIT STATEMENT.—The notice under clause (i) for a violation described in clause (i)(I)(aa) shall include the following statement: "The entry for this clinical trial was not complete at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.".

(iv) SUBMISSION OF FALSE INFORMATION STATEMENT.—The notice under clause (i) for a violation described in clause (i)(I)(bb) shall include the following statement: "The entry for this clinical trial was found to be false or misleading and therefore not in compliance with the law.".

(v) NON-SUBMISSION OF STATEMENT.—The notice under clause (ii) for a violation described in clause (ii) shall include the following statement: "The entry for this clinical trial did not contain information on the primary and secondary outcomes at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.".

(vi) COMPLIANCE SEARCHES.—The Director of NIH shall provide that the public may easily search the registry and results data bank for entries that include notices required under this subparagraph.

(6) LIMITATION ON DISCLOSURE OF CLINICAL TRIAL INFORMATION.—

(A) IN GENERAL.—Nothing in this subsection (or under section 552 of title 5, United States Code) shall require the Secretary to publicly disclose, by any means other than the registry and results data bank, information described in subparagraph (B).

(B) INFORMATION DESCRIBED.—Information described in this subparagraph is—

(i) information submitted to the Director of NIH under this subsection, or information of the same gen-

eral nature as (or integrally associated with) the information so submitted; and

(ii) information not otherwise publicly available, including because it is protected from disclosure under section 552 of title 5, United States Code.

(7) STANDARDIZATION.—The Director of NIH shall—

(A) ensure that the registry and results data bank is easily used by the public;

(B) ensure that entries in the registry and results data bank are easily compared;

(C) ensure that information required to be submitted to the registry and results data bank, including recruitment information under paragraph (2)(A)(ii)(II), is submitted by persons and posted by the Director of NIH in a standardized format and includes at least—

(i) the disease or indication being studied;

(ii) inclusion criteria such as age, gender, diagnosis or diagnoses, laboratory values, or imaging results; and

(iii) exclusion criteria such as specific diagnosis or diagnoses, laboratory values, or prohibited medications; and

(D) to the extent possible, in carrying out this paragraph, make use of standard health care terminologies, such as the International Classification of Diseases or the Current Procedural Terminology, that facilitate electronic matching to data in electronic health records or other relevant health information technologies.

[(7)**]** *(8)* AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection $10,000,000 for each fiscal year.

(k)(1) The Director of NIH may establish a program to provide day care services for the employees of the National Institutes of Health similar to those services provided by other Federal agencies (including the availability of day care service on a 24-hour-a-day basis).

(2) Any day care provider at the National Institutes of Health shall establish a sliding scale of fees that takes into consideration the income and needs of the employee.

(3) For purposes regarding the provision of day care services, the Director of NIH may enter into rental or lease purchase agreements.

(l) COUNCIL OF COUNCILS.—

(1) ESTABLISHMENT.—Not later than 90 days after the date of the enactment of the National Institutes of Health Reform Act of 2006, the Director of NIH shall establish within the Office of the Director an advisory council to be known as the "Council of Councils" (referred to in this subsection as the "Council") for the purpose of advising the Director on matters related to the policies and activities of the Division of Program Coordination, Planning, and Strategic Initiatives, including making recommendations with respect to the conduct and support of research described in subsection (b)(7).

(2) MEMBERSHIP.—

(A) IN GENERAL.—The Council shall be composed of 27 members selected by the Director of NIH with approval from the Secretary from among the list of nominees under subparagraph (C).

(B) CERTAIN REQUIREMENTS.—In selecting the members of the Council, the Director of NIH shall ensure—

(i) the representation of a broad range of disciplines and perspectives; and

(ii) the ongoing inclusion of at least 1 representative from each national research institute whose budget is substantial relative to a majority of the other institutes.

(C) NOMINATION.—The Director of NIH shall maintain an updated list of individuals who have been nominated to serve on the Council, which list shall consist of the following:

(i) For each national research institute and national center, 3 individuals nominated by the head of such institute or center from among the members of the advisory council of the institute or center, of which—

(I) two shall be scientists; and

(II) one shall be from the general public or shall be a leader in the field of public policy, law, health policy, economics, or management.

(ii) For each office within the Division of Program Coordination, Planning, and Strategic Initiatives, 1 individual nominated by the head of such office.

(iii) Members of the Council of Public Representatives.

(3) TERMS.—

(A) IN GENERAL.—The term of service for a member of the Council shall be 6 years, except as provided in subparagraphs (B) and (C).

(B) TERMS OF INITIAL APPOINTEES.—Of the initial members selected for the Council, the Director of NIH shall designate—

(i) nine for a term of 6 years;

(ii) nine for a term of 4 years; and

(iii) nine for a term of 2 years.

(C) VACANCIES.—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office.

(m) RESEARCH STRATEGIC PLAN.—

(1) FIVE-YEAR PLANS FOR BIOMEDICAL RESEARCH STRATEGY.—

(A) IN GENERAL.—For each successive five-year period beginning with the period of fiscal years 2016 through 2020, the Director of NIH, in consultation with the entities described in subparagraph (B), shall develop and maintain a biomedical research strategic plan that—

(i) is designed to increase the efficient and effective focus of biomedical research in a manner that

leverages the best scientific opportunities through a deliberative planning process;

(ii) identifies areas, to be known as strategic focus areas, in which the resources of the National Institutes of Health can best contribute to the goal of expanding knowledge on human health in the United States through biomedical research; and

(iii) includes objectives for each such strategic focus area.

(B) ENTITIES DESCRIBED.—The entities described in this subparagraph are the directors of the national research institutes and national centers, researchers, patient advocacy groups, and industry leaders.

(2) USE OF PLAN.—The Director of NIH and the directors of the national research institutes and national centers shall use the strategic plan—

(A) to identify research opportunities; and

(B) to develop individual strategic plans for the research activities of each of the national research institutes and national centers that—

(i) have a common template; and

(ii) identify strategic focus areas in which the resources of the national research institutes and national centers can best contribute to the goal of expanding knowledge on human health in the United States through biomedical research.

(3) CONTENTS OF PLANS.—

(A) STRATEGIC FOCUS AREAS.—The strategic focus areas identified pursuant to paragraph (1)(A)(ii) shall—

(i) be identified in a manner that—

(I) considers the return on investment to the United States public through the investments of the National Institutes of Health in biomedical research; and

(II) contributes to expanding knowledge to improve the United States public's health through biomedical research; and

(ii) include overarching and trans-National Institutes of Health strategic focus areas, to be known as Mission Priority Focus Areas, which best serve the goals of preventing or eliminating the burden of a disease or condition and scientifically merit enhanced and focused research over the next 5 years.

(B) RARE AND PEDIATRIC DISEASES AND CONDITIONS.—In developing and maintaining a strategic plan under this subsection, the Director of NIH shall ensure that rare and pediatric diseases and conditions remain a priority.

(C) WORKFORCE.—In developing and maintaining a strategic plan under this subsection, the Director of NIH shall ensure that maintaining the biomedical workforce of the future, including the participation by scientists from groups traditionally underrepresented in the scientific workforce, remains a priority.

(4) INITIAL PLAN.—Not later than 270 days after the date of enactment of this subsection, the Director of NIH and the direc-

tors of the national research institutes and national centers shall—

(A) complete the initial strategic plan required by paragraphs (1) and (2); and

(B) make such initial strategic plan publicly available on the website of the National Institutes of Health.

(5) REVIEW; UPDATES.—

(A) PROGRESS REVIEWS.—Not less than annually, the Director of NIH, in consultation with the directors of the national research institutes and national centers, shall conduct progress reviews for each strategic focus area identified under paragraph (1)(A)(ii).

(B) UPDATES.—Not later than the end of the 5-year period covered by the initial strategic plan under this subsection, and every 5 years thereafter, the Director of NIH, in consultation with the directors of the national research institutes and national centers, stakeholders in the scientific field, advocates, and the public at large, shall—

(i) conduct a review of the plan, including each strategic focus area identified under paragraph (2)(B); and

(ii) update such plan in accordance with this section.

(n) SHARING OF DATA GENERATED THROUGH NIH-FUNDED RESEARCH.—

(1) AUTHORITY.—Subject to paragraph (2), the Director of NIH may require recipients of the award of an NIH grant or other financial support, provided that the research is fully funded through such grant or other support, to share scientific data generated from research conducted through such support for research purposes.

(2) LIMITATION.—The Director of NIH shall not require the sharing of data that is inconsistent with applicable law and policy protecting—

(A) privacy and confidentiality;

(B) proprietary interests;

(C) business confidential information;

(D) intellectual property rights; and

(E) other relevant rights.

SEC. 402A. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—

(1) THIS TITLE.—For purposes of carrying out this title, there are authorized to be appropriated—

(A) $30,331,309,000 for fiscal year 2007;

(B) $32,831,309,000 for fiscal year 2008; **[**and**]**

(C) such sums as may be necessary for fiscal year 2009**[**.**]***;*

(D) $31,811,000,000 for fiscal year 2016;

(E) $33,331,000,000 for fiscal year 2017; and

(F) $34,851,000,000 for fiscal year 2018.

(2) FUNDING FOR 10-YEAR PEDIATRIC RESEARCH INITIATIVE THROUGH COMMON FUND.—For the purpose of carrying out section 402(b)(7)(B)(ii), there is authorized to be appropriated to the Common Fund, out of the 10-Year Pediatric Research Initiative Fund described in section 9008 of the Internal Revenue Code of 1986, and in addition to amounts otherwise made available under paragraph (1) of this subsection and reserved

under subsection (c)(1)(B)(i) of this section, $12,600,000 for each of fiscal years 2014 through 2023.

(b) OFFICE OF THE DIRECTOR.—Of the amount authorized to be appropriated under subsection (a) for a fiscal year, there are authorized to be appropriated for programs and activities under this title carried out through the Office of the Director of NIH such sums as may be necessary for each of the fiscal years 2007 through 2009.

(c) TRANS-NIH RESEARCH.—

(1) COMMON FUND.—

(A) ACCOUNT.—For the purpose of allocations under section 402(b)(7)(B) (relating to research identified by the Division of Program Coordination, Planning, and Strategic Initiatives), there is established an account to be known as the Common Fund.

(B) RESERVATION.—

(i) IN GENERAL.—Of the total amount appropriated under subsection (a)(1) for fiscal year 2007 or any subsequent fiscal year, the Director of NIH shall reserve an amount for the Common Fund, subject to any applicable provisions in appropriations Acts.

(ii) MINIMUM AMOUNT.—For each fiscal year, the percentage constituted by the amount reserved under clause (i) relative to the total amount appropriated under subsection (a)(1) for such year may not be less than the percentage constituted by the amount so reserved for the preceding fiscal year relative to the total amount appropriated under subsection (a)(1) for such preceding fiscal year, subject to any applicable provisions in appropriations Acts.

(C) COMMON FUND STRATEGIC PLANNING REPORT.—Not later than June 1, 2007, and every 2 years thereafter, the Secretary, acting through the Director of NIH, shall submit a report to the Congress containing a strategic plan for funding research described in section 402(b)(7)(A)(i) (including personnel needs) through the Common Fund. Each such plan shall include the following:

(i) An estimate of the amounts determined by the Director of NIH to be appropriate for maximizing the potential of such research.

(ii) An estimate of the amounts determined by the Director of NIH to be sufficient only for continuing to fund research activities previously identified by the Division of Program Coordination, Planning, and Strategic Initiatives.

(iii) An estimate of the amounts determined by the Director of NIH to be necessary to fund research described in section 402(b)(7)(A)(i)—

(I) that is in addition to the research activities described in clause (ii); and

(II) for which there is the most substantial need.

(D) EVALUATION.—During the 6-month period following the end of the first fiscal year for which the total amount reserved under subparagraph (B) is equal to 5 percent of

the total amount appropriated under subsection (a)(1) for such fiscal year, the Secretary, acting through the Director of NIH, in consultation with the advisory council established under section 402(k), shall submit recommendations to the Congress for changes regarding amounts for the Common Fund.

(2) TRANS-NIH RESEARCH REPORTING.—

(A) LIMITATION.—With respect to the total amount appropriated under subsection (a) for fiscal year 2008 or any subsequent fiscal year, if the head of a national research institute or national center fails to submit the report required by subparagraph (B) for the preceding fiscal year, the amount made available for the institute or center for the fiscal year involved may not exceed the amount made available for the institute or center for fiscal year 2006.

(B) REPORTING.—Not later than January 1, 2008, and each January 1st thereafter—

(i) the head of each national research institute or national center shall submit to the Director of NIH a report on the amount made available by the institute or center for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers; and

(ii) the Secretary shall submit a report to the Congress identifying the percentage of funds made available by each national research institute and national center with respect to such fiscal year for conducting or supporting research described in clause (i).

(C) DETERMINATION.—For purposes of determining the amount or percentage of funds to be reported under subparagraph (B), any amounts made available to an institute or center under section 402(b)(7)(B) shall be included.

(D) VERIFICATION OF AMOUNTS.—Upon receipt of each report submitted under subparagraph (B)(i), the Director of NIH shall review and, in cases of discrepancy, verify the accuracy of the amounts specified in the report.

(E) WAIVER.—At the request of any national research institute or national center, the Director of NIH may waive the application of this paragraph to such institute or center if the Director finds that the conduct or support of research described in subparagraph (B)(i) is inconsistent with the mission of such institute or center.

(d) TRANSFER AUTHORITY.—Of the total amount appropriated under subsection (a)(1) for a fiscal year, the Director of NIH may (in addition to the reservation under subsection (c)(1) for such year) transfer not more than 1 percent for programs or activities that are authorized in this title and identified by the Director to receive funds pursuant to this subsection. In making such transfers, the Director may not decrease any appropriation account under subsection (a)(1) by more than 1 percent.

(e) NIH INNOVATION FUND.—

(1) ESTABLISHMENT.—For the purpose of allocations under section 402(b)(25), there is established a fund to be known as the NIH Innovation Fund. The Director of NIH shall, with re-

spect to funds appropriated to the NIH Innovation Fund, allocate such funds to support biomedical research through the funding of basic, translational, and clinical research.

(2) AMOUNTS MADE AVAILABLE TO FUND.—

(A) IN GENERAL.—Subject to subparagraph (B), there is authorized to be appropriated, and appropriated, to the NIH Innovation Fund out of any funds in the Treasury not otherwise appropriated, $2,000,000,000 for each of fiscal years 2016 through 2020. The amounts appropriated to the Fund by the preceding sentence shall be in addition to any amounts otherwise made available to the National Institutes of Health.

(B) AVAILABILITY SUBJECT TO APPROPRIATIONS.—Amounts in the Fund shall not be available except to the extent and in such amounts as are provided in advance in appropriation Acts.

(C) ALLOCATION OF AMOUNTS.—Of the amounts made available from the NIH Innovation Fund for allocations under section 402(b)(25) for a fiscal year—

(i) not less than $500,000,000 shall be for the Accelerating Advancement Program under paragraph (5);

(ii) not less than 35 percent of such amounts remaining after subtracting the allocation for the Accelerating Advancement Program shall be for early stage investigators (as defined in paragraph (7));

(iii) not less than 20 percent of such amounts remaining after subtracting the allocation for the Accelerating Advancement Program shall be for high-risk, high-reward research under section 409K; and

(iv) not more than 10 percent of such amounts (without subtracting the allocation for the Accelerating Advancement Program) shall be for intramural research.

(D) INAPPLICABILITY OF CERTAIN PROVISIONS.—Amounts in the NIH Innovation Fund shall not be subject to—

(i) any transfer authority of the Secretary or the Director of NIH under section 241, subsection (c), subsection (d), or any other provision of law (other than section 402(b)(25) and this subsection); or

(ii) the Nonrecurring expenses fund under section 223 of division G of the Consolidated Appropriations Act, 2008 (42 U.S.C. 3514a).

(3) AUTHORIZED USES.—Amounts in the NIH Innovation Fund established under paragraph (1) may be used only to conduct or support innovative biomedical research through the following:

(A) Research in which—

(i) a principal investigator has a specific project or specific objectives; and

(ii) funding is tied to pursuit of such project or objectives.

(B) Research in which—

(i) a principal investigator has shown promise in biomedical research; and

(ii) funding is not tied to a specific project or specific objectives.

(C) Research to be carried out by an early stage investigator (as defined in paragraph (7)).

(D) Research to be carried out by a small business concern (as defined in section 3 of the Small Business Act).

(E) The Accelerating Advancement Program under paragraph (5).

(F) Development and implementation of the strategic plan under paragraph (6).

(4) COORDINATION.—In funding programs and activities through the NIH Innovation Fund, the Secretary, acting through the Director of NIH, shall—

(A) ensure coordination among the national research institutes, the national centers, and other departments, agencies, and offices of the Federal Government; and

(B) minimize unnecessary duplication.

(5) ACCELERATING ADVANCEMENT PROGRAM.—The Director of NIH shall establish a program, to be known as the Accelerating Advancement Program, under which—

(A) the Director of NIH partners with national research institutes and national centers to accomplish important biomedical research objectives; and

(B) for every $1 made available by the Director of NIH to a national research institute or national center for a research project, the institute or center makes $1 available for such project from funds that are not derived from the NIH Innovation Fund.

(6) STRATEGIC PLAN.—

(A) IN GENERAL.—The Director of NIH shall ensure that scientifically based strategic planning is implemented in support of research priorities, including through development, use, and updating of a research strategic plan that—

(i) is designed to increase the efficient and effective focus of biomedical research in a manner that leverages the best scientific opportunities through a deliberative planning process;

(ii) identifies areas, to be known as strategic focus areas, in which the resources of the NIH Innovation Fund can contribute to the goals of expanding knowledge to address, and find more effective treatments for, unmet medical needs in the United States, including the areas of—

(I) biomarkers;

(II) precision medicine;

(III) infectious diseases, including pathogens listed as a qualifying pathogen under section 505E(f) of the Federal Food, Drug, and Cosmetic Act or listed or designated as a tropical disease under section 524 of such Act; and

(IV) antibiotics;

(iii) includes objectives for each such strategic focus area; and

(iv) ensures that basic research remains a priority.

(B) UPDATES AND REVIEWS.—The Director shall review and, as appropriate, update the research strategic plan under subparagraph (A) not less than every 18 months.

(7) DEFINITION.—In this subsection, the term "early stage investigator" means an investigator who—

(A) will be the principal investigator or the program director of the proposed research;

(B) has never been awarded, or has been awarded only once, a substantial, competing grant by the National Institutes of Health for independent research; and

(C) is within 10 years of having completed—

(i) the investigator's terminal degree; or

(ii) a medical residency (or the equivalent).

[(e)**]** *(f)* RULE OF CONSTRUCTION.—This section may not be construed as affecting the authorities of the Director of NIH under section 401.

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PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

APPOINTMENT AND AUTHORITY OF THE DIRECTORS OF THE NATIONAL RESEARCH INSTITUTES

SEC. 405. **[**(a) The Director of the National Cancer Institute shall be appointed by the President and the Directors of the other national research institutes shall be appointed by the Secretary. Each Director of a national research institute shall report directly to the Director of NIH.**]** *(a)* APPOINTMENT; TERMS.—

(1) APPOINTMENT.—The Director of the National Cancer Institute shall be appointed by the President and the directors of the other national research institutes, as well as the directors of the national centers, shall be appointed by the Director of NIH. The directors of the national research institutes, as well as national centers, shall report directly to the Director of NIH.

(2) TERMS.—

(A) IN GENERAL.—The term of office of a director of a national research institute or national center shall be 5 years.

(B) REMOVAL.—The director of a national research institute or national center may be removed from office by the Director of NIH prior to the expiration of such director's 5-year term.

(C) REAPPOINTMENT.—At the end of the term of a director of a national research institute or national center, the director may be reappointed. There is no limit on the number of terms a director may serve.

(D) VACANCIES.—If the office of a director of a national research institute or national center becomes vacant before the end of such director's term, the director appointed to fill the vacancy shall be appointed for a 5-year term starting on the date of such appointment.

(E) TRANSITIONAL PROVISION.—Each director of a national research institute or national center serving on the date of enactment of the 21st Century Cures Act is deemed to be appointed for a 5-year term under this subsection starting on such date of enactment.

(b)(1) In carrying out the purposes of section 301 with respect to human diseases or disorders or other aspects of human health for

which the national research institutes were established, the Secretary, acting through the Director of each national research institute—

(A) shall encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences related to—

(i) the maintenance of health,

(ii) the detection, diagnosis, treatment, and prevention of human diseases and disorders,

(iii) the rehabilitation of individuals with human diseases, disorders, and disabilities, and

(iv) the expansion of knowledge of the processes underlying human diseases, disorders, and disabilities, the processes underlying the normal and pathological functioning of the body and its organ systems, and the processes underlying the interactions between the human organism and the environment;

(B) may, subject to the peer review prescribed under section 492(b) and any advisory council review under section 406(a)(3)(A)(i), conduct the research, investigations, experiments, demonstrations, and studies referred to in subparagraph (A);

(C) may conduct and support research training (i) for which fellowship support is not provided under section 487, and (ii) which is not residency training of physicians or other health professionals;

(D) may develop, implement, and support demonstrations and programs for the application of the results of the activities of the institute to clinical practice and disease prevention activities;

(E) may develop, conduct, and support public and professional education and information programs;

(F) may secure, develop and maintain, distribute, and support the development and maintenance of resources needed for research;

(G) may make available the facilities of the institute to appropriate entities and individuals engaged in research activities and cooperate with and assist Federal and State agencies charged with protecting the public health;

(H) may accept unconditional gifts made to the institute for its activities, and, in the case of gifts of a value in excess of $50,000, establish suitable memorials to the donor;

(I) may secure for the institute consultation services and advice of persons from the United States or abroad;

(J) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(K) may accept voluntary and uncompensated services; and

(L) may perform such other functions as the Secretary determines are needed to carry out effectively the purposes of the institute.

The indemnification provisions of section 2354, title 10, United States Code, shall apply with respect to contracts entered into under this subsection and section 402(b).

(2) Support for an activity or program under this subsection may be provided through grants, contracts, and cooperative agreements. The Secretary, acting through the Director of each national research institute—

(A) may enter into a contract for research, training, or demonstrations only if the contract has been recommended after technical and scientific peer review required by regulations under section 492;

(B) may make grants and cooperative agreements under paragraph (1) for research, training, or demonstrations, except that—

(i) if the direct cost of the grant or cooperative agreement to be made does not exceed $50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 492, and

(ii) if the direct cost of the grant or cooperative agreement to be made exceeds $50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 492 and is recommended under section 406(a)(3)(A)(ii) by the advisory council for the national research institute involved; and

(C) shall, subject to section 2353(d)(2), receive from the President and the Office of Management and Budget directly all funds appropriated by the Congress for obligation and expenditure by the Institute.

(3) Before an award is made by a national research institute or by a national center for a grant for a research program or project (commonly referred to as an "R-series grant"), other than an award constituting a noncompeting renewal of such grant, or a noncompeting administrative supplement to such grant, the director of such national research institute or national center—

(A) shall review and approve the award; and

(B) shall take into consideration—

(i) the mission of the national research institute or national center and the scientific priorities identified in the strategic plan under section 402(m); and

(ii) whether other agencies are funding programs or projects to accomplish the same goal.

(c) In carrying out subsection (b), each Director of a national research institute—

(1) shall coordinate, as appropriate, the activities of the institute with similar programs of other public and private entities;

(2) shall cooperate with the Directors of the other national research institutes in the development and support of multidisciplinary research and research that involves more than one institute;

(3) may, in consultation with the advisory council for the Institute and with the approval of the Director of NIH—

(A) establish technical and scientific peer review groups in addition to those appointed under section 402(b)(16); and

(B) appoint the members of peer review groups established under subparagraph (A); and

(4) may publish, or arrange for the publication of, information with respect to the purpose of the Institute without regard to section 501 of title 44, United States Code.

The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under paragraph (3).

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PEDIATRIC RESEARCH INITIATIVE

SEC. 409D. (a) ESTABLISHMENT.—The Secretary shall establish within the Office of the Director of NIH a Pediatric Research Initiative (referred to in this section as the "Initiative") to conduct and support research that is directly related to diseases, disorders, and other conditions in children. The Initiative shall be headed by the Director of NIH.

(b) PURPOSE.—The purpose of the Initiative is to provide funds to enable the Director of NIH—

(1) to increase support for pediatric biomedical research within the National Institutes of Health to realize the expanding opportunities for advancement in scientific investigations and care for children;

(2) to enhance collaborative efforts among the Institutes to conduct and support multidisciplinary research in the areas that the Director deems most promising; and

(3) in coordination with the Food and Drug Administration, to increase the development of adequate pediatric clinical trials and pediatric use information to promote the safer and more effective use of prescription drugs in the pediatric population.

(c) DUTIES.—In carrying out subsection (b), the Director of NIH shall—

(1) consult with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the other national research institutes, in considering their requests for new or expanded pediatric research efforts, and consult with the Administrator of the Health Resources and Services Administration and other advisors as the Director determines to be appropriate;

(2) have broad discretion in the allocation of any Initiative assistance among the Institutes, among types of grants, and between basic and clinical research so long as the assistance is directly related to the illnesses and conditions of children; and

(3) be responsible for the oversight of any newly appropriated Initiative funds and annually report to Congress and the public on the extent of the total funds obligated to conduct or support pediatric research across the National Institutes of Health, including the specific support and research awards allocated through the Initiative.

(d) NATIONAL PEDIATRIC RESEARCH NETWORK.—

(1) NETWORK.—In carrying out the Initiative, the Director of NIH, [in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and in collaboration with other appropriate national

research institutes and national centers that carry out activities involving pediatric research] *in collaboration with the national research institutes and national centers that carry out activities involving pediatric research*, [may] *shall* provide for the establishment of a National Pediatric Research Network in order to more effectively support pediatric research and optimize the use of Federal resources. Such National Pediatric Research Network [may be comprised of, as appropriate—]

[(A) the pediatric research consortia] *may be comprised of, as appropriate, the pediatric research consortia* receiving awards under paragraph (2)[; or].

[(B) other consortia, centers, or networks focused on pediatric research that are recognized by the Director of NIH and established pursuant to the authorities vested in the National Institutes of Health by other sections of this Act.]

(2) PEDIATRIC RESEARCH CONSORTIA.—

(A) IN GENERAL.—The Director of NIH [may] *shall* award funding, including through grants, contracts, or other mechanisms, to public or private nonprofit entities for providing support for pediatric research consortia, including with respect to—

(i) basic, clinical, behavioral, or translational research to meet unmet needs for pediatric research; and

(ii) training researchers in pediatric research techniques in order to address unmet pediatric research needs.

(B) RESEARCH.—The Director of NIH shall, as appropriate, ensure that—

(i) each consortium receiving an award under subparagraph (A) conducts or supports at least one category of research described in subparagraph (A)(i) and collectively such consortia conduct or support such categories of research; and

(ii) one or more such consortia provide training described in subparagraph (A)(ii).

(C) ORGANIZATION OF CONSORTIUM.—Each consortium receiving an award under subparagraph (A) shall—

(i) be formed from a collaboration of cooperating institutions;

(ii) be coordinated by a lead institution or institutions;

(iii) agree to disseminate scientific findings, including from clinical trials, rapidly and efficiently, as appropriate, to—

(I) other consortia;

(II) the National Institutes of Health;

(III) the Food and Drug Administration;

(IV) and other relevant agencies; and

(iv) meet such requirements as may be prescribed by the Director of NIH.

(D) SUPPLEMENT, NOT SUPPLANT.—Any support received by a consortium under subparagraph (A) shall be used to supplement, and not supplant, other public or private sup-

port for activities authorized to be supported under this paragraph.

(E) DURATION OF SUPPORT.—Support of a consortium under subparagraph (A) [may] *shall* be for a period of not to exceed 5 years. Such period may be extended at the discretion of the Director of NIH.

(3) COORDINATION OF CONSORTIA ACTIVITIES.—The Director of NIH shall, as appropriate—

(A) provide for the coordination of activities (including the exchange of information and regular communication) among the consortia established pursuant to paragraph (2); and

(B) require the periodic preparation and submission to the Director of reports on the activities of each such consortium.

(4) ASSISTANCE WITH REGISTRIES.—Each consortium receiving an award under paragraph (2)(A) may provide assistance, as appropriate, to the Centers for Disease Control and Prevention for activities related to patient registries and other surveillance systems upon request by the Director of the Centers for Disease Control and Prevention.

(e) RESEARCH ON PEDIATRIC RARE DISEASES OR CONDITIONS.—In making awards under subsection (d)(2) for pediatric research consortia, the Director of NIH shall ensure that an appropriate number of such awards are awarded to such consortia that agree to—

(1) consider pediatric rare diseases or conditions, or those related to birth defects; and

(2) conduct or coordinate one or more multisite clinical trials of therapies for, or approaches to, the prevention, diagnosis, or treatment of one or more pediatric rare diseases or conditions.

(f) TRANSFER OF FUNDS.—The Director of NIH may transfer amounts appropriated under this section to any of the Institutes for a fiscal year to carry out the purposes of the Initiative under this section.

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SEC. 409K. HIGH-RISK, HIGH-REWARD RESEARCH PROGRAM.

The director of each national research institute shall, as appropriate—

(1) establish programs to conduct or support research projects that pursue innovative approaches to major contemporary challenges in biomedical research that involve inherent high risk, but have the potential to lead to breakthroughs; and

(2) set aside a specific percentage of funding, to be determined by the Director of NIH for each national research institute, for such projects.

PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

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Subpart 20—National Institute on Minority Health and Health Disparities

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SEC. 464z–5. LOAN REPAYMENT PROGRAM FOR MINORITY HEALTH DISPARITIES RESEARCH.

(a) IN GENERAL.—The Director of the Institute shall establish a program of entering into contracts with qualified health professionals under which such health professionals agree to engage in minority health disparities research or other health disparities research in consideration of the Federal Government agreeing to repay, for each year of engaging in such research, not more than [$35,000] *$50,000* of the principal and interest of the educational loans of such health professionals. *Subsection (b) of section 487H shall apply with respect to the maximum amount specified in this subsection in the same manner as it applies to the maximum amount specified in subsection (a) of such section.*

(b) SERVICE PROVISIONS.—The provisions of sections 338B, 338C, and 338E shall, except as inconsistent with subsection (a), apply to the program established in such subsection to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III.

(c) REQUIREMENT REGARDING HEALTH DISPARITY POPULATIONS.—The Director of the Institute shall ensure that not fewer than 50 percent of the contracts entered into under subsection (a) are for appropriately qualified health professionals who are members of a health disparity population.

(d) PRIORITY.—With respect to minority health disparities research and other health disparities research under subsection (a), the Secretary shall ensure that priority is given to conducting projects of biomedical research.

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PART E—OTHER AGENCIES OF NIH

Subpart 1—National Center for Advancing Translational Sciences

SEC. 479. NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES.

(a) PURPOSE.—The purpose of the National Center for Advancing Translational Sciences (in this subpart referred to as the "Center") is to advance translational sciences, including by—

(1) coordinating and developing resources that leverage basic research in support of translational science; and

(2) developing partnerships and working cooperatively to foster synergy in ways that do not create duplication, redundancy, and competition with industry activities.

(b) CLINICAL TRIAL ACTIVITIES.—

(1) IN GENERAL.—The Center may develop and provide infrastructure and resources for all phases of clinical trials research. Except as provided in paragraph (2), the Center may support clinical trials only through the end of phase [IIA] *IIB*.

(2) EXCEPTION.—The Center may support clinical trial activities through the end of phase [IIB] *III* for a treatment for a rare disease or condition (as defined in section 526 of the Federal Food, Drug, and Cosmetic Act) so long as—

(A) the Center gives public notice for a period of at least 120 days of the Center's intention to support the clinical trial activities in phase [IIB] *III*;

(B) no public or private organization provides credible written intent to the Center that the organization has timely plans to further the clinical trial activities or conduct clinical trials of a similar nature beyond phase [IIA] *IIB*; and

(C) the Center ensures that support of the clinical trial activities in phase [IIB] *III* will not increase the Federal Government's liability beyond the award value of the Center's support.

(c) ANNUAL REPORT.—The Center shall publish an annual report that, with respect to all research supported by the Center, includes a complete list of—

(1) the molecules being studied;

(2) clinical trial activities being conducted;

(3) the methods and tools in development;

(4) ongoing partnerships, including—

(A) the rationale for each partnership;

(B) the status of each partnership;

(C) the funding provided by the Center to other entities pursuant to each partnership, and

(D) the activities which have been transferred to industry pursuant to each partnership; and

(5) known research activity of other entities that is or will expand upon research activity of the Center.

SEC. 480. CURES ACCELERATION NETWORK.

(a) DEFINITIONS.—In this section:

(1) BIOLOGICAL PRODUCT.—The term "biological product" has the meaning given such term in section 351 of the Public Health Service Act.

(2) DRUG; DEVICE.—The terms "drug" and "device" have the meanings given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act.

(3) HIGH NEED CURE.—The term "high need cure" means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, biological product (as that term is defined by section 262(i)), or device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act) that, in the determination of the Director of the Center—

(A) is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition; and

(B) for which the incentives of the commercial market are unlikely to result in its adequate or timely development.

(4) MEDICAL PRODUCT.—The term "medical product" means a drug, device, biological product, or product that is a combination of drugs, devices, and biological products.

(b) ESTABLISHMENT OF THE CURES ACCELERATION NETWORK.—Subject to [the appropriation of funds as described in subsection (g)] *the availability of funds as described in subsection (f)*, there is established within the Center a program to be known as the Cures Acceleration Network (referred to in this section as "CAN"), which shall—

(1) be under the direction of the Director of the Center, taking into account the recommendations of a CAN Review Board

(referred to in this section as the "Board"), described in subsection (d); and

(2) award grants and contracts to eligible entities, as described in subsection (e), to accelerate the development of high need cures, including through the development of medical products and behavioral therapies.

(c) FUNCTIONS.—The functions of the CAN are to—

(1) conduct and support revolutionary advances in basic research, translating scientific discoveries from bench to bedside;

(2) award grants and contracts to eligible entities to accelerate the development of high need cures;

(3) provide the resources necessary for government agencies, independent investigators, research organizations, biotechnology companies, academic research institutions, and other entities to develop high need cures;

(4) reduce the barriers between laboratory discoveries and clinical trials for new therapies; and

(5) facilitate review in the Food and Drug Administration for the high need cures funded by the CAN, through activities that may include—

(A) the facilitation of regular and ongoing communication with the Food and Drug Administration regarding the status of activities conducted under this section;

(B) ensuring that such activities are coordinated with the approval requirements of the Food and Drug Administration, with the goal of expediting the development and approval of countermeasures and products; and

(C) connecting interested persons with additional technical assistance made available under section 565 of the Federal Food, Drug, and Cosmetic Act.

(d) CAN BOARD.—

(1) ESTABLISHMENT.—There is established a Cures Acceleration Network Review Board (referred to in this section as the "Board"), which shall advise the Director of the Center on the conduct of the activities of the Cures Acceleration Network.

(2) MEMBERSHIP.—

(A) IN GENERAL.—

(i) APPOINTMENT.—The Board shall be comprised of 24 members who are appointed by the Secretary and who serve at the pleasure of the Secretary.

(ii) CHAIRPERSON AND VICE CHAIRPERSON.—The Secretary shall designate, from among the 24 members appointed under clause (i), one Chairperson of the Board (referred to in this section as the "Chairperson") and one Vice Chairperson.

(B) TERMS.—

(i) IN GENERAL.—Each member shall be appointed to serve a 4-year term, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed for the remainder of such term.

(ii) CONSECUTIVE APPOINTMENTS; MAXIMUM TERMS.—A member may be appointed to serve not more than

3 terms on the Board, and may not serve more than 2 such terms consecutively.

(C) QUALIFICATIONS.—

(i) IN GENERAL.—The Secretary shall appoint individuals to the Board based solely upon the individual's established record of distinguished service in one of the areas of expertise described in clause (ii). Each individual appointed to the Board shall be of distinguished achievement and have a broad range of disciplinary interests.

(ii) EXPERTISE.—The Secretary shall select individuals based upon the following requirements:

(I) For each of the fields of—

(aa) basic research;

(bb) medicine;

(cc) biopharmaceuticals;

(dd) discovery and delivery of medical products;

(ee) bioinformatics and gene therapy;

(ff) medical instrumentation; and

(gg) regulatory review and approval of medical products,

the Secretary shall select at least 1 individual who is eminent in such fields.

(II) At least 4 individuals shall be recognized leaders in professional venture capital or private equity organizations and have demonstrated experience in private equity investing.

(III) At least 8 individuals shall represent disease advocacy organizations.

(3) EX-OFFICIO MEMBERS.—

(A) APPOINTMENT.—In addition to the 24 Board members described in paragraph (2), the Secretary shall appoint as ex-officio members of the Board—

(i) a representative of the National Institutes of Health, recommended by the Secretary of the Department of Health and Human Services;

(ii) a representative of the Office of the Assistant Secretary of Defense for Health Affairs, recommended by the Secretary of Defense;

(iii) a representative of the Office of the Under Secretary for Health for the Veterans Health Administration, recommended by the Secretary of Veterans Affairs;

(iv) a representative of the National Science Foundation, recommended by the Chair of the National Science Board; and

(v) a representative of the Food and Drug Administration, recommended by the Commissioner of Food and Drugs.

(B) TERMS.—Each ex-officio member shall serve a 3-year term on the Board, except that the Chairperson may adjust the terms of the initial ex-officio members in order to provide for a staggered term of appointment for all such members.

(4) RESPONSIBILITIES OF THE BOARD AND THE DIRECTOR OF THE CENTER.—

(A) RESPONSIBILITIES OF THE BOARD.—

(i) IN GENERAL.—The Board shall advise, and provide recommendations to, the Director of the Center with respect to—

(I) policies, programs, and procedures for carrying out the duties of the Director of the Center under this section; and

(II) significant barriers to successful translation of basic science into clinical application (including issues under the purview of other agencies and departments).

(ii) REPORT.—In the case that the Board identifies a significant barrier, as described in clause (i)(II), the Board shall submit to the Secretary a report regarding such barrier.

(B) RESPONSIBILITIES OF THE DIRECTOR OF THE CENTER.—With respect to each recommendation provided by the Board under subparagraph (A)(i), the Director of the Center shall respond in writing to the Board, indicating whether such Director will implement such recommendation. In the case that the Director of the Center indicates a recommendation of the Board will not be implemented, such Director shall provide an explanation of the reasons for not implementing such recommendation.

(5) MEETINGS.—

(A) IN GENERAL.—The Board shall meet 4 times per calendar year, at the call of the Chairperson.

(B) QUORUM; REQUIREMENTS; LIMITATIONS.—

(i) QUORUM.—A quorum shall consist of a total of 13 members of the Board, excluding ex-officio members, with diverse representation as described in clause (iii).

(ii) CHAIRPERSON OR VICE CHAIRPERSON.—Each meeting of the Board shall be attended by either the Chairperson or the Vice Chairperson.

(iii) DIVERSE REPRESENTATION.—At each meeting of the Board, there shall be not less than one scientist, one representative of a disease advocacy organization, and one representative of a professional venture capital or private equity organization.

(6) COMPENSATION AND TRAVEL EXPENSES.—

(A) COMPENSATION.—Members shall receive compensation at a rate to be fixed by the Chairperson but not to exceed a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which the member is engaged in the performance of the duties of the Board. All members of the Board who are officers or employees of the United States shall serve without compensation in addition to that received for their services as officers or employees of the United States.

(B) TRAVEL EXPENSES.—Members of the Board shall be allowed travel expenses, including per diem in lieu of sub-

sistence, at rates authorized for persons employed intermittently by the Federal Government under section 5703(b) of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Board.

(e) GRANT PROGRAM.—

(1) SUPPORTING INNOVATION.—To carry out the purposes described in this section, the Director of the Center shall award contracts, grants, or cooperative agreements to the entities described in paragraph (2), to—

(A) promote innovation in technologies supporting the advanced research and development and production of high need cures, including through the development of medical products and behavioral therapies.

(B) accelerate the development of high need cures, including through the development of medical products, behavioral therapies, and biomarkers that demonstrate the safety or effectiveness of medical products; or

(C) help the award recipient establish protocols that comply with Food and Drug Administration standards and otherwise permit the recipient to meet regulatory requirements at all stages of development, manufacturing, review, approval, and safety surveillance of a medical product.

(2) ELIGIBLE ENTITIES.—To receive assistance under paragraph (1), an entity shall—

(A) be a public or private entity, which may include a private or public research institution, an institution of higher education, a medical center, a biotechnology company, a pharmaceutical company, a disease advocacy organization, a patient advocacy organization, or an academic research institution;

(B) submit an application containing—

(i) a detailed description of the project for which the entity seeks such grant or contract;

(ii) a timetable for such project;

(iii) an assurance that the entity will submit—

(I) interim reports describing the entity's—

(aa) progress in carrying out the project; and

(bb) compliance with all provisions of this section and conditions of receipt of such grant or contract; and

(II) a final report at the conclusion of the grant period, describing the outcomes of the project; and

(iv) a description of the protocols the entity will follow to comply with Food and Drug Administration standards and regulatory requirements at all stages of development, manufacturing, review, approval, and safety surveillance of a medical product; and

(C) provide such additional information as the Director of the Center may require.

(3) AWARDS.—

(A) THE CURES ACCELERATION PARTNERSHIP AWARDS.—

(i) INITIAL AWARD AMOUNT.—Each award under this subparagraph shall be not more than $15,000,000 per

project for the first fiscal year for which the project is funded, which shall be payable in one payment.

(ii) FUNDING IN SUBSEQUENT FISCAL YEARS.—An eligible entity receiving an award under clause (i) may apply for additional funding for such project by submitting to the Director of the Center the information required under subparagraphs (B) and (C) of paragraph (2). The Director may fund a project of such eligible entity in an amount not to exceed $15,000,000 for a fiscal year subsequent to the initial award under clause (i).

(iii) MATCHING FUNDS.—As a condition for receiving an award under this subsection, an eligible entity shall contribute to the project non-Federal funds in the amount of $1 for every $3 awarded under clauses (i) and (ii), except that the Director of the Center may waive or modify such matching requirement in any case where the Director determines that the goals and objectives of this section cannot adequately be carried out unless such requirement is waived.

(B) THE CURES ACCELERATION GRANT AWARDS.—

(i) INITIAL AWARD AMOUNT.—Each award under this subparagraph shall be not more than $15,000,000 per project for the first fiscal year for which the project is funded, which shall be payable in one payment.

(ii) FUNDING IN SUBSEQUENT FISCAL YEARS.—An eligible entity receiving an award under clause (i) may apply for additional funding for such project by submitting to the Board the information required under subparagraphs (B) and (C) of paragraph (2). The Director of the Center may fund a project of such eligible entity in an amount not to exceed $15,000,000 for a fiscal year subsequent to the initial award under clause (i).

[(C) THE CURES ACCELERATION FLEXIBLE RESEARCH AWARDS.—If the Director of the Center determines that the goals and objectives of this section cannot adequately be carried out through a contract, grant, or cooperative agreement, the Director of the Center shall have flexible research authority to use other transactions to fund projects in accordance with the terms and conditions of this section. Awards made under such flexible research authority for a fiscal year shall not exceed 20 percent of the total funds appropriated under subsection (g)(1) for such fiscal year.]

(C) OTHER TRANSACTIONS AUTHORITY.—The Director of the Center shall have other transactions authority in entering into transactions to fund projects in accordance with the terms and conditions of this section.

(4) SUSPENSION OF AWARDS FOR DEFAULTS, NONCOMPLIANCE WITH PROVISIONS AND PLANS, AND DIVERSION OF FUNDS; REPAYMENT OF FUNDS.—The Director of the Center may suspend the award to any entity upon noncompliance by such entity with provisions and plans under this section or diversion of funds.

(5) AUDITS.—The Director of the Center may enter into agreements with other entities to conduct periodic audits of the projects funded by grants or contracts awarded under this subsection.

(6) CLOSEOUT PROCEDURES.—At the end of a grant or contract period, a recipient shall follow the closeout procedures under section 74.71 of title 45, Code of Federal Regulations (or any successor regulation).

(7) REVIEW.—A determination by the Director of the Center as to whether a drug, device, or biological product is a high need cure (for purposes of subsection (a)(3)) shall not be subject to judicial review.

[(f) COMPETITIVE BASIS OF AWARDS.—Any grant, cooperative agreement, or contract awarded under this section shall be awarded on a competitive basis.**]**

[(g)**]** *(f)* AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For purposes of carrying out this section, there are authorized to be appropriated $500,000,000 for fiscal year 2010, and such sums as may be necessary for subsequent fiscal years. Funds appropriated under this section shall be available until expended.

(2) LIMITATION ON USE OF FUNDS OTHERWISE APPROPRIATED.—No funds appropriated under this Act, other than funds appropriated under paragraph (1), may be allocated to the Cures Acceleration Network.

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PART G—AWARDS AND TRAINING

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LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

SEC. 487A. (a) IN GENERAL.—The Secretary shall carry out a program of entering into agreements with appropriately qualified health professionals under which such health professionals agree to conduct, as employees of the National Institutes of Health, research with respect to acquired immune deficiency syndrome in consideration of the Federal Government agreeing to repay, for each year of such service, not more than **[**$35,000**]** *$50,000* of the principal and interest of the educational loans of such health professionals. *Subsection (b) of section 487H shall apply with respect to the maximum amount specified in this subsection in the same manner as it applies to the maximum amount specified in subsection (a) of such section.*

(b) APPLICABILITY OF CERTAIN PROVISIONS.—With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III, the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in such subsection (a) in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program established in such subpart.

LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO CONTRACEPTION AND INFERTILITY

SEC. 487B. (a) The Secretary, in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, shall establish a program of entering into contracts with qualified health professionals (including graduate students) under which such health professionals agree to conduct research with respect to contraception, or with respect to infertility, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than **[**$35,000**]** *$50,000* of the principal and interest of the educational loans of such health professionals. *Subsection (b) of section 487H shall apply with respect to the maximum amount specified in this subsection in the same manner as it applies to the maximum amount specified in such subsection (a) of such section.*

(b) The provisions of sections 338B, 338C, and 338E shall, except as inconsistent with subsection (a) of this section, apply to the program established in subsection (a) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III.

(c) Amounts available for carrying out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were made available.

LOAN REPAYMENT PROGRAM FOR RESEARCH GENERALLY

SEC. 487C. (a) IN GENERAL.—

(1) AUTHORITY FOR PROGRAM.—Subject to paragraph (2), the Secretary shall carry out a program of entering into contracts with appropriately qualified health professionals under which such health professionals agree to conduct research, as employees of the National Institutes of Health, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than **[**$35,000**]** *$50,000* of the principal and interest of the educational loans of such health professionals. *Subsection (b) of section 487H shall apply with respect to the maximum amount specified in this paragraph in the same manner as it applies to the maximum amount specified in such subsection (a) of such section.*

(2) LIMITATION.—The Secretary may not enter into an agreement with a health professional pursuant to paragraph (1) unless such professional—

(A) has a substantial amount of educational loans relative to income; and

(B) agrees to serve as an employee of the National Institutes of Health for purposes of paragraph (1) for a period of not less than 3 years.

(b) APPLICABILITY OF CERTAIN PROVISIONS.—With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III, the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in such subsection (a) in the same manner and to the same extent as such provisions apply to

the National Health Service Corps Loan Repayment Program established in such subpart.

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LOAN REPAYMENT PROGRAM REGARDING CLINICAL RESEARCHERS FROM DISADVANTAGED BACKGROUNDS

SEC. 487E. (a) IMPLEMENTATION OF PROGRAM.—

(1) IN GENERAL.—Subject to section 487(a)(1)(C), the Secretary, acting through the Director of NIH may, subject to paragraph (2), carry out a program of entering into contracts with appropriately qualified health professionals who are from disadvantaged backgrounds under which such health professionals agree to conduct clinical research in consideration of the Federal Government agreeing to pay, for each year of such service, not more than [$35,000] *$50,000* of the principal and interest of the educational loans of the health professionals. *Subsection (b) of section 487H shall apply with respect to the maximum amount specified in this paragraph in the same manner as it applies to the maximum amount specified in such subsection (a) of such section.*

(2) LIMITATION.—The Director of NIH may not enter into a contract with a health professional pursuant to paragraph (1) unless such professional has a substantial amount of education loans relative to income.

(3) APPLICABILITY OF CERTAIN PROVISIONS REGARDING OBLIGATED SERVICE.—Except to the extent inconsistent with this section, the provisions of sections 338B, 338C and 338E shall apply to the program established in paragraph (1) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in section 338B.

(b) AVAILABILITY OF AUTHORIZATION OF APPROPRIATIONS.—Amounts appropriated for a fiscal year for contracts under subsection (a) shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.

SEC. 487F. LOAN REPAYMENT PROGRAM REGARDING CLINICAL RESEARCHERS.

(a) IN GENERAL.—The Secretary, acting through the Director of the National Institutes of Health, shall establish a program to enter into contracts with qualified health professionals under which such health professionals agree to conduct clinical research, in consideration of the Federal Government agreeing to repay, for each year of service conducting such research, not more than [$35,000] *$50,000* of the principal and interest of the educational loans of such health professionals. *Subsection (b) of section 487H shall apply with respect to the maximum amount specified in this subsection in the same manner as it applies to the maximum amount specified in such subsection (a) of such section.*

(b) APPLICATION OF PROVISIONS.—The provisions of sections 338B, 338C, and 338E shall, except as inconsistent with subsection (a) of this section, apply to the program established under subsection (a) to the same extent and in the same manner as such pro-

visions apply to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III.

PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM

SEC. [487F] *487G*. (a) IN GENERAL.—The Secretary, in consultation with the Director of NIH, may establish a pediatric research loan repayment program. Through such program—

(1) the Secretary shall enter into contracts with qualified health professionals under which such professionals will agree to conduct pediatric research, including pediatric pharmacological research, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than [$35,000] *$50,000* of the principal and interest of the educational loans of such professionals; and

(2) the Secretary shall, for the purpose of providing reimbursements for tax liability resulting from payments made under paragraph (1) on behalf of an individual, make payments, in addition to payments under such paragraph, to the individual in an amount equal to 39 percent of the total amount of loan repayments made for the taxable year involved.

(b) APPLICATION OF OTHER PROVISIONS.—The provisions of sections 338B, 338C, and 338E shall, except as inconsistent with paragraph (1), apply to the program established under such paragraph to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established under subpart III of part D of title III. *Subsection (b) of section 487H shall apply with respect to the maximum amount specified in this subsection in the same manner as it applies to the maximum amount specified in such subsection (a) of such section.*

(c) FUNDING.—

(1) IN GENERAL.—For the purpose of carrying out this section with respect to a national research institute the Secretary may reserve, from amounts appropriated for such institute for the fiscal year involved, such amounts as the Secretary determines to be appropriate.

(2) AVAILABILITY OF FUNDS.—Amounts made available to carry out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which such amounts were made available.

SEC. 487H. LOAN REPAYMENT PROGRAM.

(a) IN GENERAL.—The Secretary shall establish a program, based on workforce and scientific needs, of entering into contracts with qualified health professionals under which such health professionals agree to engage in research in consideration of the Federal Government agreeing to pay, for each year of engaging in such research, not more than $50,000 of the principal and interest of the educational loans of such health professionals.

(b) ADJUSTMENT FOR INFLATION.—Beginning with respect to fiscal year 2017, the Secretary may increase the maximum amount specified in subsection (a) by an amount that is determined by the Secretary, on an annual basis, to reflect inflation.

(c) LIMITATION.—The Secretary may not enter into a contract with a health professional pursuant to subsection (a) unless such profes-

sional has a substantial amount of educational loans relative to income.

(d) APPLICABILITY OF CERTAIN PROVISIONS REGARDING OBLIGATED SERVICE.—Except to the extent inconsistent with this section, the provisions of sections 338B, 338C, and 338E shall apply to the program established under this section to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established under section 338B.

(e) AVAILABILITY OF APPROPRIATIONS.—Amounts appropriated for a fiscal year for contracts under subsection (a) are authorized to remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.

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SEC. 490. CAPSTONE AWARD.

(a) IN GENERAL.—The Secretary may make awards (each of which, hereafter in this section, referred to as a "Capstone Award") to support outstanding scientists who have been funded by the National Institutes of Health.

(b) PURPOSE.—Capstone Awards shall be made to facilitate the successful transition or conclusion of research programs, or for other purposes, as determined by the Director of NIH, in consultation with the directors of the national research institutes and national centers.

(c) DURATION AND AMOUNT.—The duration and amount of each Capstone Award shall be determined by the Director of NIH in consultation with the directors of the national research institutes and national centers.

(d) LIMITATION.—Individuals who have received a Capstone Award shall not be eligible to have principle investigator status on subsequent awards from the National Institutes of Health.

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TITLE XXI—VACCINES

Subtitle 1—National Vaccine Program

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PROGRAM RESPONSIBILITIES

SEC. 2102. (a) The Director of the Program shall have the following responsibilities:

(1) VACCINE RESEARCH.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for research carried out in or through the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development on means to induce human immunity against naturally occurring infectious diseases and to prevent adverse reactions to vaccines.

(2) VACCINE DEVELOPMENT.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for activities carried out in or through the National Institutes of Health, the Office of Biologics Re-

search and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development to develop the techniques needed to produce safe and effective vaccines.

(3) SAFETY AND EFFICACY TESTING OF VACCINES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for safety and efficacy testing of vaccines carried out in or through the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development.

(4) LICENSING OF VACCINE MANUFACTURERS AND VACCINES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for the allocation of resources in the implementation of the licensing program under section 353.

(5) PRODUCTION AND PROCUREMENT OF VACCINES.—The Director of the Program shall, through the plan issued under section 2103, ensure that the governmental and non-governmental production and procurement of safe and effective vaccines by the Public Health Service, the Department of Defense, and the Agency for International Development meet the needs of the United States population and fulfill commitments of the United States to prevent human infectious diseases in other countries.

(6) DISTRIBUTION AND USE OF VACCINES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction to the Centers for Disease Control and Prevention and assistance to States, localities, and health practitioners in the distribution and use of vaccines, including efforts to encourage public acceptance of immunizations and to make health practitioners and the public aware of potential adverse reactions and contraindications to vaccines.

(7) EVALUATING THE NEED FOR AND THE EFFECTIVENESS AND ADVERSE EFFECTS OF VACCINES AND IMMUNIZATION ACTIVITIES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction to the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the National Center for Health Statistics, the National Center for Health Services Research and Health Care Technology Assessment, and the Centers for Medicare & Medicaid Services in monitoring the need for and the effectiveness and adverse effects of vaccines and immunization activities.

(8) COORDINATING GOVERNMENTAL AND NON-GOVERNMENTAL ACTIVITIES.—The Director of the Program shall, through the plan issued under section 2103, provide for the exchange of information between Federal agencies involved in the implementation of the Program and non-governmental entities engaged in the development and production of vaccines and in vaccine research and encourage the investment of non-governmental resources complementary to the governmental activities under the Program.

(9) FUNDING OF FEDERAL AGENCIES.—The Director of the Program shall make available to Federal agencies involved in the implementation of the plan issued under section 2103 funds appropriated under section 2106 to supplement the funds otherwise available to such agencies for activities under the plan.

(10) ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.—

(A) STANDARD PERIODS OF TIME FOR MAKING RECOMMENDATIONS.—Upon the licensure of any vaccine or any new indication for a vaccine, the Director of the Program shall direct the Advisory Committee on Immunization Practices, at its next regularly scheduled meeting, to consider the use of the vaccine.

(B) EXPEDITED REVIEW PURSUANT TO REQUEST BY SPONSOR OR MANUFACTURER.—If the Advisory Committee does not make recommendations with respect to the use of a vaccine at the Advisory Committee's first regularly scheduled meeting after the licensure of the vaccine or any new indication for the vaccine, the Advisory Committee, at the request of the sponsor of the vaccine, shall make such recommendations on an expedited basis.

(C) EXPEDITED REVIEW FOR BREAKTHROUGH THERAPIES AND FOR USE DURING PUBLIC HEALTH EMERGENCIES.—If a vaccine is designated as a breakthrough therapy under section 506 of the Federal Food, Drug, and Cosmetic Act and is licensed under section 351 of this Act, the Advisory Committee shall make recommendations with respect to the use of the vaccine on an expedited basis.

(D) DEFINITION.—In this paragraph, the terms "Advisory Committee on Immunization Practices" and "Advisory Committee" mean the advisory committee on immunization practices established by the Secretary pursuant to section 222, acting through the Director of the Centers for Disease Control and Prevention.

(b) In carrying out subsection (a) and in preparing the plan under section 2103, the Director shall consult with all Federal agencies involved in research on and development, testing, licensing, production, procurement, distribution, and use of vaccines.

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TITLE XXX—HEALTH INFORMATION TECHNOLOGY AND QUALITY

SEC. 3000. DEFINITIONS.

In this title:

[(1) CERTIFIED EHR TECHNOLOGY.—The term "certified EHR technology" means a qualified electronic health record that is certified pursuant to section 3001(c)(5) as meeting standards adopted under section 3004 that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).]

(1) CERTIFIED EHR TECHNOLOGY.—The term "certified EHR technology" means a qualified electronic health record that is

certified pursuant to section 3001(c)(5) as meeting the certification criteria defined in subparagraph (B) of such section that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals) including, beginning January 1, 2018, with respect to which the vendor or other entity offering such technology is in compliance with the requirements under section 3001(c)(5)(C)(i).

(2) ENTERPRISE INTEGRATION.—The term "enterprise integration" means the electronic linkage of health care providers, health plans, the government, and other interested parties, to enable the electronic exchange and use of health information among all the components in the health care infrastructure in accordance with applicable law, and such term includes related application protocols and other related standards.

(3) HEALTH CARE PROVIDER.—The term "health care provider" includes a hospital, skilled nursing facility, nursing facility, home health entity or other long term care facility, health care clinic, community mental health center (as defined in section 1913(b)(1)), renal dialysis facility, blood center, ambulatory surgical center described in section 1833(i) of the Social Security Act, emergency medical services provider, Federally qualified health center, group practice, a pharmacist, a pharmacy, a laboratory, a physician (as defined in section 1861(r) of the Social Security Act), a practitioner (as described in section 1842(b)(18)(C) of the Social Security Act), a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act), tribal organization, or urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act), a rural health clinic, a covered entity under section 340B, an ambulatory surgical center described in section 1833(i) of the Social Security Act, a therapist (as defined in section 1848(k)(3)(B)(iii) of the Social Security Act), and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.

(4) HEALTH INFORMATION.—The term "health information" has the meaning given such term in section 1171(4) of the Social Security Act.

(5) HEALTH INFORMATION TECHNOLOGY.—The term "health information technology" means hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information

(6) HEALTH PLAN.—The term "health plan" has the meaning given such term in section 1171(5) of the Social Security Act.

(7) HIT POLICY COMMITTEE.—The term "HIT Policy Committee" means such Committee established under section 3002(a).

(8) HIT STANDARDS COMMITTEE.—The term "HIT Standards Committee" means such Committee established under section 3003(a).

(9) INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION.—The term "individually identifiable health information" has the meaning given such term in section 1171(6) of the Social Security Act.

(10) LABORATORY.—The term "laboratory" has the meaning given such term in section 353(a).

(11) NATIONAL COORDINATOR.—The term "National Coordinator" means the head of the Office of the National Coordinator for Health Information Technology established under section 3001(a).

(12) PHARMACIST.—The term "pharmacist" has the meaning given such term in section 804(2) of the Federal Food, Drug, and Cosmetic Act.

(13) QUALIFIED ELECTRONIC HEALTH RECORD.—The term "qualified electronic health record" means an electronic record of health-related information on an individual that—

(A) includes patient demographic and clinical health information, such as medical history and problem lists; and

(B) has the capacity—

(i) to provide clinical decision support;

(ii) to support physician order entry;

(iii) to capture and query information relevant to health care quality; and

(iv) to exchange electronic health information with, and integrate such information from other sources.

(14) STATE.—The term "State" means each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

(15) WIDESPREAD INTEROPERABILITY.—The term "widespread interoperability" means that, on a nationwide basis—

(A) health information technology is interoperable, in accordance with section 3010; and

(B) such technology is employed by meaningful EHR users under the specified meaningful use incentive programs (as defined in section 3010A(e)) and by other clinicians and health care providers.

Subtitle A—Promotion of Health Information Technology

SEC. 3001. OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY.

(a) ESTABLISHMENT.—There is established within the Department of Health and Human Services an Office of the National Coordinator for Health Information Technology (referred to in this section as the "Office"). The Office shall be headed by a National Coordinator who shall be appointed by the Secretary and shall report directly to the Secretary.

(b) PURPOSE.—The National Coordinator shall perform the duties under subsection (c) in a manner consistent with the development

of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information and that—

(1) ensures that each patient's health information is secure and protected, in accordance with applicable law;

(2) improves health care quality, reduces medical errors, reduces health disparities, and advances the delivery of patient-centered medical care;

(3) reduces health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information;

(4) provides appropriate information to help guide medical decisions at the time and place of care;

(5) ensures the inclusion of meaningful public input in such development of such infrastructure;

(6) improves the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information;

(7) improves public health activities and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks;

(8) facilitates health and clinical research and health care quality;

(9) promotes early detection, prevention, and management of chronic diseases;

(10) promotes a more effective marketplace, greater competition, greater systems analysis, increased consumer choice, and improved outcomes in health care services; and

(11) improves efforts to reduce health disparities.

(c) DUTIES OF THE NATIONAL COORDINATOR.—

(1) STANDARDS.—The National Coordinator shall—

(A) *for recommendations made before the date of the enactment of the 21st Century Cures Act,* review and determine whether to endorse each standard, implementation specification, and certification criterion for the electronic exchange and use of health information that is recommended by the HIT Standards Committee under section 3003 for purposes of adoption under section 3004;

(B) make such determinations under subparagraph (A), and report to the Secretary such determinations, not later than 45 days after the date the recommendation is received by the Coordinator; and

(C) review Federal health information technology investments to ensure that Federal health information technology programs are meeting the objectives of the strategic plan published under paragraph (3).

(2) HIT POLICY COORDINATION.—

(A) IN GENERAL.—The National Coordinator shall coordinate health information technology policy and programs of the Department with those of other relevant executive branch agencies with a goal of avoiding duplication of efforts and of helping to ensure that each agency undertakes health information technology activities primarily within

the areas of its greatest expertise and technical capability and in a manner towards a coordinated national goal.

(B) HIT POLICY AND STANDARDS COMMITTEES.—The National Coordinator shall be a leading member in the establishment and operations of the HIT Policy Committee and the HIT Standards Committee and shall serve as a liaison among those two Committees and the Federal Government.

(3) STRATEGIC PLAN.—

(A) IN GENERAL.—The National Coordinator shall, in consultation with other appropriate Federal agencies (including the National Institute of Standards and Technology), update the Federal Health IT Strategic Plan (developed as of June 3, 2008) to include specific objectives, milestones, and metrics with respect to the following:

(i) The electronic exchange and use of health information and the enterprise integration of such information.

(ii) The utilization of an electronic health record for each person in the United States by 2014.

(iii) The incorporation of privacy and security protections for the electronic exchange of an individual's individually identifiable health information.

(iv) Ensuring security methods to ensure appropriate authorization and electronic authentication of health information and specifying technologies or methodologies for rendering health information unusable, unreadable, or indecipherable.

(v) Specifying a framework for coordination and flow of recommendations and policies under this subtitle among the Secretary, the National Coordinator, the HIT Policy Committee, the HIT Standards Committee, and other health information exchanges and other relevant entities.

(vi) Methods to foster the public understanding of health information technology.

(vii) Strategies to enhance the use of health information technology in improving the quality of health care, reducing medical errors, reducing health disparities, improving public health, increasing prevention and coordination with community resources, and improving the continuity of care among health care settings.

(viii) Specific plans for ensuring that populations with unique needs, such as children, are appropriately addressed in the technology design, as appropriate, which may include technology that automates enrollment and retention for eligible individuals.

(B) COLLABORATION.—The strategic plan shall be updated through collaboration of public and private entities.

(C) MEASURABLE OUTCOME GOALS.—The strategic plan update shall include measurable outcome goals.

(D) PUBLICATION.—The National Coordinator shall republish the strategic plan, including all updates.

(4) WEBSITE.—The National Coordinator shall maintain and frequently update an Internet website on which there is posted information on the work, schedules, reports, recommendations, and other information to ensure transparency in promotion of a nationwide health information technology infrastructure.

(5) CERTIFICATION.—

(A) IN GENERAL.—The National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle. Such program shall include, as appropriate, testing of the technology in accordance with section 13201(b) of the Health Information Technology for Economic and Clinical Health Act.

[(B) CERTIFICATION CRITERIA DESCRIBED.—In this title, the term "certification criteria" means, with respect to standards and implementation specifications for health information technology, criteria to establish that the technology meets such standards and implementation specifications.]

(B) CERTIFICATION CRITERIA DESCRIBED.—In this title, the term "certification criteria" means, with respect to qualified electronic health records—

(i) for certifications made before January 1, 2018, criteria to establish that the records meet standards and implementation specifications adopted under subsections (a) and (b) of section 3004 for qualified electronic health records; and

(ii) for certifications made on or after January 1, 2018, criteria described in clause (i) and criteria to establish that the records are interoperable, in accordance with section 3010, including by being in compliance with interoperability standards adopted under section 3004.

(C) ENFORCEMENT; DECERTIFICATIONS.—

(i) REQUIREMENTS.—Under any program kept or recognized under subparagraph (A), the Secretary shall ensure that any vendor of or other entity offering qualified electronic health records seeking a certification of such records under such program on or after January 1, 2018, shall, as a condition of certification (and maintenance of certification) of such a record under such program—

(I) provide to the Secretary an attestation—

(aa) that the entity, unless for a legitimate purpose specified by the Secretary, has not taken any action, including through any financial, administrative, or technological barrier, which the entity knows or should know (as defined in section 1128A(i)(7) of the Social Security Act), is to limit or restrict the exchange of information or to prevent or disincentivize widespread interoperability be-

tween any providers using such records or other health information technology in connection with such record;

(bb) on the pricing information described in clause (v) for purposes of the portal created under paragraph (9); that such information will be available on a public Web site of such entity and in marketing materials, communications statements, and other assertions of such entity related to such record; and that the entity will voluntarily provide such information to customers prior to providing any qualified electronic health records or related product or service (including subsequent updates, add-ons, or additional products or services to be provided during the course of an on-going contract), prospective customers (such as persons who request or receive a quotation, estimate, or other similar marketing or promotional material), and other persons who request such information;

(cc) that the software with respect to such records have published application programming interfaces for medical records data, search and indexing, semantic harmonization and vocabulary translation, and user interface applications;

(dd) that the entity has successfully tested the use of the record in the type of setting in which it would be marketed;

(ee) the entity has in place implementation guidelines for such record that support interoperability, consistent with section 3010; and

(ff) that the entity has in place data sharing programs or capabilities based on common data elements through application programming interfaces without the requirement for vendor-specific interfaces;

(II) publish application programming interfaces and associated documentation, with respect to such records, for medical records data, search and indexing, semantic harmonization and vocabulary translation, and user interface applications; and

(III) demonstrate to the satisfaction of the Secretary that data from such records are able to be exchanged through the use of application programming interfaces and used in a manner that allows for exchange and everyday use, as authorized under applicable law, of such records.

(ii) DECERTIFICATION.—Under any program kept or recognized under subparagraph (A), the Secretary shall ensure that beginning January 1, 2019, any qualified electronic health records that do not satisfy the certification criteria described in section 3001(c)(5)(B)(ii) or with respect to which the vendor or other entity de-

scribed in clause (i) does not satisfy the requirements under such clause (or is determined to be in violation of the terms of the attestation or other requirements under such clause) shall no longer be considered as certified under such program.

(iii) ANNUAL PUBLICATION.—For 2019 and each subsequent year, the Secretary shall post on the public Internet website of the Department of Health and Human Services a list of any vendors of or other entities offering qualified electronic health records with respect to which certification has been withdrawn under clause (ii) during such year.

(iv) PERIODIC REVIEW.—The Secretary shall periodically review and confirm that vendors of and other entities offering qualified electronic health records have publicly published application programming interfaces and associated documentation as required by clause (i)(II) for purposes of certification and maintaining certification under any program kept or recognized under subparagraph (A).

(v) PRICING INFORMATION.—For purposes of clause (i)(I)(bb), the pricing information described in this clause, with respect to a vendor of or other entity offering a qualified electronic health record, is the following:

(I) Additional types of costs or fees (whether fixed, recurring, transaction based, or otherwise) imposed by the entity (or any third-party from whom the entity purchases, licenses, or obtains any technology, products, or services in connection with the qualified electronic health record) to purchase, license, implement, maintain, upgrade, use, or otherwise enable and support the use of capabilities to which such record is to be certified under this section; or in connection with any data generated in the course of using any capability to which the record is to be so certified.

(II) Limitations, whether by contract or otherwise, on the use of any capability to which the record is to be certified under this section for any purpose within the scope of the record's certification; or in connection with any data generated in the course of using any capability to which the record is to be certified under this section.

(III) Limitations, including technical or practical limitations of technology or its capabilities, that could prevent or impair the successful implementation, configuration, customization, maintenance, support, or use of any capabilities to which the record is to be certified under this section; or that could prevent or limit the use, exchange, or portability of any data generated in the course of using any capability to which the record is to be so certified.

(6) REPORTS AND PUBLICATIONS.—

(A) REPORT ON ADDITIONAL FUNDING OR AUTHORITY NEEDED.—Not later than 12 months after the date of the enactment of this title, the National Coordinator shall submit to the appropriate committees of jurisdiction of the House of Representatives and the Senate a report on any additional funding or authority the Coordinator or the HIT Policy Committee or HIT Standards Committee requires to evaluate and develop standards, implementation specifications, and certification criteria, or to achieve full participation of stakeholders in the adoption of a nationwide health information technology infrastructure that allows for the electronic use and exchange of health information.

(B) IMPLEMENTATION REPORT.—The National Coordinator shall prepare a report that identifies lessons learned from major public and private health care systems in their implementation of health information technology, including information on whether the technologies and practices developed by such systems may be applicable to and usable in whole or in part by other health care providers.

(C) ASSESSMENT OF IMPACT OF HIT ON COMMUNITIES WITH HEALTH DISPARITIES AND UNINSURED, UNDERINSURED, AND MEDICALLY UNDERSERVED AREAS.—The National Coordinator shall assess and publish the impact of health information technology in communities with health disparities and in areas with a high proportion of individuals who are uninsured, underinsured, and medically underserved individuals (including urban and rural areas) and identify practices to increase the adoption of such technology by health care providers in such communities, and the use of health information technology to reduce and better manage chronic diseases.

(D) EVALUATION OF BENEFITS AND COSTS OF THE ELECTRONIC USE AND EXCHANGE OF HEALTH INFORMATION.—The National Coordinator shall evaluate and publish evidence on the benefits and costs of the electronic use and exchange of health information and assess to whom these benefits and costs accrue.

(E) RESOURCE REQUIREMENTS.—The National Coordinator shall estimate and publish resources required annually to reach the goal of utilization of an electronic health record for each person in the United States by 2014, including—

(i) the required level of Federal funding;

(ii) expectations for regional, State, and private investment;

(iii) the expected contributions by volunteers to activities for the utilization of such records; and

(iv) the resources needed to establish a health information technology workforce sufficient to support this effort (including education programs in medical informatics and health information management).

(7) ASSISTANCE.—The National Coordinator may provide financial assistance to consumer advocacy groups and not-for-profit entities that work in the public interest for purposes of defraying the cost to such groups and entities to participate

under, whether in whole or in part, the National Technology Transfer Act of 1995 (15 U.S.C. 272 note).

(8) GOVERNANCE FOR NATIONWIDE HEALTH INFORMATION NETWORK.—The National Coordinator shall establish a governance mechanism for the nationwide health information network.

(9) PORTAL.—Not later than January 1, 2019, the National Coordinator shall create a portal to make the information described in paragraph (5)(C)(I)(i)(bb) available to the public in a manner that allows for comparison of price information among health information technology products and that aids in making informed decisions for purchasing such a product.

(d) DETAIL OF FEDERAL EMPLOYEES.—

(1) IN GENERAL.—Upon the request of the National Coordinator, the head of any Federal agency is authorized to detail, with or without reimbursement from the Office, any of the personnel of such agency to the Office to assist it in carrying out its duties under this section.

(2) EFFECT OF DETAIL.—Any detail of personnel under paragraph (1) shall—

(A) not interrupt or otherwise affect the civil service status or privileges of the Federal employee; and

(B) be in addition to any other staff of the Department employed by the National Coordinator.

(3) ACCEPTANCE OF DETAILEES.—Notwithstanding any other provision of law, the Office may accept detailed personnel from other Federal agencies without regard to whether the agency described under paragraph (1) is reimbursed.

(e) CHIEF PRIVACY OFFICER OF THE OFFICE OF THE NATIONAL COORDINATOR.—Not later than 12 months after the date of the enactment of this title, the Secretary shall appoint a Chief Privacy Officer of the Office of the National Coordinator, whose duty it shall be to advise the National Coordinator on privacy, security, and data stewardship of electronic health information and to coordinate with other Federal agencies (and similar privacy officers in such agencies), with State and regional efforts, and with foreign countries with regard to the privacy, security, and data stewardship of electronic individually identifiable health information.

SEC. 3002. HIT POLICY COMMITTEE.

(a) ESTABLISHMENT.—There is established a HIT Policy Committee to make policy recommendations to the [National Coordinator] *Secretary, in consultation with the National Coordinator,* relating to the implementation of a nationwide health information technology infrastructure, including implementation of the strategic plan described in section 3001(c)(3). *The HIT Policy Committee is authorized only to provide policy and priority recommendations to the Secretary and not authorized to otherwise affect the development or modification of any standard, implementation specification, or certification criterion under this title.*

(b) DUTIES.—

(1) RECOMMENDATIONS ON HEALTH INFORMATION TECHNOLOGY INFRASTRUCTURE.—The HIT Policy Committee shall recommend a policy framework for the development and adoption of a nationwide health information technology infrastructure that permits the electronic exchange and use of health information as is consistent with the strategic plan under section

3001(c)(3) and that includes the recommendations under paragraph (2). The Committee shall update such recommendations and make new recommendations as appropriate.

(2) SPECIFIC AREAS OF STANDARD DEVELOPMENT.—

(A) IN GENERAL.—[The HIT Policy Committee] *Subject to subparagraph (D), the HIT Policy Committee* shall recommend the areas in which standards, implementation specifications, and certification criteria are needed for the electronic exchange and use of health information for purposes of adoption under section 3004 *(including the areas in which modifications and additions to interoperability standards under section 3010 are needed for the electronic exchange and use of health information for purposes of adoption of such modifications and additions under section 3004)* and shall recommend an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria among the areas so recommended. Such standards and implementation specifications shall include named standards, architectures, and software schemes for the authentication and security of individually identifiable health information and other information as needed to ensure the reproducible development of common solutions across disparate entities.

(B) AREAS REQUIRED FOR CONSIDERATION.—For purposes of subparagraph (A), the HIT Policy Committee shall make recommendations for at least the following areas:

(i) Technologies that protect the privacy of health information and promote security in a qualified electronic health record, including for the segmentation and protection from disclosure of specific and sensitive individually identifiable health information with the goal of minimizing the reluctance of patients to seek care (or disclose information about a condition) because of privacy concerns, in accordance with applicable law, and for the use and disclosure of limited data sets of such information.

(ii) A nationwide health information technology infrastructure that allows for the electronic use and accurate exchange of health information.

(iii) The utilization of a certified electronic health record for each person in the United States by 2014.

(iv) Technologies that as a part of a qualified electronic health record allow for an accounting of disclosures made by a covered entity (as defined for purposes of regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996) for purposes of treatment, payment, and health care operations (as such terms are defined for purposes of such regulations).

(v) The use of certified electronic health records to improve the quality of health care, such as by promoting the coordination of health care and improving continuity of health care among health care providers, by reducing medical errors, by improving population health, by reducing health disparities, by reducing

chronic disease, and by advancing research and education.

(vi) Technologies that allow individually identifiable health information to be rendered unusable, unreadable, or indecipherable to unauthorized individuals when such information is transmitted in the nationwide health information network or physically transported outside of the secured, physical perimeter of a health care provider, health plan, or health care clearinghouse.

(vii) The use of electronic systems to ensure the comprehensive collection of patient demographic data, including, at a minimum, race, ethnicity, primary language, and gender information.

(viii) Technologies that address the needs of children and other vulnerable populations.

(C) OTHER AREAS FOR CONSIDERATION.—In making recommendations under subparagraph (A), the HIT Policy Committee may consider the following additional areas:

(i) The appropriate uses of a nationwide health information infrastructure, including for purposes of—

(I) the collection of quality data and public reporting;

(II) biosurveillance and public health;

(III) medical and clinical research; and

(IV) drug safety.

(ii) Self-service technologies that facilitate the use and exchange of patient information and reduce wait times.

(iii) Telemedicine technologies, in order to reduce travel requirements for patients in remote areas.

(iv) Technologies that facilitate home health care and the monitoring of patients recuperating at home.

(v) Technologies that help reduce medical errors.

(vi) Technologies that facilitate the continuity of care among health settings.

(vii) Technologies that meet the needs of diverse populations.

(viii) Methods to facilitate secure access by an individual to such individual's protected health information.

(ix) Methods, guidelines, and safeguards to facilitate secure access to patient information by a family member, caregiver, or guardian acting on behalf of a patient due to age-related and other disability, cognitive impairment, or dementia.

(x) Any other technology that the HIT Policy Committee finds to be among the technologies with the greatest potential to improve the quality and efficiency of health care.

(D) SPECIAL RULE RELATED TO INTEROPERABILITY.—Any recommendation made by the HIT Policy Committee on or after the date of the enactment of this subparagraph with respect to interoperability of health information technology

shall be consistent with the criteria described in subsection (a) of section 3010.

(3) FORUM.—The HIT Policy Committee shall serve as a forum for broad stakeholder input with specific expertise in policies relating to the matters described in paragraphs (1) and (2).

(4) CONSISTENCY WITH EVALUATION CONDUCTED UNDER MIPPA.—

(A) REQUIREMENT FOR CONSISTENCY.—The HIT Policy Committee shall ensure that recommendations made under paragraph (2)(B)(vi) are consistent with the evaluation conducted under section 1809(a) of the Social Security Act.

(B) SCOPE.—Nothing in subparagraph (A) shall be construed to limit the recommendations under paragraph (2)(B)(vi) to the elements described in section 1809(a)(3) of the Social Security Act.

(C) TIMING.—The requirement under subparagraph (A) shall be applicable to the extent that evaluations have been conducted under section 1809(a) of the Social Security Act, regardless of whether the report described in subsection (b) of such section has been submitted.

(c) MEMBERSHIP AND OPERATIONS.—

(1) IN GENERAL.—The National Coordinator shall take a leading position in the establishment and operations of the HIT Policy Committee.

(2) MEMBERSHIP.—The HIT Policy Committee shall be composed of members to be appointed as follows:

(A) 3 members shall be appointed by the Secretary, 1 of whom shall be appointed to represent the Department of Health and Human Services and 1 of whom shall be a public health official.

(B) 1 member shall be appointed by the majority leader of the Senate.

(C) 1 member shall be appointed by the minority leader of the Senate.

(D) 1 member shall be appointed by the Speaker of the House of Representatives.

(E) 1 member shall be appointed by the minority leader of the House of Representatives.

(F) Such other members as shall be appointed by the President as representatives of other relevant Federal agencies.

(G) 13 members shall be appointed by the Comptroller General of the United States of whom—

(i) 3 members shall advocates for patients or consumers;

(ii) 2 members shall represent health care providers, one of which shall be a physician;

(iii) 1 member shall be from a labor organization representing health care workers;

(iv) 1 member shall have expertise in health information privacy and security;

(v) 1 member shall have expertise in improving the health of vulnerable populations;

(vi) 1 member shall be from the research community;

(vii) 1 member shall represent health plans or other third-party payers;

(viii) 1 member shall represent information technology vendors;

(ix) 1 member shall represent purchasers or employers; and

(x) 1 member shall have expertise in health care quality measurement and reporting.

(3) PARTICIPATION.—The members of the HIT Policy Committee appointed under paragraph (2) shall represent a balance among various sectors of the health care system so that no single sector unduly influences the recommendations of the Policy Committee.

(4) TERMS.—

(A) IN GENERAL.—The terms of the members of the HIT Policy Committee shall be for 3 years, except that the Comptroller General shall designate staggered terms for the members first appointed.

(B) VACANCIES.—Any member appointed to fill a vacancy in the membership of the HIT Policy Committee that occurs prior to the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has been appointed. A vacancy in the HIT Policy Committee shall be filled in the manner in which the original appointment was made.

(5) OUTSIDE INVOLVEMENT.—The HIT Policy Committee shall ensure an opportunity for the participation in activities of the Committee of outside advisors, including individuals with expertise in the development of policies for the electronic exchange and use of health information, including in the areas of health information privacy and security.

(6) QUORUM.—A majority of the member of the HIT Policy Committee shall constitute a quorum for purposes of voting, but a lesser number of members may meet and hold hearings.

(7) FAILURE OF INITIAL APPOINTMENT.—If, on the date that is 45 days after the date of enactment of this title, an official authorized under paragraph (2) to appoint one or more members of the HIT Policy Committee has not appointed the full number of members that such paragraph authorizes such official to appoint, the Secretary is authorized to appoint such members.

(8) CONSIDERATION.—The National Coordinator shall ensure that the relevant and available recommendations and comments from the National Committee on Vital and Health Statistics are considered in the development of policies.

(d) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.), other than section 14 of such Act, shall apply to the HIT Policy Committee.

(e) PUBLICATION.—The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Tech-

nology of all policy recommendations made by the HIT Policy Committee under this section.

SEC. 3003. HIT STANDARDS COMMITTEE.

(a) ESTABLISHMENT.—There is established a committee to be known as the HIT Standards Committee to recommend to the National Coordinator standards, implementation specifications, and certification criteria for the electronic exchange and use of health information for purposes of adoption under section 3004, consistent with the implementation of the strategic plan described in section 3001(c)(3) and beginning with the areas listed in section 3002(b)(2)(B) in accordance with policies developed by the HIT Policy Committee.

(b) DUTIES.—

(1) STANDARDS DEVELOPMENT.—

(A) IN GENERAL.—The HIT Standards Committee shall recommend to the National Coordinator standards, implementation specifications, and certification criteria described in subsection (a) that have been developed, harmonized, or recognized by the HIT Standards Committee. The HIT Standards Committee shall update such recommendations and make new recommendations as appropriate, including in response to a notification sent under section 3004(a)(2)(B). Such recommendations shall be consistent with the latest recommendations made by the HIT Policy Committee.

(B) HARMONIZATION.—The HIT Standards Committee recognize harmonized or updated standards from an entity or entities for the purpose of harmonizing or updating standards and implementation specifications in order to achieve uniform and consistent implementation of the standards and implementation specifications.

(C) PILOT TESTING OF STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—In the development, harmonization, or recognition of standards and implementation specifications, the HIT Standards Committee shall, as appropriate, provide for the testing of such standards and specifications by the National Institute for Standards and Technology under section 13201(a) of the Health Information Technology for Economic and Clinical Health Act.

(D) CONSISTENCY.—The standards, implementation specifications, and certification criteria recommended under this subsection shall be consistent with the standards for information transactions and data elements adopted pursuant to section 1173 of the Social Security Act.

(2) FORUM.—The HIT Standards Committee shall serve as a forum for the participation of a broad range of stakeholders to provide input on the development, harmonization, and recognition of standards, implementation specifications, and certification criteria necessary for the development and adoption of a nationwide health information technology infrastructure that allows for the electronic use and exchange of health information.

(3) SCHEDULE.—Not later than 90 days after the date of the enactment of this title, the HIT Standards Committee shall develop a schedule for the assessment of policy recommendations

developed by the HIT Policy Committee under section 3002. The HIT Standards Committee shall update such schedule annually. The Secretary shall publish such schedule in the Federal Register.

(4) PUBLIC INPUT.—The HIT Standards Committee shall conduct open public meetings and develop a process to allow for public comment on the schedule described in paragraph (3) and recommendations described in this subsection. Under such process comments shall be submitted in a timely manner after the date of publication of a recommendation under this subsection.

(5) CONSIDERATION.—The National Coordinator shall ensure that the relevant and available recommendations and comments from the National Committee on Vital and Health Statistics are considered in the development of standards.

(c) MEMBERSHIP AND OPERATIONS.—

(1) IN GENERAL.—The National Coordinator shall take a leading position in the establishment and operations of the HIT Standards Committee.

(2) MEMBERSHIP.—The membership of the HIT Standards Committee shall at least reflect providers, ancillary healthcare workers, consumers, purchasers, health plans, technology vendors, researchers, relevant Federal agencies, and individuals with technical expertise on health care quality, privacy and security, and on the electronic exchange and use of health information.

(3) PARTICIPATION.—The members of the HIT Standards Committee appointed under this subsection shall represent a balance among various sectors of the health care system so that no single sector unduly influences the recommendations of such Committee.

(4) OUTSIDE INVOLVEMENT.—The HIT Policy Committee shall ensure an opportunity for the participation in activities of the Committee of outside advisors, including individuals with expertise in the development of standards for the electronic exchange and use of health information, including in the areas of health information privacy and security.

(5) BALANCE AMONG SECTORS.—In developing the procedures for conducting the activities of the HIT Standards Committee, the HIT Standards Committee shall act to ensure a balance among various sectors of the health care system so that no single sector unduly influences the actions of the HIT Standards Committee.

(6) ASSISTANCE.—For the purposes of carrying out this section, the Secretary may provide or ensure that financial assistance is provided by the HIT Standards Committee to defray in whole or in part any membership fees or dues charged by such Committee to those consumer advocacy groups and not for profit entities that work in the public interest as a part of their mission.

(d) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.), other than section 14, shall apply to the HIT Standards Committee.

(e) PUBLICATION.—The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the

Office of the National Coordinator for Health Information Technology of all recommendations made by the HIT Standards Committee under this section.

(f) TERMINATION.—The HIT Standards Committee shall terminate on the date that is 90 days after the date of the enactment of this subsection.

SEC. 3003A. RECOMMENDATIONS FOR STANDARDS THROUGH CONTRACTS WITH STANDARDS DEVELOPMENT ORGANIZATIONS.

(a) CONTRACTS.—

(1) IN GENERAL.—For purposes of activities conducted under this title, the Secretary shall enter into contracts with health care standards development organizations accredited by the American National Standards Institute to carry out the duties described in subsection (b), as applicable.

(2) 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 paragraph (1).

(3) PERIOD OF CONTRACT.—Each contract under paragraph (1) shall be for a period determined necessary by the Secretary, in consultation with the National Coordinator, to carry out the applicable duties described in subsection (b).

(4) APPROPRIATE ORGANIZATIONS.—The Secretary shall ensure the most appropriate organizations described in paragraph (1) are selected for each contract under such paragraph.

(5) ALLOWANCE FOR VARIATIONS.—Standards developed pursuant to a contract under this subsection, and the methods to test such standards, shall allow for variations on such standards as long as such variations are consistent with the standards so developed under this section.

(b) DUTIES.—

(1) INITIAL CONTRACT.—Under the initial contract under subsection (a)(1), the standards development organizations—

(A) shall provide to the Secretary, in consultation with the National Coordinator, for adoption under section 3004, recommendations, in accordance with section 3010, for interoperability standards, and methods to test such standards, consistent with the criteria described in subsection (a) of such section and with respect to the categories described in subsection (b)(1) of such section; and

(B) may provide to the Secretary recommendations described in paragraph (2).

(2) SUBSEQUENT CONTRACTS.—Under each subsequent contract, the organizations shall provide to the Secretary, in consultation with the National Coordinator, for adoption under section 3004 recommendations for any standards (including interoperability standards and methods to test such standards), implementation specifications, and certification criteria (and modifications, including additions, to such standards, specifications, and criteria), which are in accordance with the policies and priorities developed by the Secretary, in consultation with the National Coordinator.

(3) MULTIPLE METHODS TO TEST INTEROPERABILITY STANDARDS.—For the purposes of developing methods to test interoperability standards for adoption under section 3004, the Secretary

shall ensure that contracts under this section allow for multiple methods to test such standards to account for variations in the adoption of such standards that do not conflict with section 3010(a).

(c) MODIFICATIONS AND SUBSEQUENT CONTRACTS.—

(1) IN GENERAL.—The Secretary, in consultation with the National Coordinator, shall periodically conduct hearings to evaluate and review the standards, implementation specifications, and certification criteria adopted under section 3004 for purposes of determining if modifications, including any additions, are needed with respect to such standards, specifications, and criteria.

(2) CONTRACT TRIGGER.—Based on the needs for standards, implementation specifications, and certification criteria (and modifications, including additions, to such standards, specifications, and criteria) under this title, as determined by the Secretary, in consultation with the National Coordinator, the Secretary shall, as needed, enter into contracts under subsection (a) in addition to the initial contract.

(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $10,000,000 for contracts under subsection (a), to remain available until expended.

SEC. 3004. PROCESS FOR ADOPTION OF ENDORSED RECOMMENDATIONS; ADOPTION OF INITIAL SET OF STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.

(a) PROCESS FOR ADOPTION OF ENDORSED RECOMMENDATIONS.—

(1) REVIEW OF ENDORSED STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—Not later than 90 days after the date of receipt of standards, implementation specifications, or certification criteria endorsed under section 3001(c) *(or, subject to subsection (c), in the case of a standard, specification, or criterion recommended on or after the date of the enactment of the 21st Century Cures Act, after the date of submission of the recommendation to the Secretary under section 3003A)*, the Secretary, in consultation with representatives of other relevant Federal agencies, shall jointly review such standards, implementation specifications, or certification criteria and shall determine whether or not to propose adoption of such standards, implementation specifications, or certification criteria.

(2) DETERMINATION TO ADOPT STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—If the Secretary determines—

(A) to propose adoption of any grouping of such standards, implementation specifications, or certification criteria, the Secretary shall, by regulation under section 553 of title 5, United States Code, determine whether or not to adopt such grouping of standards, implementation specifications, or certification criteria; or

(B) not to propose adoption of any grouping of standards, implementation specifications, or certification criteria, the Secretary shall notify the National Coordinator [and the HIT Standards Committee] in writing of such determina-

tion and the reasons for not proposing the adoption of such recommendation.

(3) PUBLICATION.—The Secretary shall provide for publication in the Federal Register of all determinations made by the Secretary under paragraph (1).

(b) ADOPTION OF STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—

(1) IN GENERAL.—Not later than December 31, 2009, the Secretary shall, through the rulemaking process consistent with subsection (a)(2)(A), adopt an initial set of standards, implementation specifications, and certification criteria for the areas required for consideration under section 3002(b)(2)(B). The rulemaking for the initial set of standards, implementation specifications, and certification criteria may be issued on an interim, final basis.

(2) APPLICATION OF CURRENT STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—The standards, implementation specifications, and certification criteria adopted before the date of the enactment of this title through the process existing through the Office of the National Coordinator for Health Information Technology may be applied towards meeting the requirement of paragraph (1).

(3) SUBSEQUENT STANDARDS ACTIVITY.—The Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent with the schedule published under section 3003(b)(2).

(4) LIMITATION.—The Secretary may not adopt any standards, implementation specifications, or certification criteria under this subsection or subsection (a) that are inconsistent with or duplicative of an interoperability standard adopted under this section, in accordance with subsections (c) and (d). In the case of a standard, specification, or criterion that has been adopted under this section and is inconsistent or duplicative of such an interoperability standard that is subsequently adopted under this section, such interoperability standard shall supercede such other standard, specification, or criterion and such other standard, specification, or criterion shall no longer be considered adopted under this section beginning on the date that such interoperability standard becomes effective.

(c) ADOPTION OF INITIAL INTEROPERABILITY STANDARDS.—Notwithstanding the previous subsections of this section, the following shall apply in the case of the initial set of interoperability standards recommended under section 3003A:

(1) REVIEW OF STANDARDS.—Not later than 90 days after the date of receipt of recommendations for such interoperability standards, the Secretary, in consultation with the National Coordinator and representatives of other relevant Federal agencies, shall jointly review such standards and shall determine whether or not to propose adoption of such standards.

(2) DETERMINATION TO ADOPT.—If the Secretary determines—

(A) to propose adoption of such standards, the Secretary shall, by regulation under section 553 of title 5, United States Code, determine whether or not to adopt such standards; or

(B) not to propose adoption of such standards, the Secretary shall notify the applicable standards development organizations with a contract under section 3003A in writing of such determination and the reasons for not proposing the adoption of the recommendation for such standards.

(3) PUBLICATION.—The Secretary shall provide for publication in the Federal Register of all determinations made by the Secretary under paragraph (1).

(4) APPLICATION.—Any standard adopted under this subsection shall be effective 12 months after the date of publication of the determination to adopt such standard.

(d) RULES FOR ADOPTION.—In the case of a standard (including interoperability standard), implementation specification, or certification criteria adopted under this section on or after the date of the enactment of the 21st Century Cures Act, the following shall apply:

(1) IN GENERAL.—Except as provided in paragraph (2), any such standard (including interoperability standard), implementation specification, or certification criterion shall be a standard, specification, or criterion that has been recommended by the standards development organizations with which the Secretary has entered into a contract under section 3003A.

(2) SPECIAL RULE IF NO STANDARD, SPECIFICATION, OR CRITERION RECOMMENDED.—If no standard is recommended under paragraph (1)—

(A) in the case of interoperability standards, relating to a category described in section 3010(b)—

(i) paragraph (1) shall not apply; and

(ii) paragraph (4) shall apply; or

(B) in the case of any other standard, implementation specification, or certification criteria, relating to a policy or priority to carry out this title, as determined by the Secretary, in consultation with the National Coordinator—

(i) paragraph (1) shall not apply; and

(ii) paragraph (4) shall apply.

(3) EFFECTIVE DATE.—Any standard, implementation specification, or certification criterion adopted under this section shall be effective 12 months after the date of publication of the final rule to adopt such standard, implementation specification, or certification criterion.

(4) ASSISTANCE TO THE SECRETARY.—In complying with the requirements of this subsection, the Secretary shall rely on the recommendations of the National Committee on Vital and Health Statistics established under section 306(k), and shall consult with appropriate Federal and State agencies and private organizations. The Secretary shall publish in the Federal Register any recommendation of the National Committee on Vital and Health Statistics regarding the adoption of a standard, implementation specification, or certification criterion under this section. Any standard, implementation specification, or certification criterion adopted pursuant to this paragraph shall be promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of title 5, United States Code.

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SEC. 3006. VOLUNTARY APPLICATION AND USE OF ADOPTED STANDARDS AND IMPLEMENTATION SPECIFICATIONS BY PRIVATE ENTITIES.

(a) IN GENERAL.—Except as provided under section 13112 of the HITECH Act, nothing in such Act or in the amendments made by such Act shall be construed—

(1) to require a private entity to adopt or comply with a standard or implementation specification adopted under section 3004*, including an interoperability standard adopted under such section*; or

(2) to provide a Federal agency authority, other than the authority such agency may have under other provisions of law, to require a private entity to comply with such a standard or implementation specification.

(b) RULE OF CONSTRUCTION.—Nothing in this subtitle shall be construed to require that a private entity that enters into a contract with the Federal Government apply or use the standards and implementation specifications adopted under section 3004*, including the interoperability standards adopted under such section* with respect to activities not related to the contract.

SEC. 3007. FEDERAL HEALTH INFORMATION TECHNOLOGY.

(a) IN GENERAL.—The National Coordinator shall support the development and routine updating of qualified electronic health record technology (as defined in section 3000) consistent with subsections (b) and (c) and make available such qualified electronic health record technology unless the Secretary determines through an assessment that the needs and demands of providers are being substantially and adequately met through the marketplace.

(b) CERTIFICATION.—In making such electronic health record technology publicly available, the National Coordinator shall ensure that the qualified electronic health record technology described in subsection (a) is certified under the program developed [under section 3001(c)(3) to be in compliance with applicable standards adopted under section 3003(a).] *under section 3001(c)(3)—*

(1) for certifications made before January 1, 2018, to be in compliance with applicable standards adopted under subsections (a) and (b) of section 3004; and

(2) for certifications made on or after January 1, 2018, to be in compliance with applicable standards adopted under subsections (a) and (b) of section 3004 and to be interoperable in accordance with section 3010, including by being in compliance with interoperability standards adopted under section 3004.

(c) AUTHORIZATION TO CHARGE A NOMINAL FEE.—The National Coordinator may impose a nominal fee for the adoption by a health care provider of the health information technology system developed or approved under subsection (a) and (b). Such fee shall take into account the financial circumstances of smaller providers, low income providers, and providers located in rural or other medically underserved areas.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require that a private or government entity adopt or use the technology provided under this section.

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SEC. 3009. MISCELLANEOUS PROVISIONS.

(a) RELATION TO HIPAA PRIVACY AND SECURITY LAW.—

(1) IN GENERAL.—With respect to the relation of this title to HIPAA privacy and security law:

(A) This title may not be construed as having any effect on the authorities of the Secretary under HIPAA privacy and security law.

(B) The purposes of this title include ensuring that the health information technology standards and implementation specifications adopted under section 3004 take into account the requirements of HIPAA privacy and security law.

(2) DEFINITION.—For purposes of this section, the term "HIPAA privacy and security law" means—

(A) the provisions of part C of title XI of the Social Security Act, section 264 of the Health Insurance Portability and Accountability Act of 1996, and subtitle D of [title IV] *title XIII* of the Health Information Technology for Economic and Clinical Health Act; and

(B) regulations under such provisions.

(b) FLEXIBILITY.—In administering the provisions of this title, the Secretary shall have flexibility in applying the definition of health care provider under section 3000(3), including the authority to omit certain entities listed in such definition when applying such definition under this title, where appropriate.

SEC. 3010. ENSURING INTEROPERABILITY OF HEALTH INFORMATION TECHNOLOGY.

(a) INTEROPERABILITY.—In order for health information technology to be considered interoperable, such technology must satisfy the following criteria:

(1) SECURE TRANSFER.—The technology allows the secure transfer of the entirety of a patient's data from any and all health information technology for authorized use under applicable law.

(2) COMPLETE ACCESS TO HEALTH DATA.—The technology allows access to the entirety of a patient's available data for authorized use under applicable law without special effort, as defined by recommendations for interoperability standards adopted under section 3004, by the requestor of such data unless such data is not disclosable under applicable law.

(3) NO INFORMATION BLOCKING.—The technology is not configured, set up, or implemented to engage in information blocking, as defined in section 3010A(f).

(b) CATEGORIES FOR INTEROPERABILITY STANDARDS.—The categories described in this subsection, with respect to standards for determining if health information technology is interoperable, consistent with the criteria described in subsection (a), include the following categories of standards:

(1) Standards with respect to vocabulary and terminology.

(2) Standards with respect to content and structure.

(3) Standards with respect to transport of information.

(4) Security standards.

(5) Service standards.

(c) DISSEMINATION OF INFORMATION.—

(1) INITIAL SUMMARY REPORT.—Not later than July 1, 2017, the Secretary, after consultation with relevant stakeholders, shall submit to Congress and provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of a report on the following:

(A) The initial set of interoperability standards adopted under section 3004(c).

(B) The strategies for achieving widespread interoperability.

(C) An overview of the extent to which electronic health records and health information technology offered as of such date satisfy such initial set.

(D) Any barriers that are preventing widespread interoperability.

(E) The plan and milestones, including specific steps, to achieve widespread interoperability.

(2) FOLLOWUP DETERMINATION AND REPORT ON WIDESPREAD INTEROPERABILITY.—Not later than December 31, 2019, the Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of the following:

(A) A determination by the Secretary whether the goal of widespread interoperability has been achieved.

(B) A list identifying the vendors of, or other entities offering, qualified electronic health records, which categorizes such entities, with respect to such records, as in compliance or not in compliance with the certification criteria described in section 3001(c)(5)(B)(ii) and with the requirements under clause (i) of section 3001(c)(5)(C) (including with the terms of the attestation and other requirements under such clause).

(C) Actions that may be taken by entities identified under subparagraph (B) as not being in compliance with such criteria and requirements in order for such entities to become in compliance with such criteria and requirements.

(D) Penalties described in section 3010A(d) to which entities, with respect to such qualified electronic health records, beginning January 1, 2019, are subject if such technology and entities are not in compliance with the certification criteria described in section 3001(c)(5)(B)(ii) and with the requirements under clause (i) of section 3001(c)(5)(C), respectively.

(3) ONGOING PUBLICATION OF RECOMMENDATIONS.—The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of all recommendations made under this section.

SEC. 3010A. ENFORCEMENT MECHANISMS.

(a) INSPECTOR GENERAL AUTHORITY.—The Inspector General of the Department of Health and Human Services shall have the authority to investigate claims of—

(1) vendors of, or other entities offering, qualified electronic health records—

(A) being in violation of an attestation made under section 3001(c)(5)(C)(i)(I), with respect to the use of such records by a health care provider under a specified meaningful use incentive program; and

(B) having engaged in information blocking (as defined in subsection (f)), unless for a legitimate purpose specified by the Secretary, with respect to the use of such records by a health care provider under such a program;

(2) health care providers, with respect to the use of such records under a specified meaningful use incentive program, having, unless for a legitimate purpose specified by the Secretary, engaged in information blocking (as so defined);

(3) health information system providers described in subsection (b) having engaged in information blocking (as so defined), unless for a legitimate purpose specified by the Secretary, with respect to the use of such records under a specified meaningful use incentive program; and

(4) vendors of, or other entities offering, health information technology (other than technology described in paragraph (1)), health care providers, with respect to the use of such technology, and health information system providers, with respect to such technology, unless for a legitimate purpose specified by the Secretary, having engaged in information blocking (as so defined).

(b) HEALTH INFORMATION SYSTEM PROVIDERS.—The Inspector General of the Department of Health and Human Services shall, in coordination with the Federal Trade Commission, ensure that health information system providers (such as operators of health information exchanges and other systems that facilitate the exchange of information) investigate claims of information blocking, with respect to the use of such records under a specified meaningful use incentive program.

(c) INFORMATION SHARING PROVISIONS.—

(1) IN GENERAL.—The National Coordinator may serve as a technical consultant to the Inspector General of the Department of Health and Human Services and the Federal Trade Commission for purposes of carrying out this section. As such technical consultant, the National Coordinator may, notwithstanding any other provision of law, share information related to claims or investigations under subsection (a) or (b) with the Federal Trade Commission for purposes of such investigations.

(2) PROTECTION FROM DISCLOSURE OF INFORMATION.—Any information shared by the National Coordinator under paragraph (1) shall not be subject to the provisions of section 552 of title 5, United States Code (commonly referred to as the Freedom of Information Act). Any information acquired pursuant to paragraph (1) shall be held in confidence and shall not be disclosed to any person except as may be necessary to carry out the purposes of subsection (a).

(3) NON-APPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code (commonly referred to as the Paperwork Reduction Act of 1995) shall not apply to the National Coordinator or to the Office of the National Coordinator for Health Information Technology with respect to the collection of complaints relating to claims described in subsection (a).

(d) PENALTY.—Any person or entity determined to have committed an act described in paragraph (1), (2), or (3) of subsection (a), in connection with a specified meaningful use incentive program, shall be subject to a civil monetary penalty of not more than $10,000 for each such act. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty applied under this subsection in the same manner as they apply to a civil money penalty or proceeding under section 1128A(a).

(e) SPECIFIED MEANINGFUL USE INCENTIVE PROGRAM.—For purposes of this section, the term "specified meaningful use incentive program" includes the following:

(1) The incentive payments under subsection (o) of section 1848 of the Social Security Act (42 U.S.C. 1395w–4) and adjustments under subsection (a)(7) of such section.

(2) The incentive payments under subsection (n) of section 1848 of such Act (42 U.S.C. 1395ww) and adjustments under subsection (b)(3)(B) of such section.

(3) The incentive payments and adjustments made under subsections (l) and (m) of section 1853 of such Act (42 U.S.C. 1395w–23).

(4) The incentive payment under paragraph (3) of section 1814(l) of such Act (42 U.S.C. 1395f(l)) and adjustment under paragraph (4) of such section.

(5) The shared savings program under section 1899 of such Act (42 U.S.C. 1395jjj).

(6) The payments to Medicaid providers described in section 1903(t) of such Act (42 U.S.C. 1396b(t)).

(f) INFORMATION BLOCKING.—

(1) IN GENERAL.—For purposes of this section and section 3010, the term "information blocking" means, with respect to the use of qualified electronic health records or other health information technology under a specified meaningful use incentive program, business, technical, and organizational practices, including practices described in paragraph (2), that—

(A) prevent or materially discourage the exchange of electronic health information;

(B) the actor knows or should know (as defined in section 1128A(i)(7) of the Social Security Act) are likely to interfere with the exchange or use of electronic health information; and

(C) do not serve to protect patient safety, maintain the privacy and security of individuals' health information or promote competition and consumer welfare.

(2) PRACTICES DESCRIBED.—For purposes of paragraph (1), the practices described in this paragraph are the following:

(A) Contract terms, policies, or other business or organizational practices that restrict individuals' access to their electronic health information or restrict the exchange or use of that information for treatment and other permitted purposes.

(B) Charging prices or fees (such as for data exchange, portability, and interfaces) that make exchanging and using electronic health information cost prohibitive.

(C) Developing or implementing health information technology in nonstandard ways that are likely to substantially

increase the costs, complexity, or burden of sharing electronic health information, especially in cases in which relevant interoperability standards or methods to measure interoperability have been adopted by the Secretary.

(D) Developing or implementing health information technology in ways that are likely to lock in users or electronic health information, such as not allowing for the full export of data; lead to fraud, waste, or abuse; or impede innovations and advancements in health information exchange and health information technology-enabled care delivery.

(g) TREATMENT OF VENDORS WITH RESPECT TO PATIENT SAFETY ORGANIZATIONS.—In applying part C of title IX—

(1) vendors shall be treated as a provider (as defined in section 921) for purposes of reporting requirements under such part, to the extent that such reports are related to attestation requirements under section 3001(c)(5)(C)(i)(I);

(2) claims of information blocking described in subsection (a) shall be treated as a patient safety activity under such part for purposes of reporting requirements under such part; and

(3) health care providers that are not members of patient safety organizations shall be treated in the same manner as health care providers that are such members for purposes of such reporting requirements with respect to claims of information blocking described in subsection (a).

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SECTION 202 OF THE DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS ACT, 1993

SEC. 202. Appropriations in this or any other Act or subsequent Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Acts shall be available for expenses for active commissioned officers in the Public Health Service Reserve Corps and for commissioned officers in the Regular Corps; expenses incident to the dissemination of health information in foreign countries through exhibits and other appropriate means; advances of funds for compensation, travel, and subsistence expenses (or per diem in lieu thereof) for persons coming from abroad to participate in health or scientific activities of the Department pursuant to law; expenses of primary and secondary schooling of dependents in foreign countries, of Public Health Service commissioned officers stationed in foreign countries, at costs for any given area not in excess of those of the Department of Defense for the same area, when it is determined by the Secretary that the schools available in the locality are unable to provide adequately for the education of such dependents, and for the transportation of such dependents, between such schools and their places of residence when the schools are not accessible to such dependents by regular means of transportation; expenses for medical care for civilian and commissioned employees of the Public Health Service and their dependents assigned abroad on a permanent basis in accordance with such regulations as the Secretary may provide; rental or lease of living quarters (for periods not exceeding five years), and provision

of heat, fuel, and light and maintenance, improvement, and repair of such quarters, and advance payments therefor, for civilian officers and employees of the Public Health Service who are United States citizens and who have a permanent station in a foreign country; purchase, erection, and maintenance of temporary or [portable structures; and for the payment of compensation to consultants or individual scientists appointed for limited periods of time pursuant to section 207(f) or section 207(g) of the Public Health Service Act, at rates established by the Assistant Secretary for Health, or the Secretary where such action is required by statute, not to exceed the per diem rate equivalent to the maximum rate payable for senior-level positions under 5 U.S.C. 5376.] *portable structures.*

TITLE 44, UNITED STATES CODE

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CHAPTER 35—COORDINATION OF FEDERAL INFORMATION POLICY

SUBCHAPTER I—FEDERAL INFORMATION POLICY

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§ 3518. Effect on existing laws and regulations

(a) Except as otherwise provided in this subchapter, the authority of an agency under any other law to prescribe policies, rules, regulations, and procedures for Federal information resources management activities is subject to the authority of the Director under this subchapter.

(b) Nothing in this subchapter shall be deemed to affect or reduce the authority of the Secretary of Commerce or the Director of the Office of Management and Budget pursuant to Reorganization Plan No. 1 of 1977 (as amended) and Executive order, relating to telecommunications and information policy, procurement and management of telecommunications and information systems, spectrum use, and related matters.

(c)(1) Except as provided in paragraph (2), this subchapter shall not apply to the collection of information—

(A) during the conduct of a Federal criminal investigation or prosecution, or during the disposition of a particular criminal matter;

(B) during the conduct of—

(i) a civil action to which the United States or any official or agency thereof is a party; or

(ii) an administrative action or investigation involving an agency against specific individuals or entities;

(C) by compulsory process pursuant to the Antitrust Civil Process Act and section 13 of the Federal Trade Commission Improvements Act of 1980[; or]*;*

(D) during the conduct of intelligence activities as defined in section 3.4(e) of Executive Order No. 12333, issued December 4, 1981, or successor orders, or during the conduct of cryptologic activities that are communications security activities[.]*; or*

(E) during the conduct of research by the National Institutes of Health.

(2) This subchapter applies to the collection of information during the conduct of general investigations (other than information collected in an antitrust investigation to the extent provided in subparagraph (C) of paragraph (1)) undertaken with reference to a category of individuals or entities such as a class of licensees or an entire industry.

(d) Nothing in this subchapter shall be interpreted as increasing or decreasing the authority conferred by sections 11331 and 11332 of title 40 on the Secretary of Commerce or the Director of the Office of Management and Budget.

(e) Nothing in this subchapter shall be interpreted as increasing or decreasing the authority of the President, the Office of Management and Budget or the Director thereof, under the laws of the United States, with respect to the substantive policies and programs of departments, agencies and offices, including the substantive authority of any Federal agency to enforce the civil rights laws.

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FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

(a)(1) The term "State", except as used in the last sentence of section 702(a), means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means the Department of Health and Human Services.

(d) The term "Secretary" means the Secretary of Health and Human Services.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any

articles specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.

(2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, [or]

(3) intended to affect the structure or any function of the body of man or other animals, [and] *or*

(4) not health software (other than software determined to be a risk to patient safety under section 524B(b)), and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means—

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(q)(1)(A) Except as provided in clause (B), the term "pesticide chemical" means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide. Notwithstanding any other provision of law, the term "pesticide" within such meaning includes ethylene oxide and propylene oxide when such substances are applied on food.

(B) In the case of the use, with respect to food, of a substance described in clause (A) to prevent, destroy, repel, or mitigate microorganisms (including bacteria, viruses, fungi, protozoa, algae, and slime), the following applies for purposes of clause (A):

(i) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is applied

for such use on food, or the substance is included for such use in water that comes into contact with the food, in the preparing, packing, or holding of the food for commercial purposes. The substance is not excluded under this subclause from such definition if the substance is ethylene oxide or propylene oxide, and is applied for such use on food. The substance is not so excluded if the substance is applied for such use on a raw agricultural commodity, or the substance is included for such use in water that comes into contact with the commodity, as follows:

(I) The substance is applied in the field.

(II) The substance is applied at a treatment facility where raw agricultural commodities are the only food treated, and the treatment is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing such commodities in such manner).

(III) The substance is applied during the transportation of such commodity between the field and such a treatment facility.

(ii) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is a food contact substance as defined in section 409(h)(6), and any of the following circumstances exist: The substance is included for such use in an object that has a food contact surface but is not intended to have an ongoing effect on any portion of the object; the substance is included for such use in an object that has a food contact surface and is intended to have an ongoing effect on a portion of the object but not on the food contact surface; or the substance is included for such use in or is applied for such use on food packaging (without regard to whether the substance is intended to have an ongoing effect on any portion of the packaging). The food contact substance is not excluded under this subclause from such definition if any of the following circumstances exist: The substance is applied for such use on a semipermanent or permanent food contact surface (other than being applied on food packaging); or the substance is included for such use in an object that has a semipermanent or permanent food contact surface (other than being included in food packaging) and the substance is intended to have an ongoing effect on the food contact surface.

With respect to the definition of the term "pesticide" that is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act, this clause does not exclude any substance from such definition.

(2) The term "pesticide chemical residue" means a residue in or on raw agricultural commodity or processed food of—

(A) a pesticide chemical; or

(B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical.

(3) Notwithstanding subparagraphs (1) and (2), the Administrator may by regulation except a substance from the definition of "pesticide chemical" or "pesticide chemical residue" if—

(A) its occurrence as a residue on or in a raw agricultural commodity or processed food is attributable primarily to nat-

ural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food; and

(B) the Administrator, after consultation with the Secretary, determines that the substance more appropriately should be regulated under one or more provisions of this Act other than sections 402(a)(2)(B) and 408.

(r) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

(1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or

(2) a pesticide chemical; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following);

(5) a new animal drug; or

(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

(t)(1) The term "color additive" means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) The term "color" includes black, white, and intermediate grays.

(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.

(u) The term "safe," as used in paragraph (s) of this section and in sections 409, 512, 571, and 721, has reference to the health of man or animal.

(v) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed—

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Provided that any drug intended for minor use or use in a minor species that is not the subject of a final regulation published by the Secretary through notice and comment rulemaking finding that the criteria of paragraphs (1) and (2) have not been met (or that the exception to the criterion in paragraph (1) has been met) is a new animal drug.

(w) The term "animal feed", as used in paragraph (w) of this section, in section 512, and in provisions of this Act referring to such paragraph or section, means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(x) The term "informal hearing" means a hearing which is not subject to section 554, 556, or 557 of title 5 of the United States Code and which provides for the following:

(1) The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

(2) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(3) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the

hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and a general summary of the information which will be presented by the Secretary at the hearing in support of such action.

(4) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action of the Secretary which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.

(5) The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.

(6) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer's report of the hearing.

(y) The term "saccharin" includes calcium saccharin, sodium saccharin, and ammonium saccharin.

(z) The term "infant formula" means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

(aa) The term "abbreviated drug application" means an application submitted under section 505(j) for the approval of a drug that relies on the approved application of another drug with the same active ingredient to establish safety and efficacy, and—

(1) in the case of section 306, includes a supplement to such an application for a different or additional use of the drug but does not include a supplement to such an application for other than a different or additional use of the drug, and

(2) in the case of sections 307 and 308, includes any supplement to such an application.

(bb) The term "knowingly" or "knew" means that a person, with respect to information—

(1) has actual knowledge of the information, or

(2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

(cc) For purposes of section 306, the term "high managerial agent"—

(1) means—

(A) an officer or director of a corporation or an association,

(B) a partner of a partnership, or

(C) any employee or other agent of a corporation, association, or partnership,

having duties such that the conduct of such officer, director, partner, employee, or agent may fairly be assumed to represent the policy of the corporation, association, or partnership, and

(2) includes persons having management responsibility for—

(A) submissions to the Food and Drug Administration regarding the development or approval of any drug product,

(B) production, quality assurance, or quality control of any drug product, or

(C) research and development of any drug product.

(dd) For purposes of sections 306 and 307, the term "drug product" means a drug subject to regulation under section 505, 512, or 802 of this Act or under section 351 of the Public Health Service Act.

(ee) The term "Commissioner" means the Commissioner of Food and Drugs.

(ff) The term "dietary supplement"—

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) means a product that—

(A)(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or

(ii) complies with section 411(c)(1)(B)(ii);

(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement; and

(3) does—

(A) include an article that is approved as a new drug under section 505 or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f); and

(B) not include—

(i) an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act.

Except for purposes of sections 201(g) and 417, a dietary supplement shall be deemed to be a food within the meaning of this Act.

(gg) The term "processed food" means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

(hh) The term "Administrator" means the Administrator of the United States Environmental Protection Agency.

(ii) The term "compounded positron emission tomography drug"—

(1) means a drug that—

(A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

(B) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and

(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.

(jj) The term "antibiotic drug" means any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.

(kk) PRIORITY SUPPLEMENT.—The term "priority supplement" means a drug application referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997 (111 Stat. 2298).

(ll)(1) The term "single-use device" means a device that is intended for one use, or on a single patient during a single procedure.

(2)(A) The term "reprocessed", with respect to a single-use device, means an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.

(B) A single-use device that meets the definition under clause (A) shall be considered a reprocessed device without regard to any description of the device used by the manufacturer of the device or other persons, including a description that uses the term "recycled" rather than the term "reprocessed".

(3) The term "original device" means a new, unused single-use device.

(mm)(1) The term "critical reprocessed single-use device" means a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use.

(2) The term "semi-critical reprocessed single-use device" means a reprocessed single-use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

(nn) The term "major species" means cattle, horses, swine, chickens, turkeys, dogs, and cats, except that the Secretary may add species to this definition by regulation.

(oo) The term "minor species" means animals other than humans that are not major species.

(pp) The term "minor use" means the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually.

(qq) The term "major food allergen" means any of the following:

(1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

(2) A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:

(A) Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.

(B) A food ingredient that is exempt under paragraph (6) or (7) of section 403(w).

(rr)(1) The term "tobacco product" means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

(2) The term "tobacco product" does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 503(g).

(3) The products described in paragraph (2) shall be subject to chapter V of this Act.

(4) A tobacco product shall not be marketed in combination with any other article or product regulated under this Act (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement).

(ss)(1) The term "health software" means software that does not, through use of an in vitro diagnostic device or signal acquisition system, acquire, process, or analyze an image or physiological signal, is not an accessory, is not an integral part of a device necessary to support the use of the device, is not used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans, and—

(A) is intended for use for administrative or operational support or the processing and maintenance of financial records;

(B) is intended for use in clinical, laboratory, or administrative workflow and related recordkeeping;

(C)(i) is intended for use solely in the transfer, aggregation, conversion (in accordance with a present specification), storage, management, retrieval, or transmission of data or information;

(ii) utilizes a connectivity software platform, electronic or electrical hardware, or a physical communications infrastructure; and

(iii) is not intended for use—

(I) in active patient monitoring; or

(II) in controlling or altering the functions or parameters of a device that is connected to such software;

(D) is intended for use to organize and present information for health or wellness education or for use in maintaining a healthy lifestyle, including medication adherence and health management tools;

(E) is intended for use to analyze information to provide general health information that does not include patient-specific recommended options to consider in the prevention, diagnosis, treatment, cure, or mitigation of a particular disease or condition; or

(F) is intended for use to analyze information to provide patient-specific recommended options to consider in the prevention, diagnosis, treatment, cure, or mitigation of a particular disease or condition.

(2) The term "accessory" means a product that—

(A) is intended for use with one or more parent devices;

(B) is intended to support, supplement, or augment the performance of one or more parent devices; and

(C) shall be classified by the Secretary—

(i) according to its intended use; and

(ii) independently of any classification of any parent device with which it is used.

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CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

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MISBRANDED DRUGS AND DEVICES

SEC. 502. A drug or device shall be deemed to be misbranded—

[(a) If its**]** *(a)(1) If its* labeling is false or misleading in any particular. Health care economic information provided to **[**a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations**]** *a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement*, shall not be considered to be false or misleading under this paragraph if the health care economic information **[**directly relates**]** *relates* to an indication approved under section 505 or under section 351(a) of the Public Health Service Act for such drug **[**and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a) or in section 351(a) of the Public Health Service Act shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph**]***, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug under*

section 505 or under section 351 of the Public Health Service Act. The requirements set forth in section 505(a) or in subsections (a) and (k) of section 351 of the Public Health Service Act shall not apply to health care economic information provided to such a payor, committee, or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. ⟦In this paragraph, the term "health care economic information" means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention.⟧

(2)(A) For purposes of this paragraph, the term "health care economic information" means any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences, which may be based on the separate or aggregated clinical consequences of the represented health outcomes, of the use of a drug. Such analysis may be comparative to the use of another drug, to another health care intervention, or to no intervention.

(B) Such term does not include any analysis that relates only to an indication that is not approved under section 505 or under section 351 of the Public Health Service Act for such drug.

(b) If in a package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided,* That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(e)(1)(A) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)—

(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name;

(ii) the established name and quantity or, if determined to be appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if determined to be appropriate by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein, except that the requirement for stating the

quantity of the active ingredients, other than the quantity of those specifically named in this subclause, shall not apply to nonprescription drugs not intended for human use; and

(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if determined to be appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Secretary, except that nothing in this subclause shall be deemed to require that any trade secret be divulged, and except that the requirements of this subclause with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics and that this subclause shall not apply to nonprescription drugs not intended for human use.

(B) For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient, except that to the extent that compliance with the requirements of subclause (ii) or (iii) of clause (A) or this clause is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(2) If it is a device and it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name (as defined in subparagraph (4)) prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such device, except that to the extent compliance with the requirements of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(3) As used in subparagraph (1), the term "established name", with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 508, or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient, except that where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopeia and in the Homeopathic Pharmacopeia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopeia shall apply.

(4) As used in subparagraph (2), the term "established name" with respect to a device means (A) the applicable official name of the device designated pursuant to section 508, (B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then any common or usual name of such device.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or

against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein. The method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopeia and the Homeopathic Pharmacopeia of the United States, it shall be subject to the requirements of the United States Pharmacopeia with respect to packaging, and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopeia of the United States, and not to those of the United States Pharmacopeia, except that in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.

(h) If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i)(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) If it is dangerous to health when used in the dosage or manner; or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

(m) If it is a color additive the intended use of which is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, as may be contained in regulations issued under section 721.

(n) In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer,

or distributor with respect to that drug a true statement of (1) the established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e), and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with section 701(a), and in the case of published direct-to-consumer advertisements the following statement printed in conspicuous text: "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1–800-FDA-1088.", except that (A) except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall, with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 12 through 17 of the Federal Trade Commission Act, as amended (15 U.S.C. 52–57). This paragraph (n) shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m) of this Act. Nothing in the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, shall be construed to prevent drug price communications to consumers. In the case of an advertisement for a drug subject to section 503(b)(1) presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner.

(o) If it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510, if it is a drug and was imported or offered for import by a commercial importer of drugs not duly registered under section 801(s), if it was not included in a list required by section 510(j), if a notice or other information respecting it was not provided as required by such section or section 510(k), or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 510(e) as the Secretary by regulation requires.

(p) If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

(q) In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 520(e).

(r) In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any

trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing. Except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement and no advertisement of a restricted device, published after the effective date of this paragraph shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act (15 U.S.C. 52–55). This paragraph shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m).

(s) If it is a device subject to a performance standard established under section 514, unless it bears such labeling as may be prescribed in such performance standard.

(t) If it is a device and there was a failure or refusal (1) to comply with any requirement prescribed under section 518 respecting the device, (2) to furnish any material or information required by or under section 519 *or 524B* respecting the device, or (3) to comply with a requirement under section 522.

(u)(1) Subject to paragraph (2), if it is a reprocessed single-use device, unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer of the reprocessed device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer.

(2) If the original device or an attachment thereto does not prominently and conspicuously bear the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, a reprocessed device may satisfy the requirements of paragraph (1) through the use of a detachable label on the packaging that identifies the manufacturer and is intended to be affixed to the medical record of a patient.

(v) If it is a reprocessed single-use device, unless all labeling of the device prominently and conspicuously bears the statement "Reprocessed device for single use. Reprocessed by ____." The name of the manufacturer of the reprocessed device shall be placed in the space identifying the person responsible for reprocessing.

(w) If it is a new animal drug—

(1) that is conditionally approved under section 571 and its labeling does not conform with the approved application or section 571(f), or that is not conditionally approved under section 571 and its label bears the statement set forth in section 571(f)(1)(A); or

(2) that is indexed under section 572 and its labeling does not conform with the index listing under section 572(e) or

572(h), or that has not been indexed under section 572 and its label bears the statement set forth in section 572(h).

(x) If it is a nonprescription drug (as defined in section 760) that is marketed in the United States, unless the label of such drug includes a domestic address or domestic phone number through which the responsible person (as described in section 760) may receive a report of a serious adverse event (as defined in section 760) with such drug.

(y) If it is a drug subject to an approved risk evaluation and mitigation strategy pursuant to section 505(p) and the responsible person (as such term is used in section 505–1) fails to comply with a requirement of such strategy provided for under subsection (d), (e), or (f) of section 505–1.

(z) If it is a drug, and the responsible person (as such term is used in section 505(o)) is in violation of a requirement established under paragraph (3) (relating to postmarket studies and clinical trials) or paragraph (4) (relating to labeling) of section 505(o) with respect to such drug.

(aa) If it is a drug, or an active pharmaceutical ingredient, and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 744B(a)(4) or for which identifying information required by section 744B(f) has not been submitted, or it contains an active pharmaceutical ingredient that was manufactured, prepared, propagated, compounded, or processed in such a facility.

(bb) If the advertising or promotion of a compounded drug is false or misleading in any particular.

(cc) If it is a drug and it fails to bear the product identifier as required by section 582.

(dd) If it is a drug approved in accordance with section 505(z) and its labeling does not meet the requirements under paragraph (3) of such subsection, subject to paragraph (5) of such subsection.

(ee) If it is an antimicrobial drug and its labeling fails to conform with the requirements under section 511(d).

EXEMPTIONS AND CONSIDERATION FOR CERTAIN DRUGS, DEVICES, AND BIOLOGICAL PRODUCTS

SEC. 503. (a) The Secretary is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded, under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

(b)(1) A drug intended for use by man which—

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug;

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 502, except paragraphs (a), (i) (2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Secretary may by regulation remove drugs subject to section 505 from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4)(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol "Rx only".

(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).

(5) Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications stated in section 3220 of the Internal Revenue Code (26 U.S.C. 3220), or to marihuana as defined in section 3238(b) of the Internal Revenue Code (26 U.S.C. 3238(b)).

(c)(1) No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. For purposes of this paragraph and subsection (d), the term "drug sample" means a unit of a drug, subject to subsection (b), which is not intended to be sold and is intended to promote the sale of the drug. Nothing in this paragraph shall subject an officer or executive of a drug manufacturer or distributor to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade in violation of this paragraph by other employees of the manufacturer or distributor.

(2) No person may sell, purchase, or trade, offer to sell, purchase, or trade, or counterfeit any coupon. For purposes of this paragraph, the term "coupon" means a form which may be redeemed, at no cost or at a reduced cost, for a drug which is prescribed in accordance with subsection (b).

(3)(A) No person may sell, purchase, or trade, or offer to sell, purchase, or trade, any drug—

(i) which is subject to subsection (b), and

(ii)(I) which was purchased by a public or private hospital or other health care entity, or

(II) which was donated or supplied at a reduced price to a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954.

(B) Subparagraph (A) does not apply to—

(i) the purchase or other acquisition by a hospital or other health care entity which is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities which are members of such organization,

(ii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by an organization described in subparagraph (A)(ii)(II) to a nonprofit affiliate of the organization to the extent otherwise permitted by law,

(iii) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities which are under common control,

(iv) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, or

(v) a sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b).

For purposes of this paragraph, the term "entity" does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law and the term "emergency medical reasons" includes transfers of a drug between health care entities or from a health care entity to a retail pharmacy undertaken to alleviate temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules.

(d)(1) Except as provided in paragraphs (2) and (3), no person may distribute any drug sample. For purposes of this subsection, the term "distribute" does not include the providing of a drug sample to a patient by a—

(A) practitioner licensed to prescribe such drug,

(B) health care professional acting at the direction and under the supervision of such a practitioner, or

(C) pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample pursuant to paragraph (2) or (3).

(2)(A) The manufacturer or authorized distributor of record of a drug subject to subsection (b) may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or other health care entities. Such a distribution of drug samples may only be made—

(i) in response to a written request for drug samples made on a form which meets the requirements of subparagraph (B), and

(ii) under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon

its delivery and the return of the receipt to the manufacturer or authorized distributor of record.

(B) A written request for a drug sample required by subparagraph (A)(i) shall contain—

(i) the name, address, professional designation, and signature of the practitioner making the request,

(ii) the identity of the drug sample requested and the quantity requested,

(iii) the name of the manufacturer of the drug sample requested, and

(iv) the date of the request.

(C) Each drug manufacturer or authorized distributor of record which makes distributions by mail or common carrier under this paragraph shall maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and shall maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to Federal and State officials engaged in the regulation of drugs and in the enforcement of laws applicable to drugs.

(3) The manufacturer or authorized distributor of record of a drug subject to subsection (b) may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or authorized distributor of record makes the distributions in accordance with subparagraph (A) and carries out the activities described in subparagraphs (B) through (F) as follows:

(A) Drug samples may only be distributed—

(i) to practitioners licensed to prescribe such drugs if they make a written request for the drug samples, or

(ii) at the written request of such a licensed practitioner, to pharmacies of hospitals or other health care entities.

A written request for drug samples shall be made on a form which contains the practitioner's name, address, and professional designation, the identity of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or authorized distributor of record of the drug sample, the date of the request and signature of the practitioner making the request.

(B) Drug manufacturers or authorized distributors of record shall store drug samples under conditions that will maintain their stability, integrity, and effectiveness and will assure that the drug samples will be free of contamination, deterioration, and adulteration.

(C) Drug manufacturers or authorized distributors of record shall conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or authorized distributor of record. Drug manufacturers or authorized distributors of record shall maintain lists of the names and address of each of their representatives who distribute drug samples and of the sites where drug samples are stored. Drug manufacturers or authorized distributors of record shall maintain records for at least 3 years of all drug samples distributed, destroyed, or returned to the

manufacturer or authorized distributor of record, of all inventories maintained under this subparagraph, of all thefts or significant losses of drug samples, and of all requests made under subparagraph (A) for drug samples. Records and lists maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to the Secretary upon request.

(D) Drug manufacturers or authorized distributors of record shall notify the Secretary of any significant loss of drug samples and any known theft of drug samples.

(E) Drug manufacturers or authorized distributors of record shall report to the Secretary any conviction of their representatives for violations of subsection (c)(1) or a State law because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(F) Drug manufacturers or authorized distributors of record shall provide to the Secretary the name and telephone number of the individual responsible for responding to a request for information respecting drug samples.

(4) In this subsection, the term "authorized distributors of record" means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.

(e)

(1) REQUIREMENT.—Subject to section 583:

(A) IN GENERAL.—No person may engage in wholesale distribution of a drug subject to subsection (b)(1) in any State unless such person—

(i)(I) is licensed by the State from which the drug is distributed; or

(II) if the State from which the drug is distributed has not established a licensure requirement, is licensed by the Secretary; and

(ii) if the drug is distributed interstate, is licensed by the State into which the drug is distributed if the State into which the drug is distributed requires the licensure of a person that distributes drugs into the State.

(B) STANDARDS.—Each Federal and State license described in subparagraph (A) shall meet the standards, terms, and conditions established by the Secretary under section 583.

(2) REPORTING AND DATABASE.—

(A) REPORTING.—Beginning January 1, 2015, any person who owns or operates an establishment that engages in wholesale distribution shall—

(i) report to the Secretary, on an annual basis pursuant to a schedule determined by the Secretary—

(I) each State by which the person is licensed and the appropriate identification number of each such license; and

(II) the name, address, and contact information of each facility at which, and all trade names under which, the person conducts business; and

(ii) report to the Secretary within a reasonable period of time and in a reasonable manner, as determined by the Secretary, any significant disciplinary actions, such as the revocation or suspension of a wholesale distributor license, taken by a State or the Federal Government during the reporting period against the wholesale distributor.

(B) DATABASE.—Not later than January 1, 2015, the Secretary shall establish a database of authorized wholesale distributors. Such database shall—

(i) identify each authorized wholesale distributor by name, contact information, and each State where such wholesale distributor is appropriately licensed to engage in wholesale distribution;

(ii) be available to the public on the Internet Web site of the Food and Drug Administration; and

(iii) be regularly updated on a schedule determined by the Secretary.

(C) COORDINATION.—The Secretary shall establish a format and procedure for appropriate State officials to access the information provided pursuant to subparagraph (A) in a prompt and secure manner.

(D) CONFIDENTIALITY.—Nothing in this paragraph shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

(3) COSTS.—

(A) AUTHORIZED FEES OF SECRETARY.—If a State does not establish a licensing program for persons engaged in the wholesale distribution of a drug subject to subsection (b), the Secretary shall license a person engaged in wholesale distribution located in such State and may collect a reasonable fee in such amount necessary to reimburse the Secretary for costs associated with establishing and administering the licensure program and conducting periodic inspections under this section. The Secretary shall adjust fee rates as needed on an annual basis to generate only the amount of revenue needed to perform this service. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

(B) STATE LICENSING FEES.—Nothing in this Act shall prohibit States from collecting fees from wholesale distributors in connection with State licensing of such distributors.

(4) For the purposes of this subsection and subsection (d), the term "wholesale distribution" means the distribution of a drug subject to subsection (b) to a person other than a con-

sumer or patient, or receipt of a drug subject to subsection (b) by a person other than the consumer or patient, but does not include—

(A) intracompany distribution of any drug between members of an affiliate or within a manufacturer;

(B) the distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;

(C) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(D) the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b)(1);

(E) the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use;

(F) the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(G) the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

(H) the distribution of a drug by the manufacturer of such drug;

(I) the receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;

(J) a common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;

(K) the distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with section 582(e);

(L) salable drug returns when conducted by a dispenser;

(M) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this subparagraph as a "medical convenience kit") if—

(i) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 510(b)(2);

(ii) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;

(iii) in the case of a medical convenience kit that includes a product, the person that manufacturers the kit—

(I) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

(II) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

(iv) in the case of a medical convenience kit that includes a product, the product is—

(I) an intravenous solution intended for the replenishment of fluids and electrolytes;

(II) a product intended to maintain the equilibrium of water and minerals in the body;

(III) a product intended for irrigation or reconstitution;

(IV) an anesthetic;

(V) an anticoagulant;

(VI) a vasopressor; or

(VII) a sympathomimetic;

(N) the distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(O) the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(P) the distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(Q) the distribution of medical gas, as defined in section 575;

(R) facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or

(S) the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in section 581(16)(B) and registered under section 510 for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

(5) THIRD-PARTY LOGISTICS PROVIDERS.—Notwithstanding paragraphs (1) through (4), each entity that meets the definition of a third-party logistics provider under section 581(22) shall obtain a license as a third-party logistics provider as described in section 584(a) and is not required to obtain a license as a wholesale distributor if the entity never assumes an ownership interest in the product it handles.

(6) AFFILIATE.—For purposes of this subsection, the term "affiliate" means a business entity that has a relationship with a second business entity if, directly or indirectly—

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has the power to control, both of the business entities.

(f)(1)(A) A drug intended for use by animals other than man, other than a veterinary feed directive drug intended for use in animal feed or an animal feed bearing or containing a veterinary feed directive drug, which—

(i) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for animal use except under the professional supervision of a licensed veterinarian, or

(ii) is limited by an approved application under subsection (b) of section 512, a conditionally-approved application under section 571, or an index listing under section 572 to use under the professional supervision of a licensed veterinarian,

shall be dispensed only by or upon the lawful written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice.

(B) For purposes of subparagraph (A), an order is lawful if the order—

(i) is a prescription or other order authorized by law,

(ii) is, if an oral order, promptly reduced to writing by the person lawfully filling the order, and filed by that person, and

(iii) is refilled only if authorized in the original order or in a subsequent oral order promptly reduced to writing by the person lawfully filling the order, and filed by that person.

(C) The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug when dispensed in accordance with paragraph (1) of this subsection—

(A) Shall be exempt from the requirements of section 502, except subsections (a), (g), (h), (i)(2), (i)(3), and (p) of such section, and

(B) shall be exempt from the packaging requirements of subsections (g), (h), and (p) of such section, if—

(i) when dispensed by a licensed veterinarian, the drug bears a label containing the name and address of the practitioner and any directions for use and cautionary statements specified by the practitioner, or

(ii) when dispensed by filling the lawful order of a licensed veterinarian, the drug bears a label containing the name and address of the dispenser, the serial number and date of the order or of its filing, the name of the licensed veterinarian, and the directions for use and cautionary statements, if any, contained in such order.

The preceding sentence shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail.

(3) The Secretary may by regulation exempt drugs for animals other than man subject to section 512, 571, or 572 from the re-

quirements of paragraph (1) when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.". A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the statement specified in the preceding sentence.

(g)(1) The Secretary shall in accordance with this subsection assign an agency center to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

(A) a drug (other than a biological product), the agency center charged with premarket review of drugs shall have primary jurisdiction,

(B) a device, the agency center charged with premarket review of devices shall have primary jurisdiction, or

(C) a biological product, the agency center charged with premarket review of biological products shall have primary jurisdiction.

(2) Nothing in this subsection shall prevent the Secretary from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.

(3) The Secretary shall promulgate regulations to implement market clearance procedures in accordance with paragraphs (1) and (2) not later than 1 year after the date of enactment of this subsection.

(4)(A) Not later than 60 days after the date of the enactment of this paragraph, the Secretary shall establish within the Office of the Commissioner of Food and Drugs an office to ensure the prompt assignment of combination products to agency centers, the timely and effective premarket review of such products, and consistent and appropriate postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law. Additionally, the office shall, in determining whether a product is to be designated a combination product, consult with the component within the Office of the Commissioner of Food and Drugs that is responsible for such determinations. Such office (referred to in this paragraph as the "Office") shall have appropriate scientific and medical expertise, and shall be headed by a director.

(B) In carrying out this subsection, the Office shall, for each combination product, promptly assign an agency center with primary jurisdiction in accordance with paragraph (1) for the premarket review of such product.

(C)(i) In carrying out this subsection, the Office shall ensure timely and effective premarket reviews by overseeing the timeliness of and coordinating reviews involving more than one agency center.

(ii) In order to ensure the timeliness of the premarket review of a combination product, the agency center with primary jurisdiction for the product, and the consulting agency center, shall be respon-

sible to the Office with respect to the timeliness of the premarket review.

(iii) Not later than 18 months after the date of the enactment of the 21st Century Cures Act, the Secretary shall issue final guidance that describes the responsibilities of each agency center regarding its review of combination products. The Secretary shall, after soliciting public comment, review and update the guidance periodically.

(D) In carrying out this subsection, the Office shall ensure the consistency and appropriateness of postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law.

(E)(i) Any dispute regarding the timeliness of the premarket review of a combination product may be presented to the Office for resolution, unless the dispute is clearly premature.

(ii) During the review process, any dispute regarding the substance of the premarket review may be presented to the Commissioner of Food and Drugs after first being considered by the agency center with primary jurisdiction of the premarket review, under the scientific dispute resolution procedures for such center. The Commissioner of Food and Drugs shall consult with the Director of the Office in resolving the substantive dispute.

(F) The Secretary, acting through the Office, shall review each agreement, guidance, or practice of the Secretary that is specific to the assignment of combination products to agency centers and shall determine whether the agreement, guidance, or practice is consistent with the requirements of this subsection. In carrying out such review, the Secretary shall consult with stakeholders and the directors of the agency centers. After such consultation, the Secretary shall determine whether to continue in effect, modify, revise, or eliminate such agreement, guidance, or practice, and shall publish in the Federal Register a notice of the availability of such modified or revised agreement, guidance or practice. Nothing in this paragraph shall be construed as preventing the Secretary from following each agreement, guidance, or practice until continued, modified, revised, or eliminated.

(G) Not later than one year after the date of the enactment of this paragraph and annually thereafter, the Secretary shall report to the appropriate committees of Congress on the activities and impact of the Office. The report shall include provisions—

(i) describing the numbers and types of combination products under review and the timeliness in days of such assignments, reviews, and dispute resolutions;

(ii) identifying the number of premarket reviews of such products that involved a consulting agency center; and

(iii) describing improvements in the consistency of postmarket regulation of combination products.

(H) Nothing in this paragraph shall be construed to limit the regulatory authority of any agency center.

(5) As used in this subsection:

(A) The term "agency center" means a center or alternative organizational component of the Food and Drug Administration.

(B) The term "biological product" has the meaning given the term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(C) The term "market clearance" includes—

(i) approval of an application under section 505, 507, 515, or 520(g),

(ii) a finding of substantial equivalence under this subchapter, and

(iii) approval of a biologics license application under subsection (a) of section 351 of the Public Health Service Act (42 U.S.C. 262).

* * * * * * *

NEW DRUGS

SEC. 505. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

(b)(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required under section 505B. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture use, or sale of the drug. If a application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims

the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(A) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

(B) TIMING OF NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(C) RECIPIENTS OF NOTICE.—An applicant required under this paragraph to give notice shall give notice to—

(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(D) CONTENTS OF NOTICE.—A notice required under this paragraph shall—

(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(4)(A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

(B) With respect to the drug for which such an application is submitted, nothing in this subsection or subsection (c)(3) prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(5)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 351 of the Public Health Service Act, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 351 of the Public Health Service Act if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size—

(i)(I) of clinical trials intended to form the primary basis of an effectiveness claim; or

(II) in the case where human efficacy studies are not ethical or feasible, of animal and any associated clinical trials which, in combination, are intended to form the primary basis of an effectiveness claim; or

(ii) with respect to an application for approval of a biological product under section 351(k) of the Public Health Service Act, of any necessary clinical study or studies.

The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 351 of the Public Health Service Act (including all scientific and medical matters, chemistry, manufacturing, and controls).

(6) An application submitted under this subsection shall be accompanied by the certification required under section 402(j)(5)(B) of the Public Health Service Act. Such certification shall not be considered an element of such application.

(c)(1) Within one hundred and eighty days after the filing of an application under subsection (b), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary, the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after the date of the enactment of this sentence, and if the holder of an approved application could not file patent information under subsection (b) because no patent had been issued when an application was filed or approved, the holder shall file such information under this sub-

section not later than thirty days after after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.

(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined by applying the following to each certification made under subsection (b)(2)(A):

(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under subsection (b)(3) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(I) the date on which the court enters judgment reflecting the decision; or

(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(ii) if before the expiration of such period the district court decides that the patent has been infringed—

(I) if the judgment of the district court is appealed, the approval shall be made effective on—

(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in clause (i); or

(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(D) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of title 28, United States Code, by an applicant referred to in subsection (b)(2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (C) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that

such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant referred to in subsection (b)(2) for the purpose of determining whether an action referred to in subparagraph (C) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under subsection (b)(2)(A)(iv) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or this subsection on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim de-

scribed in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(E)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of another application for a drug for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b).

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this clause, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under subsection (b) after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A). The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of the enactment of this clause and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the ap-

plication and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this clause and the supplement contains reports of new clinical investigations (other than bioavailabilty studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this clause, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from the date of enactment of this clause.

(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.

(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended,

or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b); or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence. **[**The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs. Nothing in the preceding sentence shall alter the criteria for evaluating an application for premarket approval of a drug.**]**

(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be

safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or (5) that the application contains any untrue statement of a material fact: *Provided,* That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or (j) with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) or to comply with the notice requirements of section 510(k)(2), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based. The Secretary may withdraw the approval of an application submitted under this section, or suspend the approval of such an application, as provided under this subsection, without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy for the drug under section 505–1(g)(2)(D).

(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the Department

designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i)(1) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(A) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, or preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(B) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings;

(C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b); and

(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

(3)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that—

(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before the date of the enactment of the Food and Drug Administration Modernization Act of 1997).

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a deci-

sion, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, [except where it is not feasible or it is contrary to the best interests of such human beings] *except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings*. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs. The Secretary shall update such regulations to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsection (j) of section 402 of the Public Health Service Act.

(j)(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 201(p), and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the

new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1);

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) RECIPIENTS OF NOTICE.—An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) CONTENTS OF NOTICE.—A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Secretary shall issue guidance defining the term "listed drug" for purposes of this subparagraph.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient show that each of the proposed conditions of use have been

previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 201(p),

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because

the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because

either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-DAY EXCLUSIVITY PERIOD.—

(I) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the com-

mercial marketing of the listed drug) by any first applicant.

(II) DEFINITIONS.—In this paragraph:

(aa) 180-DAY EXCLUSIVITY PERIOD.—The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) FIRST APPLICANT.—As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) SUBSTANTIALLY COMPLETE APPLICATION.—As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) TENTATIVE APPROVAL.—

(AA) IN GENERAL.—The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 505A, or there is a 7-year period of exclusivity for the listed drug under section 527.

(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(C) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of title 28, United States Code, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for in-

fringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be

redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).

(II) WITHDRAWAL OF APPLICATION.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) AMENDMENT OF CERTIFICATION.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) AGREEMENT WITH ANOTHER APPLICANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 1 of the Clayton Act (15 U.S.C. 12), except that the term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that that section applies to unfair methods of competition).

(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) FORFEITURE.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) SUBSEQUENT APPLICANT.—If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of enactment of this subsection and if such application contains re-

ports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) for such drug.

(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this subsection and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from the date of enactment of this subsection.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)(A)(i) Within sixty days of the date of the enactment of this subsection, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) before the date of the enactment of this subsection;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug

which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or the date of enactment, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A)(i) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(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.

(k)(1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking

subsection (e) of this section. Regulations and orders issued under this subsection and under subsection (i) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(3) ACTIVE POSTMARKET RISK IDENTIFICATION.—

(A) DEFINITION.—In this paragraph, the term "data" refers to information with respect to a drug approved under this section or under section 351 of the Public Health Service Act, including claims data, patient survey data, standardized analytic files that allow for the pooling and analysis of data from disparate data environments, and any other data deemed appropriate by the Secretary.

(B) DEVELOPMENT OF POSTMARKET RISK IDENTIFICATION AND ANALYSIS METHODS.—The Secretary shall, not later than 2 years after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, in collaboration with public, academic, and private entities—

(i) develop methods to obtain access to disparate data sources including the data sources specified in subparagraph (C);

(ii) develop validated methods for the establishment of a postmarket risk identification and analysis system to link and analyze safety data from multiple sources, with the goals of including, in aggregate—

(I) at least 25,000,000 patients by July 1, 2010; and

(II) at least 100,000,000 patients by July 1, 2012; and

(iii) convene a committee of experts, including individuals who are recognized in the field of protecting data privacy and security, to make recommendations to the Secretary on the development of tools and methods for the ethical and scientific uses for, and communication of, postmarketing data specified under subparagraph (C), including recommendations on the development of effective research methods for the study of drug safety questions.

(C) ESTABLISHMENT OF THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

(i) IN GENERAL.—The Secretary shall, not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), establish and maintain procedures—

(I) for risk identification and analysis based on electronic health data, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability

Act of 1996, and in a manner that does not disclose individually identifiable health information in violation of paragraph (4)(B);

(II) for the reporting (in a standardized form) of data on all serious adverse drug experiences (as defined in section 505–1(b)) submitted to the Secretary under paragraph (1), and those adverse events submitted by patients, providers, and drug sponsors, when appropriate;

(III) to provide for active adverse event surveillance using the following data sources, as available:

(aa) Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs);

(bb) private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data); and

(cc) other data as the Secretary deems necessary to create a robust system to identify adverse events and potential drug safety signals;

(IV) to identify certain trends and patterns with respect to data accessed by the system;

(V) to provide regular reports to the Secretary concerning adverse event trends, adverse event patterns, incidence and prevalence of adverse events, and other information the Secretary determines appropriate, which may include data on comparative national adverse event trends; and

(VI) to enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

(ii) TIMELINESS OF REPORTING.—The procedures established under clause (i) shall ensure that such data are accessed, analyzed, and reported in a timely, routine, and systematic manner, taking into consideration the need for data completeness, coding, cleansing, and standardized analysis and transmission.

(iii) PRIVATE SECTOR RESOURCES.—To ensure the establishment of the active postmarket risk identification and analysis system under this subsection not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), as required under clause (i), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

(iv) COMPLEMENTARY APPROACHES.—To the extent the active postmarket risk identification and analysis system under this subsection is not sufficient to gather data and information relevant to a priority drug safety question, the Secretary shall develop, support, and participate in complementary approaches to gather and analyze such data and information, including—

(I) approaches that are complementary with respect to assessing the safety of use of a drug in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children); and

(II) existing approaches such as the Vaccine Adverse Event Reporting System and the Vaccine Safety Datalink or successor databases.

(v) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subparagraph.

(4) ADVANCED ANALYSIS OF DRUG SAFETY DATA.—

(A) PURPOSE.—The Secretary shall establish collaborations with public, academic, and private entities, which may include the Centers for Education and Research on Therapeutics under section 912 of the Public Health Service Act, to provide for advanced analysis of drug safety data described in paragraph (3)(C) and other information that is publicly available or is provided by the Secretary, in order to—

(i) improve the quality and efficiency of postmarket drug safety risk-benefit analysis;

(ii) provide the Secretary with routine access to outside expertise to study advanced drug safety questions; and

(iii) enhance the ability of the Secretary to make timely assessments based on drug safety data.

(B) PRIVACY.—Such analysis shall not disclose individually identifiable health information when presenting such drug safety signals and trends or when responding to inquiries regarding such drug safety signals and trends.

(C) PUBLIC PROCESS FOR PRIORITY QUESTIONS.—At least biannually, the Secretary shall seek recommendations from the Drug Safety and Risk Management Advisory Committee (or any successor committee) and from other advisory committees, as appropriate, to the Food and Drug Administration on—

(i) priority drug safety questions; and

(ii) mechanisms for answering such questions, including through—

(I) active risk identification under paragraph (3); and

(II) when such risk identification is not sufficient, postapproval studies and clinical trials under subsection (o)(3).

(D) PROCEDURES FOR THE DEVELOPMENT OF DRUG SAFETY COLLABORATIONS.—

(i) IN GENERAL.—Not later than 180 days after the date of the establishment of the active postmarket risk identification and analysis system under this subsection, the Secretary shall establish and implement procedures under which the Secretary may routinely contract with one or more qualified entities to—

(I) classify, analyze, or aggregate data described in paragraph (3)(C) and information that is publicly available or is provided by the Secretary;

(II) allow for prompt investigation of priority drug safety questions, including—

(aa) unresolved safety questions for drugs or classes of drugs; and

(bb) for a newly-approved drugs, safety signals from clinical trials used to approve the drug and other preapproval trials; rare, serious drug side effects; and the safety of use in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children);

(III) perform advanced research and analysis on identified drug safety risks;

(IV) focus postapproval studies and clinical trials under subsection (o)(3) more effectively on cases for which reports under paragraph (1) and other safety signal detection is not sufficient to resolve whether there is an elevated risk of a serious adverse event associated with the use of a drug; and

(V) carry out other activities as the Secretary deems necessary to carry out the purposes of this paragraph.

(ii) REQUEST FOR SPECIFIC METHODOLOGY.—The procedures described in clause (i) shall permit the Secretary to request that a specific methodology be used by the qualified entity. The qualified entity shall work with the Secretary to finalize the methodology to be used.

(E) USE OF ANALYSES.—The Secretary shall provide the analyses described in this paragraph, including the methods and results of such analyses, about a drug to the sponsor or sponsors of such drug.

(F) QUALIFIED ENTITIES.—

(i) IN GENERAL.—The Secretary shall enter into contracts with a sufficient number of qualified entities to develop and provide information to the Secretary in a timely manner.

(ii) QUALIFICATION.—The Secretary shall enter into a contract with an entity under clause (i) only if the Secretary determines that the entity has a significant presence in the United States and has one or more of the following qualifications:

(I) The research, statistical, epidemiologic, or clinical capability and expertise to conduct and complete the activities under this paragraph, including the capability and expertise to provide the Secretary de-identified data consistent with the requirements of this subsection.

(II) An information technology infrastructure in place to support electronic data and operational standards to provide security for such data.

(III) Experience with, and expertise on, the development of drug safety and effectiveness research using electronic population data.

(IV) An understanding of drug development or risk/benefit balancing in a clinical setting.

(V) Other expertise which the Secretary deems necessary to fulfill the activities under this paragraph.

(G) CONTRACT REQUIREMENTS.—Each contract with a qualified entity under subparagraph (F)(i) shall contain the following requirements:

(i) ENSURING PRIVACY.—The qualified entity shall ensure that the entity will not use data under this subsection in a manner that—

(I) violates the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996;

(II) violates sections 552 or 552a of title 5, United States Code, with regard to the privacy of individually-identifiable beneficiary health information; or

(III) discloses individually identifiable health information when presenting drug safety signals and trends or when responding to inquiries regarding drug safety signals and trends.

Nothing in this clause prohibits lawful disclosure for other purposes.

(ii) COMPONENT OF ANOTHER ORGANIZATION.—If a qualified entity is a component of another organization—

(I) the qualified entity shall establish appropriate security measures to maintain the confidentiality and privacy of such data; and

(II) the entity shall not make an unauthorized disclosure of such data to the other components of the organization in breach of such confidentiality and privacy requirement.

(iii) TERMINATION OR NONRENEWAL.—If a contract with a qualified entity under this subparagraph is terminated or not renewed, the following requirements shall apply:

(I) CONFIDENTIALITY AND PRIVACY PROTECTIONS.—The entity shall continue to comply with the confidentiality and privacy requirements under this paragraph with respect to all data disclosed to the entity.

(II) DISPOSITION OF DATA.—The entity shall return any data disclosed to such entity under this subsection to which it would not otherwise have access or, if returning the data is not practicable, destroy the data.

(H) COMPETITIVE PROCEDURES.—The Secretary shall use competitive procedures (as defined in section 4(5) of the Federal Procurement Policy Act) to enter into contracts under subparagraph (G).

(I) REVIEW OF CONTRACT IN THE EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review the contract with a qualified entity under this paragraph in the event of a merger or acquisition of the entity in order to ensure that the requirements under this paragraph will continue to be met.

(J) COORDINATION.—In carrying out this paragraph, the Secretary shall provide for appropriate communications to the public, scientific, public health, and medical communities, and other key stakeholders, and to the extent practicable shall coordinate with the activities of private entities, professional associations, or other entities that may have sources of drug safety data.

(5) The Secretary shall—

(A) conduct regular, bi-weekly screening of the Adverse Event Reporting System database and post a quarterly report on the Adverse Event Reporting System Web site of any new safety information or potential signal of a serious risk identified by Adverse Event Reporting System within the last quarter;

(B) report to Congress not later than 2 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 on procedures and processes of the Food and Drug Administration for addressing ongoing post market safety issues identified by the Office of Surveillance and Epidemiology and how recommendations of the Office of Surveillance and Epidemiology are handled within the agency; and

(C) on an annual basis, review the entire backlog of postmarket safety commitments to determine which commitments require revision or should be eliminated, report to the Congress on these determinations, and assign start dates and estimated completion dates for such commitments.

(l)(1) Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(A) if no work is being or will be undertaken to have the application approved,

(B) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

(C) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

(D) if the Secretary has determined that such drug is not a new drug, or

(E) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval of an application under sub-

section (j) which refers to such drug could be made effective if such an application had been submitted.

(2) ACTION PACKAGE FOR APPROVAL.—

(A) ACTION PACKAGE.—The Secretary shall publish the action package for approval of an application under subsection (b) or section 351 of the Public Health Service Act on the Internet Web site of the Food and Drug Administration—

(i) not later than 30 days after the date of approval of such application for a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act; and

(ii) not later than 30 days after the third request for such action package for approval received under section 552 of title 5, United States Code, for any other drug.

(B) IMMEDIATE PUBLICATION OF SUMMARY REVIEW.—Notwithstanding subparagraph (A), the Secretary shall publish, on the Internet Web site of the Food and Drug Administration, the materials described in subparagraph (C)(iv) not later than 48 hours after the date of approval of the drug, except where such materials require redaction by the Secretary.

(C) CONTENTS.—An action package for approval of an application under subparagraph (A) shall be dated and shall include the following:

(i) Documents generated by the Food and Drug Administration related to review of the application.

(ii) Documents pertaining to the format and content of the application generated during drug development.

(iii) Labeling submitted by the applicant.

(iv) A summary review that documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and within the review team and how they were resolved, recommendations for action, and an explanation of any nonconcurrence with review conclusions.

(v) The Division Director and Office Director's decision document which includes—

(I) a brief statement of concurrence with the summary review;

(II) a separate review or addendum to the review if disagreeing with the summary review; and

(III) a separate review or addendum to the review to add further analysis.

(vi) Identification by name of each officer or employee of the Food and Drug Administration who—

(I) participated in the decision to approve the application; and

(II) consents to have his or her name included in the package.

(D) REVIEW.—A scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final.

(E) CONFIDENTIAL INFORMATION.—This paragraph does not authorize the disclosure of any trade secret, confidential com-

mercial or financial information, or other matter listed in section 552(b) of title 5, United States Code.

(m) For purposes of this section, the term "patent" means a patent issued by the United States Patent and Trademark Office.

(n)(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under section 505 or section 351 of the Public Health Service Act, the Secretary shall establish panels of experts or use panels of experts established before the date of enactment of the Food and Drug Administration Modernization Act of 1997, or both.

(2) The Secretary may delegate the appointment and oversight authority granted under section 1004 to a director of a center or successor entity within the Food and Drug Administration.

(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of—

(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;

(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;

(C) a representative of consumer interests, and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

(D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(4) The Secretary shall, as appropriate, provide education and training to each new panel member before such member participates in a panel's activities, including education regarding requirements under this Act and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.

(5) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS–15 of the General Schedule. While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

(6) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meetings.

(7) Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

(o) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING.—

(1) IN GENERAL.—A responsible person may not introduce or deliver for introduction into interstate commerce the new drug involved if the person is in violation of a requirement established under paragraph (3) or (4) with respect to the drug.

(2) DEFINITIONS.—For purposes of this subsection:

(A) RESPONSIBLE PERSON.—The term "responsible person" means a person who—

(i) has submitted to the Secretary a covered application that is pending; or

(ii) is the holder of an approved covered application.

(B) COVERED APPLICATION.—The term "covered application" means—

(i) an application under subsection (b) for a drug that is subject to section 503(b); and

(ii) an application under section 351 of the Public Health Service Act.

(C) NEW SAFETY INFORMATION; SERIOUS RISK.—The terms "new safety information", "serious risk", and "signal of a serious risk" have the meanings given such terms in section 505–1(b).

(3) STUDIES AND CLINICAL TRIALS.—

(A) IN GENERAL.—For any or all of the purposes specified in subparagraph (B), the Secretary may, subject to subparagraph (D), require a responsible person for a drug to conduct a postapproval study or studies of the drug, or a postapproval clinical trial or trials of the drug, on the basis of scientific data deemed appropriate by the Secretary, including information regarding chemically-related or pharmacologically-related drugs.

(B) PURPOSES OF STUDY OR CLINICAL TRIAL.—The purposes referred to in this subparagraph with respect to a postapproval study or postapproval clinical trial are the following:

(i) To assess a known serious risk related to the use of the drug involved.

(ii) To assess signals of serious risk related to the use of the drug.

(iii) To identify an unexpected serious risk when available data indicates the potential for a serious risk.

(C) ESTABLISHMENT OF REQUIREMENT AFTER APPROVAL OF COVERED APPLICATION.—The Secretary may require a postapproval study or studies or postapproval clinical trial or trials for a drug for which an approved covered application is in effect as of the date on which the Secretary seeks to establish such requirement only if the Secretary becomes aware of new safety information.

(D) DETERMINATION BY SECRETARY.—

(i) POSTAPPROVAL STUDIES.—The Secretary may not require the responsible person to conduct a study under this paragraph, unless the Secretary makes a determination that the reports under subsection (k)(1) and the active postmarket risk identification and analysis system as available under subsection (k)(3) will not be sufficient to meet the purposes set forth in subparagraph (B).

(ii) POSTAPPROVAL CLINICAL TRIALS.—The Secretary may not require the responsible person to conduct a clinical trial under this paragraph, unless the Secretary makes a determination that a postapproval study or studies will not be sufficient to meet the purposes set forth in subparagraph (B).

(E) NOTIFICATION; TIMETABLES; PERIODIC REPORTS.—

(i) NOTIFICATION.—The Secretary shall notify the responsible person regarding a requirement under this paragraph to conduct a postapproval study or clinical trial by the target dates for communication of feedback from the review team to the responsible person regarding proposed labeling and postmarketing study commitments as set forth in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

(ii) TIMETABLE; PERIODIC REPORTS.—For each study or clinical trial required to be conducted under this paragraph, the Secretary shall require that the responsible person submit a timetable for completion of the study or clinical trial. With respect to each study required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such study including whether any difficulties in completing the study have been encountered. With respect to each clinical trial required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such clinical trial including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to the requirements under section 402(j) of the Public Health Service Act. If the responsible person fails to

comply with such timetable or violates any other requirement of this subparagraph, the responsible person shall be considered in violation of this subsection, unless the responsible person demonstrates good cause for such noncompliance or such other violation. The Secretary shall determine what constitutes good cause under the preceding sentence.

(F) DISPUTE RESOLUTION.—The responsible person may appeal a requirement to conduct a study or clinical trial under this paragraph using dispute resolution procedures established by the Secretary in regulation and guidance.

(4) SAFETY LABELING CHANGES REQUESTED BY SECRETARY.—

(A) NEW SAFETY INFORMATION.—If the Secretary becomes aware of new safety information that the Secretary believes should be included in the labeling of the drug, the Secretary shall promptly notify the responsible person or, if the same drug approved under section 505(b) is not currently marketed, the holder of an approved application under 505(j).

(B) RESPONSE TO NOTIFICATION.—Following notification pursuant to subparagraph (A), the responsible person or the holder of the approved application under section 505(j) shall within 30 days—

(i) submit a supplement proposing changes to the approved labeling to reflect the new safety information, including changes to boxed warnings, contraindications, warnings, precautions, or adverse reactions; or

(ii) notify the Secretary that the responsible person or the holder of the approved application under section 505(j) does not believe a labeling change is warranted and submit a statement detailing the reasons why such a change is not warranted.

(C) REVIEW.—Upon receipt of such supplement, the Secretary shall promptly review and act upon such supplement. If the Secretary disagrees with the proposed changes in the supplement or with the statement setting forth the reasons why no labeling change is necessary, the Secretary shall initiate discussions to reach agreement on whether the labeling for the drug should be modified to reflect the new safety information, and if so, the contents of such labeling changes.

(D) DISCUSSIONS.—Such discussions shall not extend for more than 30 days after the response to the notification under subparagraph (B), unless the Secretary determines an extension of such discussion period is warranted.

(E) ORDER.—Within 15 days of the conclusion of the discussions under subparagraph (D), the Secretary may issue an order directing the responsible person or the holder of the approved application under section 505(j) to make such a labeling change as the Secretary deems appropriate to address the new safety information. Within 15 days of such an order, the responsible person or the holder of the approved application under section 505(j) shall submit a supplement containing the labeling change.

(F) DISPUTE RESOLUTION.—Within 5 days of receiving an order under subparagraph (E), the responsible person or the holder of the approved application under section 505(j) may appeal using dispute resolution procedures established by the Secretary in regulation and guidance.

(G) VIOLATION.—If the responsible person or the holder of the approved application under section 505(j) has not submitted a supplement within 15 days of the date of such order under subparagraph (E), and there is no appeal or dispute resolution proceeding pending, the responsible person or holder shall be considered to be in violation of this subsection. If at the conclusion of any dispute resolution procedures the Secretary determines that a supplement must be submitted and such a supplement is not submitted within 15 days of the date of that determination, the responsible person or holder shall be in violation of this subsection.

(H) PUBLIC HEALTH THREAT.—Notwithstanding subparagraphs (A) through (F), if the Secretary concludes that such a labeling change is necessary to protect the public health, the Secretary may accelerate the timelines in such subparagraphs.

(I) RULE OF CONSTRUCTION.—This paragraph shall not be construed to affect the responsibility of the responsible person or the holder of the approved application under section 505(j) to maintain its label in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations).

(5) NON-DELEGATION.—Determinations by the Secretary under this subsection for a drug shall be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

(p) RISK EVALUATION AND MITIGATION STRATEGY.—

(1) IN GENERAL.—A person may not introduce or deliver for introduction into interstate commerce a new drug if—

(A)(i) the application for such drug is approved under subsection (b) or (j) and is subject to section 503(b); or

(ii) the application for such drug is approved under section 351 of the Public Health Service Act; and

(B) a risk evaluation and mitigation strategy is required under section 505–1 with respect to the drug and the person fails to maintain compliance with the requirements of the approved strategy or with other requirements under section 505–1, including requirements regarding assessments of approved strategies.

(2) CERTAIN POSTMARKET STUDIES.—The failure to conduct a postmarket study under section 506, subpart H of part 314, or subpart E of part 601 of title 21, Code of Federal Regulations (or any successor regulations), is deemed to be a violation of paragraph (1).

(q) PETITIONS AND CIVIL ACTIONS REGARDING APPROVAL OF CERTAIN APPLICATIONS.—

(1) IN GENERAL.—

(A) DETERMINATION.—The Secretary shall not delay approval of a pending application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act because of any request to take any form of action relating to the application, either before or during consideration of the request, unless—

(i) the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations); and

(ii) the Secretary determines, upon reviewing the petition, that a delay is necessary to protect the public health.

Consideration of the petition shall be separate and apart from review and approval of any application.

(B) NOTIFICATION.—If the Secretary determines under subparagraph (A) that a delay is necessary with respect to an application, the Secretary shall provide to the applicant, not later than 30 days after making such determination, the following information:

(i) Notification of the fact that a determination under subparagraph (A) has been made.

(ii) If applicable, any clarification or additional data that the applicant should submit to the docket on the petition to allow the Secretary to review the petition promptly.

(iii) A brief summary of the specific substantive issues raised in the petition which form the basis of the determination.

(C) FORMAT.—The information described in subparagraph (B) shall be conveyed via either, at the discretion of the Secretary—

(i) a document; or

(ii) a meeting with the applicant involved.

(D) PUBLIC DISCLOSURE.—Any information conveyed by the Secretary under subparagraph (C) shall be considered part of the application and shall be subject to the disclosure requirements applicable to information in such application.

(E) DENIAL BASED ON INTENT TO DELAY.—If the Secretary determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues, the Secretary may deny the petition at any point based on such determination. The Secretary may issue guidance to describe the factors that will be used to determine under this subparagraph whether a petition is submitted with the primary purpose of delaying the approval of an application.

(F) FINAL AGENCY ACTION.—The Secretary shall take final agency action on a petition not later than 150 days after the date on which the petition is submitted. The Secretary shall not extend such period for any reason, including—

(i) any determination made under subparagraph (A);

(ii) the submission of comments relating to the petition or supplemental information supplied by the petitioner; or

(iii) the consent of the petitioner.

(G) EXTENSION OF 30-MONTH PERIOD.—If the filing of an application resulted in first-applicant status under subsection (j)(5)(D)(i)(IV) and approval of the application was delayed because of a petition, the 30-month period under such subsection is deemed to be extended by a period of time equal to the period beginning on the date on which the Secretary received the petition and ending on the date of final agency action on the petition (inclusive of such beginning and ending dates), without regard to whether the Secretary grants, in whole or in part, or denies, in whole or in part, the petition.

(H) CERTIFICATION.—The Secretary shall not consider a petition for review unless the party submitting such petition does so in written form and the subject document is signed and contains the following certification: "I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.", with the date on which such information first became known to such party and the names of such persons or organizations inserted in the first and second blank space, respectively.

(I) VERIFICATION.—The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and the subject document is signed and contains the following verification: "I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of

perjury that the foregoing is true and correct as of the date of the submission of this petition.", with the date on which such information first became known to the party and the names of such persons or organizations inserted in the first and second blank space, respectively.

(2) EXHAUSTION OF ADMINISTRATIVE REMEDIES.—

(A) FINAL AGENCY ACTION WITHIN 150 DAYS.—The Secretary shall be considered to have taken final agency action on a petition if—

(i) during the 150-day period referred to in paragraph (1)(F), the Secretary makes a final decision within the meaning of section 10.45(d) of title 21, Code of Federal Regulations (or any successor regulation); or

(ii) such period expires without the Secretary having made such a final decision.

(B) DISMISSAL OF CERTAIN CIVIL ACTIONS.—If a civil action is filed against the Secretary with respect to any issue raised in the petition before the Secretary has taken final agency action on the petition within the meaning of subparagraph (A), the court shall dismiss without prejudice the action for failure to exhaust administrative remedies.

(C) ADMINISTRATIVE RECORD.—For purposes of judicial review related to the approval of an application for which a petition under paragraph (1) was submitted, the administrative record regarding any issue raised by the petition shall include—

(i) the petition filed under paragraph (1) and any supplements and comments thereto;

(ii) the Secretary's response to such petition, if issued; and

(iii) other information, as designated by the Secretary, related to the Secretary's determinations regarding the issues raised in such petition, as long as the information was considered by the agency no later than the date of final agency action as defined under subparagraph (2)(A), and regardless of whether the Secretary responded to the petition at or before the approval of the application at issue in the petition.

(3) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITIONS.—The Secretary shall annually submit to the Congress a report that specifies—

(A) the number of applications that were approved during the preceding 12-month period;

(B) the number of such applications whose effective dates were delayed by petitions referred to in paragraph (1) during such period;

(C) the number of days by which such applications were so delayed; and

(D) the number of such petitions that were submitted during such period.

(4) EXCEPTIONS.—

(A) This subsection does not apply to—

(i) a petition that relates solely to the timing of the approval of an application pursuant to subsection (j)(5)(B)(iv); or

(ii) a petition that is made by the sponsor of an application and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

(B) Paragraph (2) does not apply to a petition addressing issues concerning an application submitted pursuant to section 351(k) of the Public Health Service Act.

(5) DEFINITIONS.—

(A) APPLICATION.—For purposes of this subsection, the term "application" means an application submitted under subsection (b)(2) or (j) of the Act or 351(k) of the Public Health Service Act.

(B) PETITION.—For purposes of this subsection, other than paragraph (1)(A)(i), the term "petition" means a request described in paragraph (1)(A)(i).

(r) POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS.—

(1) ESTABLISHMENT.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall improve the transparency of information about drugs and allow patients and health care providers better access to information about drugs by developing and maintaining an Internet Web site that—

(A) provides links to drug safety information listed in paragraph (2) for prescription drugs that are approved under this section or licensed under section 351 of the Public Health Service Act; and

(B) improves communication of drug safety information to patients and providers.

(2) INTERNET WEB SITE.—The Secretary shall carry out paragraph (1) by—

(A) developing and maintaining an accessible, consolidated Internet Web site with easily searchable drug safety information, including the information found on United States Government Internet Web sites, such as the United States National Library of Medicine's Daily Med and Medline Plus Web sites, in addition to other such Web sites maintained by the Secretary;

(B) ensuring that the information provided on the Internet Web site is comprehensive and includes, when available and appropriate—

(i) patient labeling and patient packaging inserts;

(ii) a link to a list of each drug, whether approved under this section or licensed under such section 351, for which a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations), is required;

(iii) a link to the registry and results data bank provided for under subsections (i) and (j) of section 402 of the Public Health Service Act;

(iv) the most recent safety information and alerts issued by the Food and Drug Administration for drugs

approved by the Secretary under this section, such as product recalls, warning letters, and import alerts;

(v) publicly available information about implemented RiskMAPs and risk evaluation and mitigation strategies under subsection (o);

(vi) guidance documents and regulations related to drug safety; and

(vii) other material determined appropriate by the Secretary;

(C) providing access to summaries of the assessed and aggregated data collected from the active surveillance infrastructure under subsection (k)(3) to provide information of known and serious side-effects for drugs approved under this section or licensed under such section 351;

(D) preparing, by 18 months after approval of a drug or after use of the drug by 10,000 individuals, whichever is later, a summary analysis of the adverse drug reaction reports received for the drug, including identification of any new risks not previously identified, potential new risks, or known risks reported in unusual number;

(E) enabling patients, providers, and drug sponsors to submit adverse event reports through the Internet Web site;

(F) providing educational materials for patients and providers about the appropriate means of disposing of expired, damaged, or unusable medications; and

(G) supporting initiatives that the Secretary determines to be useful to fulfill the purposes of the Internet Web site.

(3) POSTING OF DRUG LABELING.—The Secretary shall post on the Internet Web site established under paragraph (1) the approved professional labeling and any required patient labeling of a drug approved under this section or licensed under such section 351 not later than 21 days after the date the drug is approved or licensed, including in a supplemental application with respect to a labeling change.

(4) PRIVATE SECTOR RESOURCES.—To ensure development of the Internet Web site by the date described in paragraph (1), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

(5) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subsection.

(6) REVIEW.—The Advisory Committee on Risk Communication under section 567 shall, on a regular basis, perform a comprehensive review and evaluation of the types of risk communication information provided on the Internet Web site established under paragraph (1) and, through other means, shall identify, clarify, and define the purposes and types of information available to facilitate the efficient flow of information to patients and providers, and shall recommend ways for the Food and Drug Administration to work with outside entities to help facilitate the dispensing of risk communication information to patients and providers.

(s) REFERRAL TO ADVISORY COMMITTEE.—Prior to the approval of a drug no active ingredient (including any ester or salt of the active

ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act, the Secretary shall—

(1) refer such drug to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee; or

(2) if the Secretary does not refer such a drug to a Food and Drug Administration advisory committee prior to the approval of the drug, provide in the action letter on the application for the drug a summary of the reasons why the Secretary did not refer the drug to an advisory committee prior to approval.

(t) DATABASE FOR AUTHORIZED GENERIC DRUGS.—

(1) IN GENERAL.—

(A) PUBLICATION.—The Commissioner shall—

(i) not later than 9 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, publish a complete list on the Internet Web site of the Food and Drug Administration of all authorized generic drugs (including drug trade name, brand company manufacturer, and the date the authorized generic drug entered the market); and

(ii) update the list quarterly to include each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug during the preceding 3-month period.

(B) NOTIFICATION.—The Commissioner shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the Federal Trade Commission, when the Commissioner first publishes the information described in subparagraph (A) that the information has been published and that the information will be updated quarterly.

(2) INCLUSION.—The Commissioner shall include in the list described in paragraph (1) each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug after January 1, 1999.

(3) AUTHORIZED GENERIC DRUG.—In this section, the term "authorized generic drug" means a listed drug (as that term is used in subsection (j)) that—

(A) has been approved under subsection (c); and

(B) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug.

(u) CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.—

(1) IN GENERAL.—For purposes of subsections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an application is submitted under subsection (b) for a non-racemic drug containing as an active ingredient (including any ester or salt of the active ingredient) a single enantiomer that is contained in a racemic drug approved in another application under subsection (b), the applicant may, in the application for such non-racemic drug, elect to have the

single enantiomer not be considered the same active ingredient as that contained in the approved racemic drug, if—

(A)(i) the single enantiomer has not been previously approved except in the approved racemic drug; and

(ii) the application submitted under subsection (b) for such non-racemic drug—

(I) includes full reports of new clinical investigations (other than bioavailability studies)—

(aa) necessary for the approval of the application under subsections (c) and (d); and

(bb) conducted or sponsored by the applicant; and

(II) does not rely on any clinical investigations that are part of an application submitted under subsection (b) for approval of the approved racemic drug; and

(B) the application submitted under subsection (b) for such non-racemic drug is not submitted for approval of a condition of use—

(i) in a therapeutic category in which the approved racemic drug has been approved; or

(ii) for which any other enantiomer of the racemic drug has been approved.

(2) LIMITATION.—

(A) NO APPROVAL IN CERTAIN THERAPEUTIC CATEGORIES.—Until the date that is 10 years after the date of approval of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph, the Secretary shall not approve such non-racemic drug for any condition of use in the therapeutic category in which the racemic drug has been approved.

(B) LABELING.—If applicable, the labeling of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph shall include a statement that the non-racemic drug is not approved, and has not been shown to be safe and effective, for any condition of use of the racemic drug.

(3) DEFINITION.—

(A) IN GENERAL.—For purposes of this subsection, the term "therapeutic category" means a therapeutic category identified in the list developed by the United States Pharmacopeia pursuant to section 1860D–4(b)(3)(C)(ii) of the Social Security Act and as in effect on the date of the enactment of this subsection.

(B) PUBLICATION BY SECRETARY.—The Secretary shall publish the list described in subparagraph (A) and may amend such list by regulation.

(4) AVAILABILITY.—The election referred to in paragraph (1) may be made only in an application that is submitted to the Secretary after the date of the enactment of this subsection and before October 1, 2017.

(v) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997.—

(1) ANTIBIOTIC DRUGS APPROVED BEFORE NOVEMBER 21, 1997.—

(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable.

(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of the enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of an application approved by the Secretary under section 507 of this Act (as in effect before November 21, 1997).

(2) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997, BUT NOT APPROVED.—

(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) may elect to be eligible for, with respect to the drug—

(i)(I) the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; and

(II) the 5-year exclusivity period referred to under clause (ii) of subsection (c)(3)(E) and under clause (ii) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; or

(ii) a patent term extension under section 156 of title 35, United States Code, subject to the requirements of such section.

(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of the enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of 1 or more applications received by the Secretary under section 507 of this Act (as in effect before November 21, 1997), none of which was approved by the Secretary under such section.

(3) LIMITATIONS.—

(A) EXCLUSIVITIES AND EXTENSIONS.—Paragraphs (1)(A) and (2)(A) shall not be construed to entitle a drug that is the subject of an approved application described in subparagraphs (1)(B)(i) or (2)(B)(i), as applicable, to any market exclusivities or patent extensions other than those exclusivities or extensions described in paragraph (1)(A) or (2)(A).

(B) CONDITIONS OF USE.—Paragraphs (1)(A) and (2)(A)(i) shall not apply to any condition of use for which the drug referred to in subparagraph (1)(B)(i) or (2)(B)(i), as applicable, was approved before the date of the enactment of this subsection.

(4) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding section 125, or any other provision, of the Food and Drug Administration Modernization Act of 1997, or any other provision of law, and subject to the limitations in paragraphs (1), (2), and (3), the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply to any drug subject to paragraph (1) or any drug with respect to which an election is made under paragraph (2)(A).

(w) DEADLINE FOR DETERMINATION ON CERTAIN PETITIONS.—The Secretary shall issue a final, substantive determination on a petition submitted pursuant to subsection (b) of section 314.161 of title 21, Code of Federal Regulations (or any successor regulations), no later than 270 days after the date the petition is submitted.

(x) STRUCTURED RISK-BENEFIT ASSESSMENT FRAMEWORK.—

(1) IN GENERAL.—The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process—

(A) to facilitate the balanced consideration of benefits and risks; and

(B) to develop and implement a consistent and systematic approach to the discussion of, regulatory decisionmaking with respect to, and the communication of, the benefits and risks of new drugs.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall alter the criteria for evaluating an application for premarket approval of a drug.

(y) DEVELOPMENT AND USE OF PATIENT EXPERIENCE DATA TO ENHANCE STRUCTURED RISK-BENEFIT ASSESSMENT FRAMEWORK.—

(1) IN GENERAL.—Not later than two years after the date of the enactment of this subsection, the Secretary shall establish and implement processes under which—

(A) an entity seeking to develop patient experience data may submit to the Secretary—

(i) initial research concepts for feedback from the Secretary; and

(ii) with respect to patient experience data collected by the entity, draft guidance documents, completed data, and summaries and analyses of such data;

(B) the Secretary may request such an entity to submit such documents, data, and summaries and analyses; and

(C) patient experience data may be developed and used to enhance the structured risk-benefit assessment framework under subsection (x).

(2) PATIENT EXPERIENCE DATA.—In this subsection, the term "patient experience data" means data collected by patients, parents, caregivers, patient advocacy organizations, disease research foundations, medical researchers, research sponsors, or other parties determined appropriate by the Secretary that is intended to facilitate or enhance the Secretary's risk-benefit assessments, including information about the impact of a disease or a therapy on patients' lives.

(z) APPROVAL OF CERTAIN ANTIBACTERIAL AND ANTIFUNGAL DRUGS FOR USE IN A LIMITED POPULATION OF PATIENTS.—

(1) PROCESS.—At the request of the sponsor of an antibacterial or antifungal drug that is intended to treat a serious or life-threatening infection, the Secretary—

(A) may execute a written agreement with the sponsor on the process for developing data to support an application for approval of such drug, for use in a limited population of patients in accordance with this subsection;

(B) shall proceed in accordance with this subsection only if a written agreement is reached under subparagraph (A);

(C) shall provide the sponsor with an opportunity to request meetings under paragraph (2);

(D) if a written agreement is reached under subparagraph (A), may approve the drug under this subsection for such use—

(i) in a limited population of patients for which there is an unmet medical need;

(ii) based on a streamlined development program; and

(iii) only if the standards for approval under subsections (c) and (d) of this section or licensure under section 351 of the Public Health Service Act, as applicable, are met; and

(E) in approving a drug in accordance with this subsection, subject to subparagraph (D)(iii), may rely upon—

(i) traditional endpoints, alternate endpoints, or a combination of traditional and alternate endpoints, and, as appropriate, data sets of a limited size; and

(ii)(I) additional data, including preclinical, pharmacologic, or pathophysiologic evidence;

(II) nonclinical susceptibility and pharmacokinetic data;

(III) data from phase 2 clinical trials; and

(IV) such other confirmatory evidence as the Secretary determines appropriate to approve the drug.

(2) FORMAL MEETINGS.—

(A) IN GENERAL.—To help to expedite and facilitate the development and review of a drug for which a sponsor intends to request approval in accordance with this subsection, the Secretary may, at the request of the sponsor, conduct meetings that provide early consultation, timely advice, and sufficient opportunities to develop an agreement described in paragraph (1)(A) and help the sponsor design and conduct a drug development program as efficiently as possible, including the following types of meetings:

(i) An early consultation meeting.

(ii) An assessment meeting.

(iii) A postapproval meeting.

(B) NO ALTERING OF GOALS.—Nothing in this paragraph shall be construed to alter agreed upon goals and procedures identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012.

(C) BREAKTHROUGH THERAPIES.—In the case of a drug designated as a breakthrough therapy under section 506(a), the sponsor of such drug may elect to utilize meetings provided under such section with respect to such drug in lieu of meetings described in subparagraph (A).

(3) LABELING REQUIREMENT.—The labeling of an antibacterial or antifungal drug approved in accordance with this subsection shall contain the statement "Limited Population" in a prominent manner and adjacent to, and not more prominent than, the brand name of the product. The prescribing information for such antibacterial or antifungal drug required by section 201.57 of title 21, Code of Federal Regulations (or any successor regulation) shall also include the following statement: "This drug is indicated for use in a limited and specific population of patients.".

(4) PROMOTIONAL MATERIALS.—The provisions of section 506(c)(2)(B) shall apply with respect to approval in accordance with this subsection to the same extent and in the same manner as such provisions apply with respect to accelerated approval in accordance with section 506(c)(1).

(5) TERMINATION OF REQUIREMENTS OR CONDITIONS.—If a drug is approved in accordance with this subsection for an indication in a limited population of patients and is subsequently approved or licensed under this section or section 351 of the Public Health Service Act, other than in accordance with this subsection, for—

(A) the same indication and the same conditions of use, the Secretary shall remove any labeling requirements or postmarketing conditions that were made applicable to the drug under this subsection; or

(B) a different indication or condition of use, the Secretary shall not apply the labeling requirements and postmarketing conditions that were made applicable to the drug under this subsection to the subsequent approval of the drug for such different indication or condition of use.

(6) RELATION TO OTHER PROVISIONS.—Nothing in this subsection shall be construed to prohibit the approval of a drug for use in a limited population of patients in accordance with this subsection, in combination with—

(A) an agreement on the design and size of a clinical trial pursuant to subparagraphs (B) and (C) of subsection (b)(5);

(B) designation and treatment of the drug as a breakthrough therapy under section 506(a);

(C) designation and treatment of the drug as a fast track product under section 506(b); or

(D) accelerated approval of the drug in accordance with section 506(c).

(7) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed—

(A) to alter the standards of evidence under subsection (c) or (d) (including the substantial evidence standard in subsection (d));

(B) to waive or otherwise preclude the application of requirements under subsection (o);

(C) to otherwise, in any way, limit the authority of the Secretary to approve products pursuant to this Act and the Public Health Service Act as authorized prior to the date of enactment of this subsection; or

(D) to restrict in any manner, the prescribing of antibiotics or other products by health care providers, or to otherwise limit or restrict the practice of health care.

(8) EFFECTIVE IMMEDIATELY.—The Secretary shall have the authorities vested in the Secretary by this subsection beginning on the date of enactment of this subsection, irrespective of when and whether the Secretary promulgates final regulations or guidance.

(9) DEFINITIONS.—In this subsection:

(A) EARLY CONSULTATION MEETING.—The term "early consultation meeting" means a pre-investigational new drug meeting or an end-of-phase-1 meeting that—

(i) is conducted to review and reach a written agreement—

(I) on the scope of the streamlined development plan for a drug for which a sponsor intends to request approval in accordance with this subsection; and

(II) which, as appropriate, may include agreement on the design and size of necessary preclinical and clinical studies early in the development process, including clinical trials whose data are intended to form the primary basis for an effectiveness claim; and

(ii) provides an opportunity to discuss expectations of the Secretary regarding studies or other information that the Secretary deems appropriate for purposes of applying paragraph (5), relating to the termination of labeling requirements or postmarketing conditions.

(B) ASSESSMENT MEETING.—The term "assessment meeting" means an end-of-phase 2 meeting, pre-new drug application meeting, or pre-biologics license application meeting conducted to resolve questions and issues raised during the course of clinical investigations, and details addressed in the written agreement regarding postapproval commitments or expansion of approved uses.

(C) POSTAPPROVAL MEETING.—The term "postapproval meeting" means a meeting following initial approval or licensure of the drug for use in a limited population, to discuss any issues identified by the Secretary or the sponsor regarding postapproval commitments or expansion of approved uses.

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SEC. 505A. PEDIATRIC STUDIES OF DRUGS.

(a) DEFINITIONS.—As used in this section, the term "pediatric studies" or "studies" means at least one clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age groups (including neonates in appropriate cases) in which a drug is anticipated to be used, and, at the discretion of the Secretary, may include preclinical studies.

(b) MARKET EXCLUSIVITY FOR NEW DRUGS.—

(1) IN GENERAL.—Except as provided in paragraph (2), if, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with subsection (d)(3)—

(A)(i)(I) the period referred to in subsection (c)(3)(E)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

(II) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(E) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and

(ii) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and

(B)(i) if the drug is the subject of—

(I) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

(II) a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

(ii) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application

may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

(2) EXCEPTION.—The Secretary shall not extend the period referred to in paragraph (1)(A) or (1)(B) if the determination made under subsection (d)(3) is made later than 9 months prior to the expiration of such period.

(3) RELATION TO EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in paragraph (1) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in paragraph (1) shall be in addition to any extensions under section 505G.

(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—

(1) IN GENERAL.—Except as provided in paragraph (2), if the Secretary determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under section 505(b)(1) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with subsection (d)(3)—

(A)(i)(I) the period referred to in subsection (c)(3)(E)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

(II) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(D) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and

(ii) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and

(B)(i) if the drug is the subject of—

(I) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

(II) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B)(ii) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

(ii) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

(2) EXCEPTION.—The Secretary shall not extend the period referred to in paragraph (1)(A) or (1)(B) if the determination made under subsection (d)(3) is made later than 9 months prior to the expiration of such period.

(3) RELATION TO EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in paragraph (1) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in paragraph (1) shall be in addition to any extensions under section 505G.

(d) CONDUCT OF PEDIATRIC STUDIES.—

(1) REQUEST FOR STUDIES.—

(A) IN GENERAL.—The Secretary may, after consultation with the sponsor of an application for an investigational new drug under section 505(i), the sponsor of an application for a new drug under section 505(b)(1), or the holder of an approved application for a drug under section 505(b)(1), issue to the sponsor or holder a written request for the conduct of pediatric studies for such drug. In issuing such request, the Secretary shall take into account adequate representation of children of ethnic and racial minorities. Such request to conduct pediatric studies shall be in writing and shall include a timeframe for such studies and a request to the sponsor or holder to propose pediatric labeling resulting from such studies. If a request under this subparagraph does not request studies in neonates, such request shall include a statement describing the rationale for not requesting studies in neonates.

(B) SINGLE WRITTEN REQUEST.—A single written request—

(i) may relate to more than one use of a drug; and

(ii) may include uses that are both approved and unapproved.

(2) WRITTEN REQUEST FOR PEDIATRIC STUDIES.—

(A) REQUEST AND RESPONSE.—

(i) IN GENERAL.—If the Secretary makes a written request for pediatric studies (including neonates, as appropriate) under subsection (b) or (c), the applicant or holder, not later than 180 days after receiving the written request, shall respond to the Secretary as to the intention of the applicant or holder to act on the request by—

(I) indicating when the pediatric studies will be initiated, if the applicant or holder agrees to the request; or

(II) indicating that the applicant or holder does not agree to the request and stating the reasons for declining the request.

(ii) DISAGREE WITH REQUEST.—If, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the applicant or holder does not agree to the request on the grounds that it is not possible to develop the appropriate pediatric formulation, the applicant or holder shall submit to the Secretary the reasons such pediatric formulation cannot be developed.

(B) ADVERSE EVENT REPORTS.—An applicant or holder that, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, agrees to the request for such studies shall provide the Secretary, at the same time as the submission of the reports of such studies, with all postmarket adverse event reports regarding the drug that is the subject of such studies and are available prior to submission of such reports.

(3) MEETING THE STUDIES REQUIREMENT.—Not later than 180 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 180-day period, whether the studies fairly respond to the written request, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with the requirements of the Secretary for filing.

(4) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

(5) CONSULTATION.—With respect to a drug that is a qualified countermeasure (as defined in section 319F–1 of the Public Health Service Act), a security countermeasure (as defined in section 319F–2 of the Public Health Service Act), or a qualified pandemic or epidemic product (as defined in section 319F–3 of the Public Health Service Act), the Secretary shall solicit input from the Assistant Secretary for Preparedness and Response regarding the need for and, from the Director of the Biomedical Advanced Research and Development Authority regarding the conduct of, pediatric studies under this section.

(e) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—

(1) IN GENERAL.—The Secretary shall publish a notice of any determination, made on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, that the requirements of subsection (d) have been met and that submissions and approvals under subsection (b)(2) or (j) of section 505 for a drug will be subject to the provisions of this section. Such notice shall be published not later than 30 days after the date of the Secretary's determination regarding market exclusivity and shall include a copy of the written request made under subsection (b) or (c).

(2) IDENTIFICATION OF CERTAIN DRUGS.—The Secretary shall publish a notice identifying any drug for which, on or after the

date of the enactment of the Best Pharmaceuticals for Children Act of 2007, a pediatric formulation was developed, studied, and found to be safe and effective in the pediatric population (or specified subpopulation) if the pediatric formulation for such drug is not introduced onto the market within one year after the date that the Secretary publishes the notice described in paragraph (1). Such notice identifying such drug shall be published not later than 30 days after the date of the expiration of such one year period.

(f) INTERNAL REVIEW OF WRITTEN REQUESTS AND PEDIATRIC STUDIES.—

(1) INTERNAL REVIEW.—The Secretary shall utilize the internal review committee established under section 505C to review all written requests issued on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, in accordance with paragraph (2).

(2) REVIEW OF WRITTEN REQUESTS.—The committee referred to in paragraph (1) shall review all written requests issued pursuant to this section prior to being issued.

(3) REVIEW OF PEDIATRIC STUDIES.—The committee referred to in paragraph (1) may review studies conducted pursuant to this section to make a recommendation to the Secretary whether to accept or reject such reports under subsection (d)(3).

(4) ACTIVITY BY COMMITTEE.—The committee referred to in paragraph (1) may operate using appropriate members of such committee and need not convene all members of the committee.

(5) DOCUMENTATION OF COMMITTEE ACTION.—For each drug, the committee referred to in paragraph (1) shall document, for each activity described in paragraph (2) or (3), which members of the committee participated in such activity.

(6) TRACKING PEDIATRIC STUDIES AND LABELING CHANGES.—The Secretary, in consultation with the committee referred to in paragraph (1), shall track and make available to the public, in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration—

(A) the number of studies conducted under this section and under section 409I of the Public Health Service Act;

(B) the specific drugs and drug uses, including labeled and off-labeled indications, studied under such sections;

(C) the types of studies conducted under such sections, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;

(D) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons such formulations were not developed;

(E) the labeling changes made as a result of studies conducted under such sections;

(F) an annual summary of labeling changes made as a result of studies conducted under such sections for distribution pursuant to subsection (k)(2); and

(G) information regarding reports submitted on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007.

(g) LIMITATIONS.—Notwithstanding subsection (c)(2), a drug to which the six-month period under subsection (b) or (c) has already been applied—

(1) may receive an additional six-month period under subsection (c)(1)(A)(i)(II) for a supplemental application if all other requirements under this section are satisfied, except that such drug may not receive any additional such period under subsection (c)(1)(B); and

(2) may not receive any additional such period under subsection (c)(1)(A)(ii).

(h) RELATIONSHIP TO PEDIATRIC RESEARCH REQUIREMENTS.—Exclusivity under this section shall only be granted for the completion of a study or studies that are the subject of a written request and for which reports are submitted and accepted in accordance with subsection (d)(3). Written requests under this section may consist of a study or studies required under section 505B.

(i) LABELING CHANGES.—

(1) PRIORITY STATUS FOR PEDIATRIC APPLICATIONS AND SUPPLEMENTS.—Any application or supplement to an application under section 505 proposing a labeling change as a result of any pediatric study conducted pursuant to this section—

(A) shall be considered to be a priority application or supplement; and

(B) shall be subject to the performance goals established by the Commissioner for priority drugs.

(2) DISPUTE RESOLUTION.—

(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE.—If, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Commissioner determines that the sponsor and the Commissioner have been unable to reach agreement on appropriate changes to the labeling for the drug that is the subject of the application, not later than 180 days after the date of submission of the application—

(i) the Commissioner shall request that the sponsor of the application make any labeling change that the Commissioner determines to be appropriate; and

(ii) if the sponsor of the application does not agree within 30 days after the Commissioner's request to make a labeling change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Committee.

(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A)(ii), the Pediatric Advisory Committee shall—

(i) review the pediatric study reports; and

(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.

(C) CONSIDERATION OF RECOMMENDATIONS.—The Commissioner shall consider the recommendations of the Pediatric Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application to make any la-

beling change that the Commissioner determines to be appropriate.

(D) MISBRANDING.—If the sponsor of the application, within 30 days after receiving a request under subparagraph (C), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application to be misbranded.

(E) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under this Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

(j) OTHER LABELING CHANGES.—If, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary determines that a pediatric study conducted under this section does or does not demonstrate that the drug that is the subject of the study is safe and effective, including whether such study results are inconclusive, in pediatric populations or subpopulations, the Secretary shall order the labeling of such product to include information about the results of the study and a statement of the Secretary's determination.

(k) DISSEMINATION OF PEDIATRIC INFORMATION.—

(1) IN GENERAL.—Not later than 210 days after the date of submission of a report on a pediatric study under this section, the Secretary shall make available to the public the medical, statistical, and clinical pharmacology reviews of pediatric studies conducted under subsection (b) or (c).

(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary shall include as a requirement of a written request that the sponsors of the studies that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(6)(F) distribute, at least annually (or more frequently if the Secretary determines that it would be beneficial to the public health), such information to physicians and other health care providers.

(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

(l) ADVERSE EVENT REPORTING.—

(1) REPORTING IN FIRST 18-MONTH PERIOD.—Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, during the 18-month period beginning on the date a labeling change is approved pursuant to subsection (i), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109). In considering the reports, the Director of such Office shall provide for the re-

view of the reports by the Pediatric Advisory Committee, including obtaining any recommendations of such Committee regarding whether the Secretary should take action under this Act in response to such reports.

(2) REPORTING IN SUBSEQUENT PERIODS.—Following the 18-month period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics all pediatric adverse event reports for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such Committee regarding whether the Secretary should take action in response to such reports.

(3) PRESERVATION OF AUTHORITY.—Nothing in this subsection shall prohibit the Office of Pediatric Therapeutics from providing for the review of adverse event reports by the Pediatric Advisory Committee prior to the 18-month period referred to in paragraph (1), if such review is necessary to ensure safe use of a drug in a pediatric population.

(4) EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.

(m) CLARIFICATION OF INTERACTION OF MARKET EXCLUSIVITY UNDER THIS SECTION AND MARKET EXCLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL OF A DRUG UNDER SECTION 505(j).—If a 180-day period under section 505(j)(5)(B)(iv) overlaps with a 6-month exclusivity period under this section, so that the applicant for approval of a drug under section 505(j) entitled to the 180-day period under that section loses a portion of the 180-day period to which the applicant is entitled for the drug, the 180-day period shall be extended from—

(1) the date on which the 180-day period would have expired by the number of days of the overlap, if the 180-day period would, but for the application of this subsection, expire after the 6-month exclusivity period; or

(2) the date on which the 6-month exclusivity period expires, by the number of days of the overlap if the 180-day period would, but for the application of this subsection, expire during the six-month exclusivity period.

(n) REFERRAL IF PEDIATRIC STUDIES NOT SUBMITTED.—

(1) IN GENERAL.—Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, if pediatric studies of a drug have not been submitted by the date specified in the written request issued or if the applicant or holder does not agree to the request under subsection (d) and if the Secretary, through the committee established under section 505C, determines that there is a continuing need for information relating to the use of the drug in the pediatric population (including neonates, as appropriate), the Secretary shall carry out the following:

(A) For a drug for which a listed patent has not expired, or for which a period of exclusivity eligible for extension under subsection (b)(1) or (c)(1) of this section or under subsection (m)(2) or (m)(3) of section 351 of the Public

Health Service Act has not ended, make a determination regarding whether an assessment shall be required to be submitted under section 505B(b).

(B) For a drug that has no unexpired listed patents and for which no unexpired periods of exclusivity eligible for extension under subsection (b)(1) or (c)(1) of this section or under subsection (m)(2) or (m)(3) of section 351 of the Public Health Service Act apply, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act for the conduct of studies.

(C) For a drug that is a qualified countermeasure (as defined in section 319F–1 of the Public Health Service Act), a security countermeasure (as defined in section 319F–2 of the Public Health Service Act), or a qualified pandemic or epidemic product (as defined in section 319F–3 of such Act), in addition to any action with respect to such drug under subparagraph (A) or (B), the Secretary shall notify the Assistant Secretary for Preparedness and Response and the Director of the Biomedical Advanced Research and Development Authority of all pediatric studies in the written request issued by the Commissioner of Food and Drugs.

(2) PUBLIC NOTICE.—The Secretary shall give the public notice of a decision under paragraph (1)(A) not to require an assessment under section 505B and the basis for such decision.

(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

(o) PROMPT APPROVAL OF DRUGS UNDER SECTION 505(j) WHEN PEDIATRIC INFORMATION IS ADDED TO LABELING.—

(1) GENERAL RULE.—A drug for which an application has been submitted or approved under section 505(j) shall not be considered ineligible for approval under that section or misbranded under section 502 on the basis that the labeling of the drug omits a pediatric indication or any other aspect of labeling pertaining to pediatric use when the omitted indication or other aspect is protected by patent or by exclusivity under clause (iii) or (iv) of section 505(j)(5)(F).

(2) LABELING.—Notwithstanding clauses (iii) and (iv) of section 505(j)(5)(F), the Secretary may require that the labeling of a drug approved under section 505(j) that omits a pediatric indication or other aspect of labeling as described in paragraph (1) include—

(A) a statement that, because of marketing exclusivity for a manufacturer—

(i) the drug is not labeled for pediatric use; or

(ii) in the case of a drug for which there is an additional pediatric use not referred to in paragraph (1), the drug is not labeled for the pediatric use under paragraph (1); and

(B) a statement of any appropriate pediatric contraindications, warnings, precautions, or other information that the Secretary considers necessary to assure safe use.

(3) PRESERVATION OF PEDIATRIC EXCLUSIVITY AND OTHER PROVISIONS.—This subsection does not affect—

(A) the availability or scope of exclusivity under this section;

(B) the availability or scope of exclusivity under section 505 for pediatric formulations;

(C) the question of the eligibility for approval of any application under section 505(j) that omits any other conditions of approval entitled to exclusivity under clause (iii) or (iv) of section 505(j)(5)(F); or

(D) except as expressly provided in paragraphs (1) and (2), the operation of section 505.

(p) INSTITUTE OF MEDICINE STUDY.—Not later than 3 years after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary shall enter into a contract with the Institute of Medicine to conduct a study and report to Congress regarding the written requests made and the studies conducted pursuant to this section. The Institute of Medicine may devise an appropriate mechanism to review a representative sample of requests made and studies conducted pursuant to this section in order to conduct such study. Such study shall—

(1) review such representative written requests issued by the Secretary since 1997 under subsections (b) and (c);

(2) review and assess such representative pediatric studies conducted under subsections (b) and (c) since 1997 and labeling changes made as a result of such studies;

(3) review the use of extrapolation for pediatric subpopulations, the use of alternative endpoints for pediatric populations, neonatal assessment tools, and ethical issues in pediatric clinical trials;

(4) review and assess the number and importance of biological products for children that are being tested as a result of the amendments made by the Biologics Price Competition and Innovation Act of 2009 and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

(5) review and assess the number, importance, and prioritization of any biological products that are not being tested for pediatric use; and

(6) offer recommendations for ensuring pediatric testing of biological products, including consideration of any incentives, such as those provided under this section or section 351(m) of the Public Health Service Act.

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SEC. 505E. EXTENSION OF EXCLUSIVITY PERIOD FOR NEW QUALIFIED INFECTIOUS DISEASE PRODUCTS.

(a) EXTENSION.—If the Secretary approves an application pursuant to section 505 for a drug that has been designated as a qualified infectious disease product under subsection (d), the 4- and 5-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 505, or the 7-year period described in section 527, as applicable, shall be extended by 5 years.

(b) [RELATION TO PEDIATRIC EXCLUSIVITY.—] RELATION TO PEDIATRIC EXCLUSIVITY AND EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITIONAny extension under subsection (a) of a period shall be in addition to [any extension of the period under section 505A] *any extension of the periods under sections 505A and 505G, as applicable,* with respect to the drug.

(c) LIMITATIONS.—Subsection (a) does not apply to the approval of—

(1) a supplement to an application under section 505(b) for any qualified infectious disease product for which an extension described in subsection (a) is in effect or has expired;

(2) a subsequent application filed with respect to a product approved under section 505 for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

(3) a product that does not meet the definition of a qualified infectious disease product under subsection (g) based upon its approved uses.

(d) DESIGNATION.—

(1) IN GENERAL.—The manufacturer or sponsor of a drug may request the Secretary to designate a drug as a qualified infectious disease product at any time before the submission of an application under section 505(b) for such drug. The Secretary shall, not later than 60 days after the submission of such a request, determine whether the drug is a qualified infectious disease product.

(2) LIMITATION.—Except as provided in paragraph (3), a designation under this subsection shall not be withdrawn for any reason, including modifications to the list of qualifying pathogens under subsection (f)(2)(C).

(3) REVOCATION OF DESIGNATION.—The Secretary may revoke a designation of a drug as a qualified infectious disease product if the Secretary finds that the request for such designation contained an untrue statement of material fact.

(e) REGULATIONS.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt final regulations implementing this section, including developing the list of qualifying pathogens described in subsection (f).

(2) PROCEDURE.—In promulgating a regulation implementing this section, the Secretary shall—

(A) issue a notice of proposed rulemaking that includes the proposed regulation;

(B) provide a period of not less than 60 days for comments on the proposed regulation; and

(C) publish the final regulation not less than 30 days before the effective date of the regulation.

(3) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2), except that the Secretary may issue interim guidance for sponsors seeking designation under subsection (d) prior to the promulgation of such regulations.

(4) DESIGNATION PRIOR TO REGULATIONS.—The Secretary shall designate drugs as qualified infectious disease products under subsection (d) prior to the promulgation of regulations under this subsection, if such drugs meet the definition of a qualified infectious disease product described in subsection (g).

(f) QUALIFYING PATHOGEN.—

(1) DEFINITION.—In this section, the term "qualifying pathogen" means a pathogen identified and listed by the Secretary under paragraph (2) that has the potential to pose a serious threat to public health, such as—

(A) resistant gram positive pathogens, including methicillin-resistant Staphylococcus aureus, vancomycin-resistant Staphylococcus aureus, and vancomycin-resistant enterococcus;

(B) multi-drug resistant gram negative bacteria, including Acinetobacter, Klebsiella, Pseudomonas, and E. coli species;

(C) multi-drug resistant tuberculosis; and

(D) Clostridium difficile.

(2) LIST OF QUALIFYING PATHOGENS.—

(A) IN GENERAL.—The Secretary shall establish and maintain a list of qualifying pathogens, and shall make public the methodology for developing such list.

(B) CONSIDERATIONS.—In establishing and maintaining the list of pathogens described under this section, the Secretary shall—

(i) consider—

(I) the impact on the public health due to drug-resistant organisms in humans;

(II) the rate of growth of drug-resistant organisms in humans;

(III) the increase in resistance rates in humans; and

(IV) the morbidity and mortality in humans; and

(ii) consult with experts in infectious diseases and antibiotic resistance, including the Centers for Disease Control and Prevention, the Food and Drug Administration, medical professionals, and the clinical research community.

(C) REVIEW.—Every 5 years, or more often as needed, the Secretary shall review, provide modifications to, and publish the list of qualifying pathogens under subparagraph (A) and shall by regulation revise the list as necessary, in accordance with subsection (e).

(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—The term "qualified infectious disease product" means an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by—

(1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or

(2) qualifying pathogens listed by the Secretary under subsection (f).

SEC. 505F. UTILIZING EVIDENCE FROM CLINICAL EXPERIENCE.

(a) IN GENERAL.—The Secretary shall establish a program to evaluate the potential use of evidence from clinical experience—

(1) to help to support the approval of a new indication for a drug approved under section 505(b); and

(2) to help to support or satisfy postapproval study requirements.

(b) EVIDENCE FROM CLINICAL EXPERIENCE DEFINED.—In this section, the term "evidence from clinical experience" means data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than randomized clinical trials, including from observational studies, registries, and therapeutic use.

(c) PROGRAM FRAMEWORK.—

(1) IN GENERAL.—Not later than 18 months after the date of enactment of this section, the Secretary shall establish a draft framework for implementation of the program under this section.

(2) CONTENTS OF FRAMEWORK.—The framework shall include information describing—

(A) the current sources of data developed through clinical experience, including ongoing safety surveillance, registry, claims, and patient-centered outcomes research activities;

(B) the gaps in current data collection activities;

(C) the current standards and methodologies for collection and analysis of data generated through clinical experience; and

(D) the priority areas, remaining challenges, and potential pilot opportunities that the program established under this section will address.

(3) CONSULTATION.—

(A) IN GENERAL.—In developing the program framework under this subsection, the Secretary shall consult with regulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, disease research foundations, and other interested parties.

(B) PROCESS.—The consultation under subparagraph (A) may be carried out through approaches such as—

(i) a public-private partnership with the entities described in such subparagraph in which the Secretary may participate; or

(ii) a contract, grant, or other arrangement, as determined appropriate by the Secretary with such a partnership or an independent research organization.

(d) PROGRAM IMPLEMENTATION.—The Secretary shall, not later than 24 months after the date of enactment of this section and in accordance with the framework established under subsection (c), implement the program to evaluate the potential use of evidence from clinical experience.

(e) GUIDANCE FOR INDUSTRY.—The Secretary shall—

(1) utilize the program established under subsection (a), its activities, and any subsequent pilots or written reports, to inform a guidance for industry on—

(A) the circumstances under which sponsors of drugs and the Secretary may rely on evidence from clinical experience for the purposes described in subsection (a)(1) or (a)(2); and

(B) the appropriate standards and methodologies for collection and analysis of evidence from clinical experience submitted for such purposes;

(2) not later than 36 months after the date of enactment of this section, issue draft guidance for industry as described in paragraph (1); and

(3) not later than 48 months after the date of enactment of this section, after providing an opportunity for public comment on the draft guidance, issue final guidance.

(f) RULE OF CONSTRUCTION.—

(1) Subject to paragraph (2), nothing in this section prohibits the Secretary from using evidence from clinical experience for purposes not specified in this section, provided the Secretary determines that sufficient basis exists for any such nonspecified use.

(2) This section shall not be construed to alter—

(A) the standards of evidence under—

(i) subsection (c) or (d) of section 505, including the substantial evidence standard in such subsection (d); or

(ii) section 351(a) of the Public Health Service Act; or

(B) the Secretary's authority to require postapproval studies or clinical trials, or the standards of evidence under which studies or trials are evaluated.

SEC. 505G. COLLECTING EVIDENCE FROM CLINICAL EXPERIENCE THROUGH TARGETED EXTENSIONS OF THE SENTINEL SYSTEM.

(a) IN GENERAL.—The Secretary shall, in parallel to implementing the program established under section 505F and in order to build capacity for utilizing the evidence from clinical experience described in that section, identify and execute pilot demonstrations to extend existing use of the Sentinel System surveillance infrastructure authorized under section 505(k).

(b) PILOT DEMONSTRATIONS.—

(1) IN GENERAL.—The Secretary—

(A) shall design and implement pilot demonstrations to utilize data captured through the Sentinel System surveillance infrastructure authorized under section 505(k) for purposes of, as appropriate—

(i) generating evidence from clinical experience to improve characterization or assessment of risks or benefits of a drug approved under section 505(c);

(ii) protecting the public health; or

(iii) advancing patient-centered care; and

(B) may make strategic linkages with sources of complementary public health data and infrastructure the Secretary determines appropriate and necessary.

(2) CONSULTATION.—In developing the pilot demonstrations under this subsection, the Secretary shall—

(A) consult with regulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, disease research foundations, and other interested parties through a public process; and

(B) develop a framework to promote appropriate transparency and dialogue about research conducted under these pilot demonstrations, including by—

(i) providing adequate notice to a sponsor of a drug approved under section 505 or section 351 of the Public Health Service Act of the Secretary's intent to conduct analyses of such sponsor's drug or drugs under these pilot demonstrations;

(ii) providing adequate notice of the findings related to analyses described in clause (i) and an opportunity for the sponsor of such drug or drugs to comment on such findings; and

(iii) ensuring the protection from public disclosure of any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

(3) PUBLIC HEALTH EXEMPTION.—The Secretary may—

(A) deem such pilot demonstrations public health activities, permitting the use and disclosure of protected health information as described in section 164.512(b)(1)(iii) of title 45, Code of Federal Regulations (or any successor regulation) and exempted as a public health activity as described in section 46.101(b)(5) of title 46, Code of Federal Regulations (or any successor regulation); and

(B) deem safety surveillance performed at the request of the Food and Drug Administration or under such jurisdiction by a sponsor with responsibility for a drug approved under this section or section 351 of the Public Health Services Act using the Sentinel System surveillance infrastructure authorized under section 505(k), including use of analytic tools and querying capabilities developed to implement the active postmarket surveillance system described in this section, public health activities as described in section 164.512(b)(1)(iii) of title 45, Code of Federal Regulations (or any successor regulation) and exempted as a public health activity as described in section 46.101(b)(5) of title 46, Code of Federal Regulations (or any successor regulation).

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $3,000,000 for each of fiscal years 2016 through 2020.

SEC. 505H. STREAMLINED DATA REVIEW PROGRAM.

(a) IN GENERAL.—The Secretary shall establish a streamlined data review program under which a holder of an approved application submitted under section 505(b)(1) or under section 351(a) of the Public Health Service Act may, to support the approval or licensure (as applicable) of the use of the drug that is the subject of such approved application for a new qualified indication, submit qualified data summaries.

(b) ELIGIBILITY.—In carrying out the streamlined data review program under subsection (a), the Secretary may authorize the holder of the approved application to include one or more qualified data summaries described in subsection (a) in a supplemental application if—

(1) the drug has been approved under section 505(c) of this Act or licensed under section 351(a) of the Public Health Service Act for one or more indications, and such approval or licensure remains in effect;

(2) the supplemental application is for approval or licensure (as applicable) under such section 505(c) or 351(a) of the use of the drug for a new qualified indication under such section 505(c) or 351(a);

(3) there is an existing database acceptable to the Secretary regarding the safety of the drug developed for one or more indications of the drug approved under such section 505(c) or licensed under such section 351(a);

(4) the supplemental application incorporates or supplements the data submitted in the application for approval or licensure referred to in paragraph (1); and

(5) the full data sets used to develop the qualified data summaries are submitted, unless the Secretary determines that the full data sets are not required.

(c) PUBLIC AVAILABILITY OF INFORMATION ON PROGRAM.—The Secretary shall post on the public website of the Food and Drug Administration and update annually—

(1) the number of applications reviewed under the streamlined data review program;

(2) the average time for completion of review under the streamlined data review program versus other review of applications for new indications; and

(3) the number of applications reviewed under the streamlined data review program for which the Food and Drug Administration made use of full data sets in addition to the qualified data summary.

(d) DEFINITIONS.—In this section:

(1) The term "qualified indication" means—

(A) an indication for the treatment of cancer, as determined appropriate by the Secretary; or

(B) such other types of indications as the Secretary determines to be subject to the streamlined data review program under this section.

(2) The term "qualified data summary" means a summary of clinical data intended to demonstrate safety and effectiveness with respect to a qualified indication for use of a drug.

SEC. 505I. EXTENSION OF EXCLUSIVITY PERIODS FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.

(a) DESIGNATION.—

(1) IN GENERAL.—The Secretary shall designate a drug as a drug approved for a new indication to prevent, diagnose, or treat a rare disease or condition for purposes of granting the extensions under subsection (b) if—

(A) prior to approval of an application or supplemental application for the new indication, the drug was approved or licensed for marketing under section 505(c) of this Act or section 351(a) of the Public Health Service Act, but was not so approved or licensed for the new indication;

(B)(i) the sponsor of the approved or licensed drug files an application or a supplemental application for approval

of the new indication for use of the drug to prevent, diagnose, or treat the rare disease or condition; and

(ii) the Secretary approves the application or supplemental application; and

(C) the application or supplemental application for the new indication contains the consent of the applicant to notice being given by the Secretary under paragraph (4) respecting the designation of the drug.

(2) REVOCATION OF DESIGNATION.—

(A) IN GENERAL.—Except as provided in subparagraph (B), a designation under paragraph (1) shall not be revoked for any reason.

(B) EXCEPTION.—The Secretary may revoke a designation of a drug under paragraph (1) if the Secretary finds that the application or supplemental application resulting in such designation contained an untrue statement of material fact.

(3) NOTIFICATION PRIOR TO DISCONTINUANCE OF PRODUCTION FOR SOLELY COMMERCIAL REASONS.—A designation of a drug under paragraph (1) shall be subject to the condition that the sponsor of the drug will notify the Secretary of any discontinuance of the production of the drug for solely commercial reasons at least one year before such discontinuance.

(4) NOTICE TO PUBLIC.—Notice respecting the designation of a drug under paragraph (1) shall be made available to the public.

(b) EXTENSION.—If the Secretary designates a drug as a drug approved for a new indication for a rare disease or condition, as described in subsection (a)(1)—

(1)(A) the 4-, 5-, and 7½-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 505, and the 7-year period described in section 527, as applicable, shall be extended by 6 months; or

(B) the 4- and 12-year periods described in subparagraphs (A) and (B) of section 351(k)(7) of the Public Health Service Act and the 7-year period described in section 527, as applicable, shall be extended by 6 months; and

(2)(A) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 or a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of 6 months after the date the patent expires (including any patent extensions); or

(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a

period of 6 months after the date the patent expires (including any patent extensions).

(c) RELATION TO PEDIATRIC AND QUALIFIED INFECTIOUS DISEASE PRODUCT EXCLUSIVITY.—Any extension under subsection (b) of a period shall be in addition to any extension of the periods under sections 505A and 505E of this Act and section 351(m) of the Public Health Service Act, as applicable, with respect to the drug.

(d) LIMITATIONS.—The extension described in subsection (b) shall not apply if the drug designated under subsection (a)(1) has previously received an extension by operation of subsection (b).

(e) DEFINITION.—In this section, the term "rare disease or condition" has the meaning given to such term in section 526(a)(2).

SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.

(a) DESIGNATION OF A DRUG AS A BREAKTHROUGH THERAPY.—

(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a drug, expedite the development and review of such drug if the drug is intended, alone or in combination with 1 or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on 1 or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. (In this section, such a drug is referred to as a "breakthrough therapy".)

(2) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a breakthrough therapy. A request for the designation may be made concurrently with, or at any time after, the submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

(3) DESIGNATION.—

(A) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a breakthrough therapy and shall take such actions as are appropriate to expedite the development and review of the application for approval of such drug.

(B) ACTIONS.—The actions to expedite the development and review of an application under subparagraph (A) may include, as appropriate—

(i) holding meetings with the sponsor and the review team throughout the development of the drug;

(ii) providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable;

(iii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

(iv) assigning a cross-disciplinary project lead for the Food and Drug Administration review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and

(v) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.

(b) DESIGNATION OF DRUG AS FAST TRACK PRODUCT.—

(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition, or if the Secretary designates the drug as a qualified infectious disease product under section 505E(d). (In this section, such a drug is referred to as a "fast track product".)

(2) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

(3) DESIGNATION.—Within 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

(c) ACCELERATED APPROVAL OF A DRUG FOR A SERIOUS OR LIFE-THREATENING DISEASE OR CONDITION, INCLUDING A FAST TRACK PRODUCT.—

(1) IN GENERAL.—

(A) ACCELERATED APPROVAL.—The Secretary may approve an application for approval of a product for a serious or life-threatening disease or condition, including a fast track product, under section 505(c) or section 351(a) of the Public Health Service Act upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. The approval described in the preceding sentence is referred to in this section as "accelerated approval".

(B) EVIDENCE.—The evidence to support that an endpoint is reasonably likely to predict clinical benefit under subparagraph (A) may include epidemiological, pathophysiological, therapeutic, pharmacologic, or other evidence developed using biomarkers, for example, or other scientific methods or tools.

(2) LIMITATION.—Approval of a product under this subsection may be subject to 1 or both of the following requirements:

(A) That the sponsor conduct appropriate postapproval studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit.

(B) That the sponsor submit copies of all promotional materials related to the product during the preapproval review period and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a product approved under accelerated approval using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing) if—

(A) the sponsor fails to conduct any required postapproval study of the drug with due diligence;

(B) a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit;

(C) other evidence demonstrates that the product is not safe or effective under the conditions of use; or

(D) the sponsor disseminates false or misleading promotional materials with respect to the product.

(d) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK PRODUCT.—

(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective, the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant—

(A) provides a schedule for submission of information necessary to make the application complete; and

(B) pays any fee that may be required under section 736.

(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

[(f)**]** *(e)* AWARENESS EFFORTS.—The Secretary shall—

(1) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions of this sec-

tion applicable to breakthrough therapies, accelerated approval, and and fast track products; and

(2) establish a program to encourage the development of surrogate and clinical endpoints, including biomarkers, and other scientific methods and tools that can assist the Secretary in determining whether the evidence submitted in an application is reasonably likely to predict clinical benefit for serious or life-threatening conditions for which significant unmet medical needs exist.

[(e)] *(f)* CONSTRUCTION.—

(1) PURPOSE.—The amendments made by the Food and Drug Administration Safety and Innovation Act to this section are intended to encourage the Secretary to utilize innovative and flexible approaches to the assessment of products under accelerated approval for treatments for patients with serious or life-threatening diseases or conditions and unmet medical needs.

(2) CONSTRUCTION.—Nothing in this section shall be construed to alter the standards of evidence under subsection (c) or (d) of section 505 (including the substantial evidence standard in section 505(d)) of this Act or under section 351(a) of the Public Health Service Act. Such sections and standards of evidence apply to the review and approval of products under this section, including whether a product is safe and effective. Nothing in this section alters the ability of the Secretary to rely on evidence that does not come from adequate and well-controlled investigations for the purpose of determining whether an endpoint is reasonably likely to predict clinical benefit as described in subsection (b)(1)(B).

(g) ACCELERATED APPROVAL DEVELOPMENT PLAN.—

(1) IN GENERAL.—In the case of a drug that the Secretary determines may be eligible for accelerated approval in accordance with subsection (c), the sponsor of such drug may request, at any time after the submission of an application for the investigation of the drug under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act, that the Secretary agree to an accelerated approval development plan described in paragraph (2).

(2) PLAN DESCRIBED.—A plan described in this paragraph, with respect to a drug described in paragraph (1), is an accelerated approval development plan, which shall include agreement on—

(A) the surrogate endpoint to be assessed under such plan;

(B) the design of the study that will utilize the surrogate endpoint; and

(C) the magnitude of the effect of the drug on the surrogate endpoint that is the subject of the agreement that would be sufficient to form the primary basis of a claim that the drug is effective.

(3) MODIFICATION; TERMINATION.—The Secretary may require the sponsor of a drug that is the subject of an accelerated approval development plan to modify or terminate the plan if additional data or information indicates that—

(A) the plan as originally agreed upon is no longer sufficient to demonstrate the safety and effectiveness of the drug involved; or

(B) the drug is no longer eligible for accelerated approval under subsection (c).

(4) SPONSOR CONSULTATION.—If the Secretary requires the modification or termination of an accelerated approval development plan under paragraph (3), the sponsor shall be granted a request for a meeting to discuss the basis of the Secretary's decision before the effective date of the modification or termination.

(5) DEFINITION.—In this section, the term "accelerated approval development plan" means a development plan agreed upon by the Secretary and the sponsor submitting the plan that contains study parameters for the use of a surrogate endpoint that—

(A) is reasonably likely to predict clinical benefit; and

(B) is intended to be the basis of the accelerated approval of a drug in accordance with subsection (c).

* * * * * * *

SEC. 507. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.

(a) PROCESS FOR QUALIFICATION.—

(1) IN GENERAL.—The Secretary shall establish a process for the qualification of drug development tools for a proposed context of use under which—

(A)(i) a requestor initiates such process by submitting a letter of intent to the Secretary; and

(ii) the Secretary shall accept or decline to accept such letter of intent;

(B)(i) if the Secretary accepts the letter of intent, a requestor shall submit a qualification plan to the Secretary; and

(ii) the Secretary shall accept or decline to accept the qualification plan; and

(C)(i) if the Secretary accepts the qualification plan, the requestor submits to the Secretary a full qualification package;

(ii) the Secretary shall determine whether to accept such qualification package for review; and

(iii) if the Secretary accepts such qualification package for review, the Secretary shall conduct such review in accordance with this section.

(2) ACCEPTANCE AND REVIEW OF SUBMISSIONS.—

(A) IN GENERAL.—The succeeding provisions of this paragraph shall apply with respect to the treatment of a letter of intent, a qualification plan, or a full qualification package submitted under paragraph (1) (referred to in this paragraph as "qualification submissions").

(B) ACCEPTANCE FACTORS; NONACCEPTANCE.—The Secretary shall determine whether to accept a qualification submission based on factors which may include the scientific merit of the submission and the available resources of the Food and Drug Administration to review the qualification submission. A determination not to accept a submission under paragraph (1) shall not be construed as a

final determination by the Secretary under this section regarding the qualification of a drug development tool for its proposed context of use.

(C) PRIORITIZATION OF QUALIFICATION REVIEW.—The Secretary may prioritize the review of a full qualification package submitted under paragraph (1) with respect to a drug development tool, based on factors determined appropriate by the Secretary, including—

(i) as applicable, the severity, rarity, or prevalence of the disease or condition targeted by the drug development tool and the availability or lack of alternative treatments for such disease or condition; and

(ii) the identification, by the Secretary or by biomedical research consortia and other expert stakeholders, of such a drug development tool and its proposed context of use as a public health priority.

(D) ENGAGEMENT OF EXTERNAL EXPERTS.—The Secretary may, for purposes of the review of qualification submissions, through the use of cooperative agreements, grants, or other appropriate mechanisms, consult with biomedical research consortia and may consider the recommendations of such consortia with respect to the review of any qualification plan submitted under paragraph (1) or the review of any full qualification package under paragraph (3).

(3) REVIEW OF FULL QUALIFICATION PACKAGE.—The Secretary shall—

(A) conduct a comprehensive review of a full qualification package accepted under paragraph (1)(C); and

(B) determine whether the drug development tool at issue is qualified for its proposed context of use.

(4) QUALIFICATION.—The Secretary shall determine whether a drug development tool is qualified for a proposed context of use based on the scientific merit of a full qualification package reviewed under paragraph (3).

(b) EFFECT OF QUALIFICATION.—

(1) IN GENERAL.—A drug development tool determined to be qualified under subsection (a)(4) for a proposed context of use specified by the requestor may be used by any person in such context of use for the purposes described in paragraph (2).

(2) USE OF A DRUG DEVELOPMENT TOOL.—Subject to paragraph (3), a drug development tool qualified under this section may be used for—

(A) supporting or obtaining approval or licensure (as applicable) of a drug or biological product (including in accordance with section 506(c)) under section 505 of this Act or section 351 of the Public Health Service Act; or

(B) supporting the investigational use of a drug or biological product under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act.

(3) RESCISSION OR MODIFICATION.—

(A) IN GENERAL.—The Secretary may rescind or modify a determination under this section to qualify a drug development tool if the Secretary determines that the drug development tool is not appropriate for the proposed context of use specified by the requestor. Such a determination may be

based on new information that calls into question the basis for such qualification.

(B) MEETING FOR REVIEW.—If the Secretary rescinds or modifies under subparagraph (A) a determination to qualify a drug development tool, the requestor involved shall be granted a request for a meeting with the Secretary to discuss the basis of the Secretary's decision to rescind or modify the determination before the effective date of the rescission or modification.

(c) TRANSPARENCY.—

(1) IN GENERAL.—Subject to paragraph (3), the Secretary shall make publicly available, and update on at least a biannual basis, on the Internet website of the Food and Drug Administration the following:

(A) Information with respect to each qualification submission under the qualification process under subsection (a), including—

(i) the stage of the review process applicable to the submission;

(ii) the date of the most recent change in stage status;

(iii) whether the external scientific experts were utilized in the development of a qualification plan or the review of a full qualification package; and

(iv) submissions from requestors under the qualification process under subsection (a), including any data and evidence contained in such submissions, and any updates to such submissions.

(B) The Secretary's formal written determinations in response to such qualification submissions.

(C) Any rescissions or modifications under subsection (b)(3) of a determination to qualify a drug development tool.

(D) Summary reviews that document conclusions and recommendations for determinations to qualify drug development tools under subsection (a).

(E) A comprehensive list of—

(i) all drug development tools qualified under subsection (a); and

(ii) all surrogate endpoints which were the basis of approval or licensure (as applicable) of a drug or biological product (including in accordance with section 506(c)) under section 505 of this Act or section 351 of the Public Health Service Act.

(2) RELATION TO TRADE SECRETS ACT.—Information made publicly available by the Secretary under paragraph (1) shall be considered a disclosure authorized by law for purposes of section 1905 of title 18, United States Code.

(3) APPLICABILITY.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information contained in an application submitted under section 505 of this Act or section 351 of the Public Health Service Act that is confidential commercial or trade secret information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) to alter the standards of evidence under subsection (c) or (d) of section 505, including the substantial evidence standard in such subsection (d), or under section 351 of the Public Health Service Act (as applicable); or

(2) to limit the authority of the Secretary to approve or license products under this Act or the Public Health Service Act, as applicable (as in effect before the date of the enactment of the 21st Century Cures Act).

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $10,000,000 for each of fiscal years 2016 through 2020.

(f) DEFINITIONS.—In this section:

(1) BIOMARKER.—(A) The term "biomarker" means a characteristic (such as a physiologic, pathologic, or anatomic characteristic or measurement) that is objectively measured and evaluated as an indicator of normal biologic processes, pathologic processes, or biological responses to a therapeutic intervention; and

(B) such term includes a surrogate endpoint.

(2) BIOMEDICAL RESEARCH CONSORTIA.—The term "biomedical research consortia" means collaborative groups that may take the form of public-private partnerships and may include government agencies, institutions of higher education (as defined in section 101(a) of the Higher Education Act of 1965, patient advocacy groups, industry representatives, clinical and scientific experts, and other relevant entities and individuals.

(3) CLINICAL OUTCOME ASSESSMENT.—(A) The term "clinical outcome assessment" means a measurement of a patient's symptoms, overall mental state, or the effects of a disease or condition on how the patient functions; and

(B) such term includes a patient-reported outcome.

(4) CONTEXT OF USE.—The term "context of use" means, with respect to a drug development tool, a statement that describes the circumstances under which the drug development tool is to be used in drug development and regulatory review.

(5) DRUG DEVELOPMENT TOOL.—The term "drug development tool" includes—

(A) a biomarker;

(B) a clinical outcome assessment; and

(C) any other method, material, or measure that the Secretary determines aids drug development and regulatory review for purposes of this section.

(6) PATIENT-REPORTED OUTCOME.—The term "patient-reported outcome" means a measurement based on a report from a patient regarding the status of the patient's health condition without amendment or interpretation of the patient's report by a clinician or any other person.

(7) QUALIFICATION.—The terms "qualification" and "qualified" mean a determination by the Secretary that a drug development tool and its proposed context of use can be relied upon to have a specific interpretation and application in drug development and regulatory review under this Act.

(8) REQUESTOR.—The term "requestor" means an entity or entities, including a drug sponsor or a biomedical research consortia, seeking to qualify a drug development tool for a proposed context of use under this section.

(9) SURROGATE ENDPOINT.—The term "surrogate endpoint" means a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure, that is not itself a direct measurement of clinical benefit, and—

(A) is known to predict clinical benefit and could be used to support traditional approval of a drug or biological product; or

(B) is reasonably likely to predict clinical benefit and could be used to support the accelerated approval of a drug or biological product in accordance with section 506(c).

* * * * * * *

SEC. 510. (a) As used in this section—

(1) the term "manufacture, preparation, propagation, compounding, or processing" shall include repackaging or otherwise changing the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user; and

(2) the term "name" shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

(b)(1) During the period beginning on October 1 and ending on December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall register with the Secretary the name of such person, places of business of such person, all such establishments, the unique facility identifier of each such establishment, and a point of contact e-mail address.

(2) During the period beginning on October 1 and ending on December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a device or devices shall register with the Secretary his name, places of business, and all such establishments.

(3) The Secretary shall specify the unique facility identifier system that shall be used by registrants under paragraph (1). The requirement to include a unique facility identifier in a registration under paragraph (1) shall not apply until the date that the identifier system is specified by the Secretary under the preceding sentence.

(c) Every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices in any establishment which he owns or operates in any State shall immediately register with the Secretary—

(1) with respect to drugs, the information described under subsection (b)(1); and

(2) with respect to devices, the information described under subsection (b)(2)..

(d) Every person duly registered in accordance with the foregoing subsections of this section shall immediately register with the Secretary any additional establishment which he owns or operates in any State and in which he begins the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices.

(e) The Secretary may assign a registration number to any person or any establishment registered in accordance with this section. The Secretary may also assign a listing number to each drug or class of drugs listed under subsection (j). Any number assigned pursuant to the preceding sentence shall be the same as that assigned pursuant to the National Drug Code. The Secretary may by regulation prescribe a uniform system for the identification of devices intended for human use and may require that persons who are required to list such devices pursuant to subsection (j) shall list such devices in accordance with such system.

(f) The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this section; except that any list submitted pursuant to paragraph (3) of subsection (j) and the information accompanying any list or notice filed under paragraph (1) or (2) of that subsection shall be exempt from such inspection unless the Secretary finds that such an exemption would be inconsistent with protection of the public health.

(g) The foregoing subsections of this section shall not apply to—

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

(2) practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in research, teaching, or chemical analysis and not for sale;

(4) any distributor who acts as a wholesale distributor of devices, and who does not manufacture, repackage, process, or relabel a device; or

(5) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health.

In this subsection, the term "wholesale distributor" means any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.

(h) INSPECTIONS.—

(1) IN GENERAL.—Every establishment that is required to be registered with the Secretary under this section shall be subject to inspection pursuant to section 704.

(2) BIENNIAL INSPECTIONS FOR DEVICES.—Every establishment described in paragraph (1), in any State, that is engaged in the manufacture, propagation, compounding, or processing of a device or devices classified in class II or III shall be so inspected by one or more officers or employees duly designated by the Secretary, or by persons accredited to conduct inspections under section 704(g), at least once in the 2-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive 2-year period thereafter.

(3) RISK-BASED SCHEDULE FOR DRUGS.—The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect establishments described in paragraph (1) that are engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs (referred to in this subsection as "drug establishments") in accordance with a risk-based schedule established by the Secretary.

(4) RISK FACTORS.—In establishing the risk-based scheduled under paragraph (3), the Secretary shall inspect establishments according to the known safety risks of such establishments, which shall be based on the following factors:

(A) The compliance history of the establishment.

(B) The record, history, and nature of recalls linked to the establishment.

(C) The inherent risk of the drug manufactured, prepared, propagated, compounded, or processed at the establishment.

(D) The inspection frequency and history of the establishment, including whether the establishment has been inspected pursuant to section 704 within the last 4 years.

(E) Whether the establishment has been inspected by a foreign government or an agency of a foreign government recognized under section 809.

(F) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

(5) EFFECT OF STATUS.—In determining the risk associated with an establishment for purposes of establishing a risk-based schedule under paragraph (3), the Secretary shall not consider whether the drugs manufactured, prepared, propagated, compounded, or processed by such establishment are drugs described in section 503(b).

(6) ANNUAL REPORT ON INSPECTIONS OF ESTABLISHMENTS.—Beginning in 2014, not later than February 1 of each year, the Secretary shall make available on the Internet Web site of the Food and Drug Administration a report regarding—

(A)(i) the number of domestic and foreign establishments registered pursuant to this section in the previous fiscal year; and

(ii) the number of such domestic establishments and the number of such foreign establishments that the Secretary inspected in the previous fiscal year;

(B) with respect to establishments that manufacture, prepare, propagate, compound, or process an active ingredient of a drug, a finished drug product, or an excipient of a drug, the number of each such type of establishment; and

(C) the percentage of the budget of the Food and Drug Administration used to fund the inspections described under subparagraph (A).

(i)(1) Every person who owns or operates any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary—

(A) upon first engaging in any such activity, immediately submit a registration to the Secretary that includes—

(i) with respect to drugs, the name and place of business of such person, all such establishments, the unique facility identifier of each such establishment, a point of contact e-mail address, the name of the United States agent of each such establishment, the name of each importer of such drug in the United States that is known to the establishment, and the name of each person who imports or offers for import such drug to the United States for purposes of importation; and

(ii) with respect to devices, the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such device in the United States that is known to the establishment, and the name of each person who imports or offers for import such device to the United States for purposes of importation; and

(B) each establishment subject to the requirements of subparagraph (A) shall thereafter register with the Secretary during the period beginning on October 1 and ending on December 31 of each year.

(2) The establishment shall also provide the information required by subsection (j).

(3) The Secretary is authorized to enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).

(4) The Secretary shall specify the unique facility identifier system that shall be used by registrants under paragraph (1) with respect to drugs. The requirement to include a unique facility identifier in a registration under paragraph (1) with respect to drugs shall not apply until the date that the identifier system is specified by the Secretary under the preceding sentence.

(j)(1) Every person who registers with the Secretary under subsection (b), (c), (d), or (i) shall, at the time of registration under any such subsection, file with the Secretary a list of all drugs and a list

of all devices and a brief statement of the basis for believing that each device included in the list is a device rather than a drug (with each drug and device in each list listed by its established name (as defined in section 502(e)) and by any proprietary name) which are being manufactured, prepared, propagated, compounded, or processed by him for commercial distribution and which he has not included in any list of drugs or devices filed by him with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by—

(A) in the case of a drug contained in the applicable list and subject to section 505 or 512, or a device intended for human use contained in the applicable list with respect to which a performance standard has been established under section 514 or which is subject to section 515, a reference to the authority for the marketing of such drug or device and a copy of all labeling for such drug or device;

(B) in the case of any other drug or device contained in an applicable list—

(i) which drug is subject to section 503(b)(1), or which device is a restricted device, a copy of all labeling for such drug or device, a representative sampling of advertisements for such drug or device, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular drug product or device, or

(ii) which drug is not subject to section 503(b)(1) or which device is not a restricted device, the label and package insert for such drug or device and a representative sampling of any other labeling for such drug or device;

(C) in the case of any drug contained in an applicable list which is described in subparagraph (B), a quantitative listing of its active ingredient or ingredients, except that with respect to a particular drug product the Secretary may require the submission of a quantitative listing of all ingredients if he finds that such submission is necessary to carry out the purposes of this Act;

(D) if the registrant filing a list has determined that a particular drug product or device contained in such list is not subject to section 505 or 512, or the particular device contained in such list is not subject to a performance standard established under section 514 or to section 515 or is not a restricted device, a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular drug product or device; and

(E) in the case of a drug contained in the applicable list, the name and place of business of each manufacturer of an excipient of the listed drug with which the person listing the drug conducts business, including all establishments used in the production of such excipient, the unique facility identifier of each such establishment, and a point of contact e-mail address for each such excipient manufacturer.

(2) Each person who registers with the Secretary under this section shall report to the Secretary, with regard to drugs once during the month of June of each year and once during the month of December of each year, and with regard to devices once each year

during the period beginning on October 1 and ending on December 31, the following information:

(A) A list of each drug or device introduced by the registrant for commercial distribution which has not been included in any list previously filed by him with the Secretary under this subparagraph or paragraph (1) of this subsection. A list under this subparagraph shall list a drug or device by its established name (as defined in section 502(e)) and by any proprietary name it may have and shall be accompanied by the other information required by paragraph (1).

(B) If since the date the registrant last made a report under this paragraph (or if he has not made a report under this paragraph, since the effective date of this subsection) he has discontinued the manufacture, preparation, propagation, compounding, or processing for commercial distribution of a drug or device included in a list filed by him under subparagraph (A) or paragraph (1); notice of such discontinuance, the date of such discontinuance, and the identity (by established name (as defined in section 502(e)) and by any proprietary name) of such drug or device.

(C) If since the date the registrant reported pursuant to subparagraph (B) a notice of discontinuance he has resumed the manufacture, preparation, propagation, compounding, or processing for commercial distribution of the drug or device with respect to which such notice of discontinuance was reported; notice of such resumption, the date of such resumption, the identity of such drug or device (by established name (as defined in section 502(e)) and by any proprietary name), and the other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary pursuant to this subparagraph.

(D) Any material change in any information previously submitted pursuant to this paragraph or paragraph (1).

(3) The Secretary may also require each registrant under this section to submit a list of each drug product which (A) the registrant is manufacturing, preparing, propagating, compounding, or processing for commercial distribution, and (B) contains a particular ingredient. The Secretary may not require the submission of such a list unless he has made a finding that the submission of such a list is necessary to carry out the purposes of this Act.

(4) The Secretary shall require persons subject to this subsection to use, for purposes of this subsection, the unique facility identifier systems specified under subsections (b)(3) and (i)(4) with respect to drugs. Such requirement shall not apply until the date that the identifier system under subsection (b)(3) or (i)(4), as applicable, is specified by the Secretary.

(k) Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary or person who is accredited under section 523(a) (in such form and manner as the Secretary shall by regulation prescribe)—

(1) the class in which the device is classified under section 513 or if such person determines that the device is not classi-

fied under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

(2) action taken by such person to comply with requirements under section 514 or 515 which are applicable to the device.

A notification submitted under this subsection that contains clinical trial data for an applicable device clinical trial (as defined in section 402(j)(1) of the Public Health Service Act) shall be accompanied by the certification required under section 402(j)(5)(B) of such Act. Such certification shall not be considered an element of such notification.

(l) ❚A report under subsection (k)❚ *(1) A report under subsection (k)* is not required for a device intended for human use that is exempted from the requirements ❚of this subsection under subsection (m)❚ *of subsection (k) under subsection (m) or section 524B* or is within a type that has been classified into class I under section 513. The exception established in the preceding sentence does not apply to any class I device that is intended for a use which is of substantial importance in preventing impairment of human health, or to any class I device that presents a potential unreasonable risk of illness or injury.

(2) Not later than 120 days after the date of the enactment of the 21st Century Cures Act, the Secretary shall identify, through publication in the Federal Register, any type of class I device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Upon such publication—

(A) each type of class I device so identified shall be exempt from the requirement for a report under subsection (k); and

(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.

(m)❚(1) Not later than 60 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall publish in the Federal Register a list of each type of class II device that does not require a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device identified by the Secretary as not requiring the report shall be exempt from the requirement to provide a report under subsection (k) as of the date of the publication of the list in the Federal Register. The Secretary shall publish such list on the Internet site of the Food and Drug Administration. The list so published shall be updated not later than 30 days after each revision of the list by the Secretary.❚ *(1) The Secretary shall—*

(A) not later than 60 days after the date of the enactment of the 21st Century Cures Act—

(i) publish in the Federal Register a notice that contains a list of each type of class II device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness; and

(ii) provide for a period of not less than 60 days for public comment beginning on the date of the publication of such notice; and

(B) not later than 180 days after the date of the enactment of 21st Century Cures Act, publish in the Federal Register a list representing the Secretary's final determination with respect to the devices included in the list published under subparagraph (A).

(2) Beginning on the date that is ⟦1 day after the date of the publication of a list under this subsection,⟧ *1 day after the date of publication of the final list under paragraph (1)(B),* the Secretary may exempt a class II device from the requirement to submit a report under subsection (k), upon the Secretary's own initiative or a petition of an interested person, if the Secretary determines that such report is not necessary to assure the safety and effectiveness of the device. The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and provide a ⟦30-day period⟧ *60-day period* for public comment. Within 120 days after the issuance of the notice in the Federal Register, the Secretary shall publish an order in the Federal Register that sets forth the final determination of the Secretary regarding the exemption of the device that was the subject of the notice. If the Secretary fails to respond to a petition within 180 days of receiving it, the petition shall be deemed to be granted.

(3) Upon the publication of the final list under paragraph (1)(B)—

(A) each type of class II device so listed shall be exempt from the requirement for a report under subsection (k); and

(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.

(n)(1) The Secretary shall review the report required in subsection (k) and make a determination under section 513(f)(1) not later than 90 days after receiving the report.

(2)(A) Not later than 18 months after the date of enactment of this paragraph, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report regarding when a premarket notification under subsection (k) should be submitted for a modification or change to a legally marketed device. The report shall include the Secretary's interpretation of the following terms: "could significantly affect the safety or effectiveness of the device", "a significant change or modification in design, material, chemical composition, energy source, or manufacturing process", and "major change or modification in the intended use of the device". The report also shall discuss possible processes for industry to use to determine whether a new submission under subsection (k) is required and shall analyze how to leverage existing quality system requirements to reduce premarket burden, facilitate continual device improvement, and provide reasonable assurance of safety and effectiveness of modified devices. In developing such report, the Secretary shall consider the input of interested stakeholders.

(B) The Secretary shall withdraw the Food and Drug Administration draft guidance entitled "Guidance for Industry and FDA Staff—510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device", dated July 27, 2011, and shall not use this draft guidance as part of,

or for the basis of, any premarket review or any compliance or enforcement decisions or actions. The Secretary shall not issue—

(i) any draft guidance or proposed regulation that addresses when to submit a premarket notification submission for changes and modifications made to a manufacturer's previously cleared device before the receipt by the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate of the report required in subparagraph (A); and

(ii) any final guidance or regulation on that topic for one year after date of receipt of such report by the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

(C) The Food and Drug Administration guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device", dated January 10, 1997, shall be in effect until the subsequent issuance of guidance or promulgation, if appropriate, of a regulation described in subparagraph (B), and the Secretary shall interpret such guidance in a manner that is consistent with the manner in which the Secretary has interpreted such guidance since 1997.

(o)(1) With respect to reprocessed single-use devices for which reports are required under subsection (k):

(A) The Secretary shall identify such devices or types of devices for which reports under such subsection must, in order to ensure that the device is substantially equivalent to a predicate device, include validation data, the types of which shall be specified by the Secretary, regarding cleaning and sterilization, and functional performance demonstrating that the single-use device will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification. Within six months after enactment of this subsection, the Secretary shall publish in the Federal Register a list of the types so identified, and shall revise the list as appropriate. Reports under subsection (k) for devices or types of devices within a type included on the list are, upon publication of the list, required to include such validation data.

(B) In the case of each report under subsection (k) that was submitted to the Secretary before the publication of the initial list under subparagraph (A), or any revision thereof, and was for a device or type of device included on such list, the person who submitted the report under subsection (k) shall submit validation data as described in subparagraph (A) to the Secretary not later than nine months after the publication of the list. During such nine-month period, the Secretary may not take any action under this Act against such device solely on the basis that the validation data for the device have not been submitted to the Secretary. After the submission of the validation data to the Secretary, the Secretary may not determine that the device is misbranded under section 502(o) or adulterated under section 501(f)(1)(B), or take action against the de-

vice under section 301(p) for failure to provide any information required by subsection (k) until (i) the review is terminated by withdrawal of the submission of the report under subsection (k); (ii) the Secretary finds the data to be acceptable and issues a letter; or (iii) the Secretary determines that the device is not substantially equivalent to a predicate device. Upon a determination that a device is not substantially equivalent to a predicate device, or if such submission is withdrawn, the device can no longer be legally marketed.

(C) In the case of a report under subsection (k) for a device identified under subparagraph (A) that is of a type for which the Secretary has not previously received a report under such subsection, the Secretary may, in advance of revising the list under subparagraph (A) to include such type, require that the report include the validation data specified in subparagraph (A).

(D) Section 502(o) applies with respect to the failure of a report under subsection (k) to include validation data required under subparagraph (A).

(2) With respect to critical or semi-critical reprocessed single-use devices that, under subsection (l) or (m), are exempt from the requirement of submitting reports under subsection (k):

(A) The Secretary shall identify such devices or types of devices for which such exemptions should be terminated in order to provide a reasonable assurance of the safety and effectiveness of the devices. The Secretary shall publish in the Federal Register a list of the devices or types of devices so identified, and shall revise the list as appropriate. The exemption for each device or type included on the list is terminated upon the publication of the list. For each report under subsection (k) submitted pursuant to this subparagraph the Secretary shall require the validation data described in paragraph (1)(A).

(B) For each device or type of device included on the list under subparagraph (A), a report under subsection (k) shall be submitted to the Secretary not later than 15 months after the publication of the initial list, or a revision of the list, whichever terminates the exemption for the device. During such 15-month period, the Secretary may not take any action under this Act against such device solely on the basis that such report has not been submitted to the Secretary. After the submission of the report to the Secretary the Secretary may not determine that the device is misbranded under section 502(o) or adulterated under section 501(f)(1)(B), or take action against the device under section 301(p) for failure to provide any information required by subsection (k) until (i) the review is terminated by withdrawal of the submission; (ii) the Secretary determines by order that the device is substantially equivalent to a predicate device; or (iii) the Secretary determines by order that the device is not substantially equivalent to a predicate device. Upon a determination that a device is not substantially equivalent to a predicate device, the device can no longer be legally marketed.

(C) In the case of semi-critical devices, the initial list under subparagraph (A) shall be published not later than 18 months after the effective date of this subsection. In the case of critical

devices, the initial list under such subparagraph shall be published not later than six months after such effective date.

(D) Section 502(o) applies with respect to the failure to submit a report under subsection (k) that is required pursuant to subparagraph (A), including a failure of the report to include validation data required in such subparagraph.

(E) The termination under subparagraph (A) of an exemption under subsection (l) or (m) for a critical or semi-critical reprocessed single-use device does not terminate the exemption under subsection (l) or (m) for the original device.

(p) ELECTRONIC REGISTRATION AND LISTING.—

(1) IN GENERAL.—Registrations and listings under this section (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.

(2) ELECTRONIC DATABASE.—Not later than 2 years after the Secretary specifies a unique facility identifier system under subsections (b) and (i), the Secretary shall maintain an electronic database, which shall not be subject to inspection under subsection (f), populated with the information submitted as described under paragraph (1) that—

(A) enables personnel of the Food and Drug Administration to search the database by any field of information submitted in a registration described under paragraph (1), or combination of such fields; and

(B) uses the unique facility identifier system to link with other relevant databases within the Food and Drug Administration, including the database for submission of information under section 801(r).

(3) RISK-BASED INFORMATION AND COORDINATION.—The Secretary shall ensure the accuracy and coordination of relevant Food and Drug Administration databases in order to identify and inform risk-based inspections under section 510(h).

[SEC. 511. CLINICAL TRIAL GUIDANCE FOR ANTIBIOTIC DRUGS.

[(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this section, the Secretary shall issue guidance for the conduct of clinical trials with respect to antibiotic drugs, including antimicrobials to treat acute bacterial sinusitis, acute bacterial otitis media, and acute bacterial exacerbation of chronic bronchitis. Such guidance shall indicate the appropriate models and valid surrogate markers.

[(b) REVIEW.—Not later than 5 years after the date of the enactment of this section, the Secretary shall review and update the guidance described under subsection (a) to reflect developments in scientific and medical information and technology.]

SEC. 511. IDENTIFYING AND UPDATING SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS.

(a) PURPOSE; IDENTIFICATION OF CRITERIA.—

(1) PURPOSE.—The purpose of this section is to provide the Secretary with an expedited, flexible method for—

(A) clearance or premarket approval of antimicrobial susceptibility testing devices utilizing updated, recognized sus-

ceptibility test interpretive criteria to characterize the in vitro susceptibility of particular bacteria, fungi, or other microorganisms to antimicrobial drugs; and

(B) providing public notice of the availability of recognized interpretive criteria to meet premarket submission requirements or other requirements under this Act for antimicrobial susceptibility testing devices.

(2) IN GENERAL.—The Secretary shall identify appropriate susceptibility test interpretive criteria with respect to antimicrobial drugs—

(A) if such criteria are available on the date of approval of the drug under section 505 of this Act or licensure of the drug under section 351 of the Public Health Service Act (as applicable), upon such approval or licensure; or

(B) if such criteria are unavailable on such date, on the date on which such criteria are available for such drug.

(3) BASES FOR INITIAL IDENTIFICATION.—The Secretary shall identify appropriate susceptibility test interpretive criteria under paragraph (2), based on the Secretary's review of, to the extent available and relevant—

(A) preclinical and clinical data, including pharmacokinetic, pharmacodynamic, and epidemiological data;

(B) Bayesian and pharmacometric statistical methodologies; and

(C) such other evidence and information as the Secretary considers appropriate.

(b) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA WEBSITE.—

(1) IN GENERAL.—Not later than 1 year after the date of the enactment of the 21st Century Cures Act, the Secretary shall establish, and maintain thereafter, on the website of the Food and Drug Administration, a dedicated website that contains a list of any appropriate new or updated susceptibility test interpretive criteria standards in accordance with paragraph (2) (referred to in this section as the "Interpretive Criteria Website").

(2) LISTING OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA STANDARDS.—

(A) IN GENERAL.—The list described in paragraph (1) shall consist of any new or updated susceptibility test interpretive criteria standards that are—

(i) established by a nationally or internationally recognized standard development organization that—

(I) establishes and maintains procedures to address potential conflicts of interest and ensure transparent decisionmaking;

(II) holds open meetings to ensure that there is an opportunity for public input by interested parties, and establishes and maintains processes to ensure that such input is considered in decisionmaking; and

(III) permits its standards to be made publicly available, through the National Library of Medicine or another similar source acceptable to the Secretary; and

(ii) recognized in whole, or in part, by the Secretary under subsection (c).

(B) OTHER LIST.—The Interpretive Criteria Website shall, in addition to the list described in subparagraph (A), include a list of interpretive criteria, if any, that the Secretary has determined to be appropriate with respect to legally marketed antimicrobial drugs, where—

(i) the Secretary does not recognize, in whole or in part, an interpretive criteria standard described under subparagraph (A) otherwise applicable to such a drug;

(ii) the Secretary withdraws under subsection (c)(1)(B) recognition of a standard, in whole or in part, otherwise applicable to such a drug;

(iii) the Secretary approves an application under section 505 of this Act or section 351 of the Public Health Service Act, as applicable, with respect to marketing of such a drug for which there are no relevant interpretive criteria included in a standard recognized by the Secretary under subsection (c); or

(iv) because the characteristics of such a drug differ from other drugs with the same active ingredient, the interpretive criteria with respect to such drug—

(I) differ from otherwise applicable interpretive criteria included in a standard listed under subparagraph (A) or interpretive criteria otherwise listed under this subparagraph; and

(II) are determined by the Secretary to be appropriate for the drug.

(C) REQUIRED STATEMENTS OF LIMITATIONS OF INFORMATION.—The Interpretive Criteria Website shall include the following:

(i) A statement that—

(I) the website provides information about the susceptibility of bacteria, fungi, or other microorganisms to a certain drug (or drugs); and

(II) the safety and efficacy of the drug in treating clinical infections due to such bacteria, fungi, or other microorganisms may not have been established in adequate and well-controlled clinical trials and the clinical significance of such susceptibility information in such trials is unknown.

(ii) A statement that directs health care practitioners to consult the approved product labeling for specific drugs to determine the uses for which the Food and Drug Administration has approved the product.

(iii) Any other statement that the Secretary determines appropriate to adequately convey the limitations of the data supporting susceptibility test interpretive criteria standard listed on the website.

(3) NOTICE.—Not later than the date on which the Interpretive Criteria Website is established, the Secretary shall publish a notice of that establishment in the Federal Register.

(4) INAPPLICABILITY OF MISBRANDING PROVISION.—The inclusion in the approved labeling of an antimicrobial drug of a reference or hyperlink to the Interpretive Criteria Website, in and of itself, shall not cause the drug to be misbranded in violation of section 502, or the regulations promulgated thereunder.

(5) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code.

(c) RECOGNITION OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FROM STANDARD DEVELOPMENT ORGANIZATIONS.—

(1) IN GENERAL.—Beginning on the date of the establishment of the Interpretive Criteria Website, and at least every 6 months thereafter, the Secretary shall—

(A) evaluate any appropriate new or updated susceptibility test interpretive criteria standards established by a nationally or internationally recognized standard development organization described in subsection (b)(2)(A)(i); and

(B) publish on the public website of the Food and Drug Administration a notice—

(i) withdrawing recognition of any different susceptibility test interpretive criteria standard, in whole or in part;

(ii) recognizing the new or updated standards;

(iii) recognizing one or more parts of the new or updated interpretive criteria specified in such a standard and declining to recognize the remainder of such standard; and

(iv) making any necessary updates to the lists under subsection (b)(2).

(2) BASES FOR UPDATING INTERPRETIVE CRITERIA STANDARDS.—In evaluating new or updated susceptibility test interpretive criteria standards under paragraph (1)(A), the Secretary may consider—

(A) the Secretary's determination that such a standard is not applicable to a particular drug because the characteristics of the drug differ from other drugs with the same active ingredient;

(B) information provided by interested third parties, including public comment on the annual compilation of notices published under paragraph (3);

(C) any bases used to identify susceptibility test interpretive criteria under subsection (a)(2); and

(D) such other information or factors as the Secretary determines appropriate.

(3) ANNUAL COMPILATION OF NOTICES.—Each year, the Secretary shall compile the notices published under paragraph (1)(B) and publish such compilation in the Federal Register and provide for public comment. If the Secretary receives comments, the Secretary will review such comments and, if the Secretary determines appropriate, update pursuant to this subsection susceptibility test interpretive criteria standards—

(A) recognized by the Secretary under this subsection; or

(B) otherwise listed on the Interpretive Criteria Website under subsection (b)(2).

(4) RELATION TO SECTION 514(C).—Any susceptibility test interpretive standard recognized under this subsection or any criteria otherwise listed under subsection (b)(2)(B) shall be deemed

to be recognized as a standard by the Secretary under section 514(c)(1).

(5) VOLUNTARY USE OF INTERPRETIVE CRITERIA.—Nothing in this section prohibits a person from seeking approval or clearance of a drug or device, or changes to the drug or the device, on the basis of susceptibility test interpretive criteria standards which differ from those recognized pursuant to paragraph (1).

(d) ANTIMICROBIAL DRUG LABELING.—

(1) DRUGS MARKETED PRIOR TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—With respect to an antimicrobial drug lawfully introduced or delivered for introduction into interstate commerce for commercial distribution before the establishment of the Interpretive Criteria Website, a holder of an approved application under section 505 of this Act or section 351 of the Public Health Service Act, as applicable, for each such drug—

(A) not later than 1 year after establishment of the Interpretive Criteria Website, shall submit to the Secretary a supplemental application for purposes of changing the drug's labeling to substitute a reference or hyperlink to such Website for any susceptibility test interpretive criteria and related information; and

(B) may begin distribution of the drug involved upon receipt by the Secretary of the supplemental application for such change.

(2) DRUGS MARKETED SUBSEQUENT TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—With respect to antimicrobial drugs lawfully introduced or delivered for introduction into interstate commerce for commercial distribution on or after the date of the establishment of the Interpretive Criteria Website, the labeling for such a drug shall include, in lieu of susceptibility test interpretive criteria and related information, a reference to such Website.

(e) SPECIAL CONDITION FOR MARKETING OF ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

(1) IN GENERAL.—Notwithstanding sections 501, 502, 510, 513, and 515, if the conditions specified in paragraph (2) are met (in addition to other applicable provisions under this chapter) with respect to an antimicrobial susceptibility testing device described in subsection (f)(1), the Secretary may authorize the marketing of such device for a use described in such subsection.

(2) CONDITIONS APPLICABLE TO ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—The conditions specified in this paragraph are the following:

(A) The device is used to make a determination of susceptibility using susceptibility test interpretive criteria that are—

(i) included in a standard recognized by the Secretary under subsection (c); or

(ii) otherwise listed on the Interpretive Criteria Website under subsection (b)(2).

(B) The labeling of such device prominently and conspicuously—

(i) includes a statement that—

(I) the device provides information about the susceptibility of bacteria and fungi to certain drugs; and

(II) the safety and efficacy of such drugs in treating clinical infections due to such bacteria or fungi may not have been established in adequate and well-controlled clinical trials and the clinical significance of such susceptibility information in those instances is unknown;

(ii) includes a statement directing health care practitioners to consult the approved labeling for drugs tested using such a device, to determine the uses for which the Food and Drug Administration has approved such drugs; and

(iii) includes any other statement the Secretary determines appropriate to adequately convey the limitations of the data supporting the interpretive criteria described in subparagraph (A).

(f) DEFINITIONS.—In this section:

(1) The term "antimicrobial susceptibility testing device" means a device that utilizes susceptibility test interpretive criteria to determine and report the in vitro susceptibility of certain microorganisms to a drug (or drugs).

(2) The term "qualified infectious disease product" means a qualified infectious disease product designated under section 505E(d).

(3) The term "susceptibility test interpretive criteria" means—

(A) one or more specific numerical values which characterize the susceptibility of bacteria or other microorganisms to the drug tested; and

(B) related categorizations of such susceptibility, including categorization of the drug as susceptible, intermediate, resistant, or such other term as the Secretary determines appropriate.

(4)(A) The term "antimicrobial drug" means, subject to subparagraph (B), a systemic antibacterial or antifungal drug that—

(i) is intended for human use in the treatment of a disease or condition caused by a bacterium or fungus;

(ii) may include a qualified infectious disease product designated under section 505E(d); and

(iii) is subject to section 503(b)(1).

(B) If provided by the Secretary through regulations, such term may include—

(i) drugs other than systemic antibacterial and antifungal drugs; and

(ii) biological products (as such term is defined in section 351 of the Public Health Service Act) to the extent such products exhibit antimicrobial activity.

(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) to alter the standards of evidence—

(A) under subsection (c) or (d) of section 505, including the substantial evidence standard in section 505(d), or

under section 351 of the Public Health Service Act (as applicable); or

(B) with respect to marketing authorization for devices, under section 510, 513, or 515;

(2) to apply with respect to any drug, device, or biological product, in any context other than—

(A) an antimicrobial drug; or

(B) an antimicrobial susceptibility testing device that uses susceptibility test interpretive criteria to characterize and report the in vitro susceptibility of certain bacteria, fungi, or other microorganisms to antimicrobial drugs in accordance with this section; or

(3) unless specifically stated, to have any effect on authorities provided under other sections of this Act, including any regulations issued under such sections.

* * * * * * *

CLASSIFICATION OF DEVICES INTENDED FOR HUMAN USE

Device Classes

SEC. 513. (a)(1) There are established the following classes of devices intended for human use:

(A) CLASS I, GENERAL CONTROLS.—

(i) A device for which the controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it—

(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and

(II) does not present a potential unreasonable risk of illness or injury,

is to be regulated by the controls referred to in clause (i).

(B) CLASS II, SPECIAL CONTROLS.—A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k)), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify

the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(C) CLASS III, PREMARKET APPROVAL.—A device which because—

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

(ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

(II) presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 515, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

(2) For purposes of this section and sections 514 and 515, the safety and effectiveness of a device are to be determined—

(A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

(3)(A) Except as authorized by subparagraph (B), the effectiveness of a device is, for purposes of this section and sections 514 and 515, to be determined, in accordance with regulations promulgated by the Secretary, on the basis of well-controlled investigations, including 1 or more clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

[(B) If the Secretary**]** *(B)(i) If the Secretary* determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A))—

[(i)**]** *(I)* which is sufficient to determine the effectiveness of a device, and

[(ii)**]** *(II)* from which it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of

use prescribed, recommended, or suggested in the labeling of the device,

then, for purposes of this section and sections 514 and 515, the Secretary may authorize the effectiveness of the device to be determined on the basis of such evidence.

(ii) For purposes of clause (i), valid scientific evidence may include—

(I) evidence described in well-documented case histories, including registry data, that are collected and monitored under an acceptable protocol;

(II) studies published in peer-reviewed journals; and

(III) data collected in countries other than the United States so long as such data otherwise meet the criteria specified in this subparagraph.

(iii) In the case of a study published in a peer-reviewed journal that is offered as valid scientific evidence for purposes of clause (i), the Secretary may request data underlying the study if—

(I) the Secretary, in making such request, complies with the requirement of subparagraph (D)(ii) to consider the least burdensome appropriate means of evaluating device effectiveness or subsection (i)(1)(D) to consider the least burdensome means of determining substantial equivalence, as applicable;

(II) the Secretary furnishes a written rationale for so requesting the underlying data together with such request; and

(III) if the requested underlying data for such a study are unavailable, the Secretary shall consider such study to be part of the totality of the evidence with respect to the device, as the Secretary determines appropriate.

(C) In making a determination of a reasonable assurance of the effectiveness of a device for which an application under section 515 has been submitted, the Secretary shall consider whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls.

(D)(i) The Secretary, upon the written request of any person intending to submit an application under section 515, shall meet with such person to determine the type of valid scientific evidence (within the meaning of subparagraphs (A) and (B)) that will be necessary to demonstrate for purposes of approval of an application the effectiveness of a device for the conditions of use proposed by such person. The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device. Within 30 days after such meeting, the Secretary shall specify in writing the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the conditions of use proposed by such person.

(ii) Any clinical data, including one or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as result of a determination by the Secretary that such data are necessary to establish device effectiveness. The Secretary shall consider, in consultation with the applicant, the least burdensome ap-

propriate means of evaluating device effectiveness that would have a reasonable likelihood of resulting in approval.

(iii) For purposes of clause (ii), the term "necessary" means the minimum required information that would support a determination by the Secretary that an application provides reasonable assurance of the effectiveness of the device.

(iv) Nothing in this subparagraph shall alter the criteria for evaluating an application for premarket approval of a device.

(v) The determination of the Secretary with respect to the specification of valid scientific evidence under clauses (i) and (ii) shall be binding upon the Secretary, unless such determination by the Secretary could be contrary to the public health.

Classification; Classification Panels

(b)(1) For purposes of—

(A) determining which devices intended for human use should be subject to the requirements of general controls, performance standards, or premarket approval, and

(B) providing notice to the manufacturers and importers of such devices to enable them to prepare for the application of such requirements to devices manufactured or imported by them,

the Secretary shall classify all such devices (other than devices classified by subsection (f)) into the classes established by subsection (a). For the purpose of securing recommendations with respect to the classification of devices, the Secretary shall establish panels of experts or use panels of experts established before the date of the enactment of this section, or both. Section 14 of the Federal Advisory Committee Act shall not apply to the duration of a panel established under this paragraph.

(2) The Secretary shall appoint to each panel established under paragraph (1) persons who are qualified by training and experience to evaluate the safety and effectiveness of the devices to be referred to the panel and who, to the extent feasible, possess skill in the use of, or experience in the development, manufacture, or utilization of, such devices. The Secretary shall make appointments to each panel so that each panel shall consist of members with adequately diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences, and other related professions. In addition, each panel shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(3) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, but not at rates exceeding the daily equivalent of the rate in effect for grade GS–18 of the General Schedule, for each day so engaged, including traveltime; and while so serving away from their homes or regular

places of business each member may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

(4) The Secretary shall furnish each panel with adequate clerical and other necessary assistance.

(5)*(A)* Classification panels covering each type of device shall be scheduled to meet at such times as may be appropriate for the Secretary to meet applicable statutory deadlines.

(B) When a device is specifically the subject of review by a classification panel, the Secretary shall—

(i) ensure that adequate expertise is represented on the classification panel to assess—

(I) the disease or condition which the device is intended to cure, treat, mitigate, prevent, or diagnose; and

(II) the technology of the device; and

(ii) as part of the process to ensure adequate expertise under clause (i), give due consideration to the recommendations of the person whose premarket submission is subject to panel review on the expertise needed among the voting members of the panel.

(C) For review by a classification panel of a premarket submission for a device, the Secretary shall—

(i) provide an opportunity for the person whose premarket submission is subject to panel review to provide recommendations on the expertise needed among the voting members of the panel; and

(ii) give due consideration to such recommendations and ensure that adequate expertise is represented on advisory panels to assess—

(I) the disease or condition for which the device is intended to cure, treat, mitigate, prevent, or diagnose; and

(II) the technology of the device.

(D) For purposes of subparagraph (B)(ii), the term "adequate expertise" means, with respect to the membership of the classification panel reviewing a premarket submission, that such membership includes—

(i) two or more voting members, with a specialty or other expertise clinically relevant to the device under review; and

(ii) at least one voting member who is knowledgeable about the technology of the device.

(6)(A) Any person whose device is specifically the subject of review by a classification panel shall have—

(i) the same access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under section 552 of title 5, United States Code) as the Secretary;

(ii) the opportunity to submit, for review by a classification panel, information that is based on the data or information provided in the application submitted under section 515 by the person, which information shall be submitted to the Secretary for prompt transmittal to the classification panel; and

(iii) the same opportunity as the Secretary to participate in meetings of the panel*, including by designating a representative who will be provided a time during the panel meeting to address the panel individually (or accompanied by experts se-*

lected by such representative) for the purpose of correcting misstatements of fact or providing clarifying information, subject to the discretion of the panel chairperson.

[(B) Any meetings of a classification panel shall provide adequate time for initial presentations and for response to any differing views by persons whose devices are specifically the subject of a classification panel review, and shall encourage free and open participation by all interested persons.]

(B)(i) Any meeting of a classification panel for a device that is specifically the subject of review shall—

(I) provide adequate time for initial presentations by the person whose device is specifically the subject of a classification panel review and by the Secretary; and

(II) encourage free and open participation by all interested persons.

(ii) Following the initial presentations described in clause (i), the panel may—

(I) pose questions to a designated representative described in subparagraph (A)(iii); and

(II) consider the responses to such questions in the panel's review of the device that is specifically the subject of review by the panel.

(7) After receiving from a classification panel the conclusions and recommendations of the panel on a matter that the panel has reviewed, the Secretary shall review the conclusions and recommendations, shall make a final decision on the matter in accordance with section 515(d)(2), and shall notify the affected persons of the decision in writing and, if the decision differs from the conclusions and recommendations of the panel, shall include the reasons for the difference.

(8) A classification panel under this subsection shall not be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act.

Classification Panel Organization and Operation

(c)(1) The Secretary shall organize the panels according to the various fields of clinical medicine and fundamental sciences in which devices intended for human use are used. The Secretary shall refer a device to be classified under this section to an appropriate panel established or authorized to be used under subsection (b) for its review and for its recommendation respecting the classification of the device. The Secretary shall by regulation prescribe the procedure to be followed by the panels in making their reviews and recommendations. In making their reviews of devices, the panels, to the maximum extent practicable, shall provide an opportunity for interested persons to submit data and views on the classification of the devices.

(2)(A) Upon completion of a panel's review of a device referred to it under paragraph (1), the panel shall, subject to subparagraphs (B) and (C), submit to the Secretary its recommendation for the classification of the device. Any such recommendation shall (i) contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the recommendation is made,

and (ii) to the extent practicable, include a recommendation for the assignment of a priority for the application of the requirements of section 514 or 515 to a device recommended to be classified in class II or class III.

(B) A recommendation of a panel for the classification of a device in class I shall include a recommendation as to whether the device should be exempted from the requirements of section 510, 519, or 520(f).

(C) In the case of a device which has been referred under paragraph (1) to a panel, and which—

(i) is intended to be implanted in the human body or is purported or represented to be for a use in supporting or sustaining human life, and

(ii)(I) has been introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this section, or

(II) is within a type of device which was so introduced or delivered before such date and is substantially equivalent to another device within that type,

such panel shall recommend to the Secretary that the device be classified in class III unless the panel determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. If a panel does not recommend that such a device be classified in class III, it shall in its recommendation to the Secretary for the classification of the device set forth the reasons for not recommending classification of the device in such class.

(3) The panels shall submit to the Secretary within one year of the date funds are first appropriated for the implementation of this section their recommendations respecting all devices of a type introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this section.

Classification

(d)(1) Upon receipt of a recommendation from a panel respecting a device, the Secretary shall publish in the Federal Register the panel's recommendation and a proposed regulation classifying such device and shall provide interested persons an opportunity to submit comments on such recommendation and the proposed regulation. After reviewing such comments, the Secretary shall, subject to paragraph (2), by regulation classify such device.

(2)(A) A regulation under paragraph (1) classifying a device in class I shall prescribe which, if any, of the requirements of section 510, 519 or 520(f) shall not apply to the device. A regulation which makes a requirement of section 510, 519, or 520(f) inapplicable to a device shall be accompanied by a statement of the reasons of the Secretary for making such requirement inapplicable.

(B) A device described in subsection (c)(2)(C) shall be classified in class III unless the Secretary determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. A proposed regulation under paragraph (1) classifying such a device in a class other than class III shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for not

classifying such device in such class and an identification of the risks to health (if any) presented by such device.

(3) In the case of devices classified in class II and devices classified under this subsection in class III and described in section 515(b)(1) the Secretary may establish priorities which, in his discretion, shall be used in applying sections 514 and 515, as appropriate, to such devices.

Classification Changes

(e)(1)(A)(i) Based on new information respecting a device, the Secretary may, upon the initiative of the Secretary or upon petition of an interested person, change the classification of such device, and revoke, on account of the change in classification, any regulation or requirement in effect under section 514 or 515 with respect to such device, by administrative order published in the Federal Register following publication of a proposed reclassification order in the Federal Register, a meeting of a device classification panel described in subsection (b), and consideration of comments to a public docket, notwithstanding subchapter II of chapter 5 of title 5, United States Code. The proposed reclassification order published in the Federal Register shall set forth the proposed reclassification, and a substantive summary of the valid scientific evidence concerning the proposed reclassification, including—

(I) the public health benefit of the use of the device, and the nature and, if known, incidence of the risk of the device;

(II) in the case of a reclassification from class II to class III, why general controls pursuant to subsection (a)(1)(A) and special controls pursuant to subsection (a)(1)(B) together are not sufficient to provide a reasonable assurance of safety and effectiveness for such device; and

(III) in the case of reclassification from class III to class II, why general controls pursuant to subsection (a)(1)(A) and special controls pursuant to subsection (a)(1)(B) together are sufficient to provide a reasonable assurance of safety and effectiveness for such device.

(ii) An order under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 514 for such device.

(B) Authority to issue such administrative order shall not be delegated below the Director of the Center for Devices and Radiological Health, acting in consultation with the Commissioner.

(2) By an order issued under paragraph (1), the Secretary may change the classification of a device from class III—

(A) to class II if the Secretary determines that special controls would provide reasonable assurance of the safety and effectiveness of the device and that general controls would not provide reasonable assurance of the safety and effectiveness of the device, or

(B) to class I if the Secretary determines that general controls would provide reasonable assurance of the safety and effectiveness of the device.

Initial Classification and Reclassification of Certain Devices

(f)(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this section is classified in class III unless—

(A) the device—

(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b), or (II) which was not so introduced or delivered before such date and has been classified in class I or II, and

(ii) is substantially equivalent to another device within such type;

(B) the Secretary in response to a petition submitted under paragraph (3) has classified such device in class I or II; or

(C) the device is classified pursuant to a request submitted under paragraph (2).

A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) or (3) classifying the device in class I or II.

(2)(A)(i) Any person who submits a report under section 510(k) for a type of device that has not been previously classified under this Act, and that is classified into class III under paragraph (1), may request, within 30 days after receiving written notice of such a classification, the Secretary to classify the device.

(ii) In lieu of submitting a report under section 510(k) and submitting a request for classification under clause (i) for a device, if a person determines there is no legally marketed device upon which to base a determination of substantial equivalence (as defined in subsection (i)), a person may submit a request under this clause for the Secretary to classify the device.

(iii) Upon receipt of a request under clause (i) or (ii), the Secretary shall classify the device subject to the request under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1) within 120 days.

(iv) Notwithstanding clause (iii), the Secretary may decline to undertake a classification request submitted under clause (ii) if the Secretary identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence under paragraph (1), or when the Secretary determines that the device submitted is not of low-moderate risk or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

(v) The person submitting the request for classification under this subparagraph may recommend to the Secretary a classification for the device and shall, if recommending classification in class II, include in the request an initial draft proposal for applicable special controls, as described in subsection (a)(1)(B), that are necessary, in conjunction with general controls, to provide reasonable assurance of safety and effectiveness and a description of how the special controls provide such assurance. Any such request shall de-

scribe the device and provide detailed information and reasons for the recommended classification.

(B)(i) The Secretary shall by written order classify the device involved. Such classification shall be the initial classification of the device for purposes of paragraph (1) and any device classified under this paragraph shall be a predicate device for determining substantial equivalence under paragraph (1).

(ii) A device that remains in class III under this subparagraph shall be deemed to be adulterated within the meaning of section 501(f)(1)(B) until approved under section 515 or exempted from such approval under section 520(g).

(C) Within 30 days after the issuance of an order classifying a device under this paragraph, the Secretary shall publish a notice in the Federal Register announcing such classification.

(3)(A) The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition.

(B)(i) Upon determining that a petition does not contain any deficiency which prevents the Secretary from making a decision on the petition, the Secretary may for good cause shown refer the petition to an appropriate panel established or authorized to be used under subsection (b). A panel to which such a petition has been referred shall not later than ninety days after the referral of the petition make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed. In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the panel shall recommend that the petition be denied unless the panel determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. If the panel recommends that such petition be approved, it shall in its recommendation to the Secretary set forth its reasons for such recommendation.

(ii) The requirements of paragraphs (1) and (2) of subsection (c) (relating to opportunities for submission of data and views and recommendations respecting priorities and exemptions from sections 510, 519, and 520(f)) shall apply with respect to consideration by panels of petitions submitted under subparagraph (A).

(C)(i) Within ninety days from the date the Secretary receives the recommendation of a panel respecting a petition (but not later than 210 days after the filing of such petition) the Secretary shall by order deny or approve the petition. If the Secretary approves the petition, the Secretary shall order the classification of the device into class I or class II in accordance with the criteria prescribed by

subsection (a)(1)(A) or (a)(1)(B). In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall deny the petition unless the Secretary determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. An order approving such petition shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for approving the petition and an identification of the risks to health (if any) presented by the device to which such order applies.

(ii) The requirements of paragraphs (1) and (2)(A) of subsection (d) (relating to publication of recommendations, opportunity for submission of comments, and exemption from sections 510, 519, and 520(f)) shall apply with respect to action by the Secretary on petitions submitted under subparagraph (A).

(4) If a manufacturer reports to the Secretary under section 510(k) that a device is substantially equivalent to another device—

(A) which the Secretary has classified as a class III device under subsection (b),

(B) which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990, and

(C) for which no final regulation requiring premarket approval has been promulgated under section 515(b),

the manufacturer shall certify to the Secretary that the manufacturer has conducted a reasonable search of all information known or otherwise available to the manufacturer respecting such other device and has included in the report under section 510(k) a summary of and a citation to all adverse safety and effectiveness data respecting such other device and respecting the device for which the section 510(k) report is being made and which has not been submitted to the Secretary under section 519. The Secretary may require the manufacturer to submit the adverse safety and effectiveness data described in the report.

(5) The Secretary may not withhold a determination of the initial classification of a device under paragraph (1) because of a failure to comply with any provision of this Act unrelated to a substantial equivalence decision, including a finding that the facility in which the device is manufactured is not in compliance with good manufacturing requirements as set forth in regulations of the Secretary under section 520(f) (other than a finding that there is a substantial likelihood that the failure to comply with such regulations will potentially present a serious risk to human health).

Information

(g) Within sixty days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under this Act, the Secretary shall provide such person a written statement of the classification (if any) of such device and the requirements of this Act applicable to the device.

Definitions

(h) For purposes of this section and sections 501, 510, 514, 515, 516, 519, and 520—

(1) a reference to "general controls" is a reference to the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520,

(2) a reference to "class I,""class II," or "class III" is a reference to a class of medical devices described in subparagraph (A), (B), or (C) of subsection (a)(1), and

(3) a reference to a "panel under section 513" is a reference to a panel established or authorized to be used under this section.

Substantial Equivalence

(i)(1)(A) For purposes of determinations of substantial equivalence under subsection (f) and section 520(l), the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device—

(i) has the same technological characteristics as the predicate device, or

(ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 523, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.

(B) For purposes of subparagraph (A), the term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

(C) To facilitate reviews of reports submitted to the Secretary under section 510(k), the Secretary shall consider the extent to which reliance on postmarket controls may expedite the classification of devices under subsection (f)(1) of this section.

(D)(i) Whenever the Secretary requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

(ii) For purposes of clause (i), the term "necessary" means the minimum required information that would support a determination of substantial equivalence between a new device and a predicate device.

(iii) Nothing in this subparagraph shall alter the standard for determining substantial equivalence between a new device and a predicate device.

(E)(i) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 510(k). However, when determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the "Director") may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing—

(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and

(II) that such use could cause harm.

(ii) Such determination shall—

(I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director's concerns regarding the proposed labeling;

(II) specify the limitations on the use of the device not included in the proposed labeling; and

(III) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for such device conforms to the limitations specified in subclause (II).

(iii) The responsibilities of the Director under this subparagraph may not be delegated.

(F) Not later than 270 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) or section 520(l).

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3)(A) As part of a submission under section 510(k) respecting a device, the person required to file a premarket notification under such section shall provide an adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request by any person.

(B) Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such device is substantially equivalent to another device.

(j) TRAINING AND OVERSIGHT IN LEAST BURDENSOME APPROPRIATE MEANS CONCEPT.—

(1) TRAINING.—Each employee of the Food and Drug Administration who is involved in the review of premarket submissions under section 515 or section 510(k), including supervisors, shall receive training regarding the meaning and implementation of the least burdensome appropriate means concept in the

context of the use of that term in subsections (a)(3)(D) and (i)(1)(D) of this section and in section 515(c)(5).

(2) GUIDANCE DOCUMENTS.—

(A) DRAFT UPDATED GUIDANCE.—Not later than 12 months after the date of enactment of the 21st Century Cures Act, the Secretary shall issue a draft guidance document updating the October 4, 2002, guidance document entitled "The Least Burdensome Provision of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry".

(B) MEETING OF STAKEHOLDERS.—In developing such draft guidance document, the Secretary shall convene a meeting of stakeholders to ensure a full record to support the publication of such document.

(3) OMBUDSMAN AUDIT.—Not later than 18 months after the date of issuance of final version of the draft guidance under paragraph (2), the ombudsman for the organizational unit of the Food and Drug Administration responsible for the premarket review of devices shall—

(A) conduct, or have conducted, an audit of the training described in paragraph (1); and

(B) include in such audit interviews with a representative sample of persons from industry regarding their experience in the device premarket review process.

PERFORMANCE STANDARDS

Provisions of Standards

SEC. 514. (a)(1) The special controls required by section 513(a)(1)(B) shall include performance standards for a class II device if the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device. A class III device may also be considered a class II device for purposes of establishing a standard for the device under subsection (b) if the device has been reclassified as a class II device under an administrative order under section 513(e) (or a regulation promulgated under such section prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act) but such order (or regulation) provides that the reclassification is not to take effect until the effective date of such a standard for the device.

(2) A performance standard established under subsection (b) for a device—

(A) shall include provisions to provide reasonable assurance of its safe and effective performance;

(B) shall, where necessary to provide reasonable assurance of its safe and effective performance, include—

(i) provisions respecting the construction, components, ingredients, and properties of the device and its compatibility with power systems and connections to such systems,

(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the device or, if it is determined that no other more practicable means are available to the Secretary to assure the conformity of the

device to the standard, provisions for the testing (on a sample basis or, if necessary, on an individual basis) by the Secretary or by another person at the direction of the Secretary,

(iii) provisions for the measurement of the performance characteristics of the device,

(iv) provisions requiring that the results of each or of certain of the tests of the device required to be made under clause (ii) show that the device is in conformity with the portions of the standard for which the test or tests were required, and

(v) a provision requiring that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 520(e); and

(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper installation, maintenance, operation, and use of the device.

(3) The Secretary shall provide for periodic evaluation of performance standards established under subsection (b) to determine if such standards should be changed to reflect new medical, scientific, or other technological data.

(4) In carrying out his duties under this subsection and subsection (b), the Secretary shall, to the maximum extent practicable—

(A) use personnel, facilities, and other technical support available in other Federal agencies,

(B) consult with other Federal agencies concerned with standard-setting and other nationally or internationally recognized standard-setting entities, and

(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, or consumer organizations who in his judgment can make a significant contribution.

Establishment of a Standard

(b)(1)(A) The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any performance standard for a device.

(B) A notice of proposed rulemaking for the establishment or amendment of a performance standard for a device shall—

(i) set forth a finding with supporting justification that the performance standard is appropriate and necessary to provide reasonable assurance of the safety and effectiveness of the device,

(ii) set forth proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate,

(iii) invite interested persons to submit to the Secretary, within 30 days of the publication of the notice, requests for changes in the classification of the device pursuant to section 513(e) based on new information relevant to the classification, and

(iv) invite interested persons to submit an existing performance standard for the device, including a draft or proposed performance standard, for consideration by the Secretary.

(C) A notice of proposed rulemaking for the revocation of a performance standard shall set forth a finding with supporting justification that the performance standard is no longer necessary to provide reasonable assurance of the safety and effectiveness of a device.

(D) The Secretary shall provide for a comment period of not less than 60 days.

(2) If, after publication of a notice in accordance with paragraph (1), the Secretary receives a request for a change in the classification of the device, the Secretary shall, within 60 days of the publication of the notice, after consultation with the appropriate panel under section 513, either deny the request or give notice of an intent to initiate such change under section 513(e).

(3)(A) After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a performance standard and after consideration of such comments and any report from an advisory committee under paragraph (5), the Secretary shall (i) promulgate a regulation establishing a performance standard and publish in the Federal Register findings on the matters referred to in paragraph (1), or (ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.

(B) A regulation establishing a performance standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before one year after the date of its publication unless (i) the Secretary determines that an earlier effective date is necessary for the protection of the public health and safety, or (ii) such standard has been established for a device which, effective upon the effective date of the standard, has been reclassified from class III to class II. Such date or dates shall be established so as to minimize, consistent with the public health and safety, economic loss to, and disruption or dislocation of, domestic and international trade.

(4)(A) The Secretary, upon his own initiative or upon petition of an interested person may by regulation, promulgated in accordance with the requirements of paragraphs (1), (2), and (3)(B) of this subsection, amend or revoke a performance standard.

(B) The Secretary may declare a proposed amendment of a performance standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if he determines that making it so effective is in the public interest. A proposed amendment of a performance standard made so effective under the preceding sentence may not prohibit, during the period in which it is so effective, the introduction or delivery for introduction into interstate commerce of a device which conforms to such standard without the change or changes provided by such proposed amendment.

(5)(A) The Secretary—

(i) may on his own initiative refer a proposed regulation for the establishment, amendment, or revocation of a performance standard, or

(ii) shall, upon the request of an interested person which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation,

to an advisory committee of experts, established pursuant to subparagraph (B) for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this subparagraph to an advisory committee, the Secretary shall provide the advisory committee with the data and information on which such proposed regulation is based. The advisory committee shall, within sixty days of the referral of a proposed regulation and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation. A copy of such report and recommendation shall be made public by the Secretary.

(B) The Secretary shall establish advisory committees (which may not be panels under section 513) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional background, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this Act. Each such committee shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Members of an advisory committee who are not officers or employees of the United States, while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule, for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate one of the members of each advisory committee to serve as chairman thereof. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

Recognition of a Standard

(c)(1)(A) In addition to establishing a performance standard under this section, the Secretary shall, by publication in the Federal Register *(or, with respect to susceptibility test interpretive cri-*

teria or standards recognized or otherwise listed under section 511, by posting on the Interpretive Criteria Website in accordance with such section), recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket submission requirement or other requirement under this Act to which such standard is applicable.

(B) If a person elects to use a standard recognized by the Secretary under subparagraph (A) to meet the requirements described in such subparagraph, the person shall provide a declaration of conformity to the Secretary that certifies that the device is in conformity with such standard. A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to meet any requirement regarding devices under this Act.

(C)(i) Any person may submit a request for recognition under subparagraph (A) of all or part of an appropriate standard established by a nationally or internationally recognized standard organization.

(ii) Not later than 60 days after the Secretary receives such a request, the Secretary shall—

(I) make a determination to recognize all, part, or none of the standard that is the subject of the request; and

(II) issue to the person who submitted such request a response in writing that states the Secretary's rationale for that determination, including the scientific, technical, regulatory, or other basis for such determination.

(iii) The Secretary shall make a response issued under clause (ii)(II) publicly available, in such manner as the Secretary determines appropriate.

(iv) The Secretary shall take such actions as may be necessary to implement all or part of a standard recognized under clause (i)(I), in accordance with subparagraph (A).

(D) The Secretary shall make publicly available, in such manner as the Secretary determines appropriate, the rationale for recognition under subparagraph (A) of part of a standard, including the scientific, technical, regulatory, or other basis for such recognition.

(2) The Secretary may withdraw such recognition of a standard through publication of a notice in the Federal Register if the Secretary determines that the standard is no longer appropriate for meeting a requirement regarding devices under this Act.

(3)(A) Subject to subparagraph (B), the Secretary shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless the Secretary finds—

(i) that the data or information submitted to support such declaration does not demonstrate that the device is in conformity with the standard identified in the declaration of conformity; or

(ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review.

(B) The Secretary may request, at any time, the data or information relied on by the person to make a declaration of conformity with respect to a standard recognized under paragraph (1).

(C) A person making a declaration of conformity with respect to a standard recognized under paragraph (1) shall maintain the data and information demonstrating conformity of the device to the standard for a period of two years after the date of the classification or approval of the device by the Secretary or a period equal to the expected design life of the device, whichever is longer.

(4) TRAINING ON USE OF STANDARDS.—The Secretary shall provide to all employees of the Food and Drug Administration who review premarket submissions for devices periodic training on the concept and use of recognized standards for purposes of meeting a premarket submission requirement or other applicable requirement under this Act, including standards relevant to an employee's area of device review.

(5) GUIDANCE.—

(A) DRAFT GUIDANCE.—The Secretary shall publish guidance identifying the principles for recognizing standards under this section. In publishing such guidance, the Secretary shall consider—

(i) the experience with, and reliance on, a standard by other Federal regulatory authorities and the device industry; and

(ii) whether recognition of a standard will promote harmonization among regulatory authorities in the regulation of devices.

(B) TIMING.—The Secretary shall publish—

(i) draft guidance under subparagraph (A) not later than 12 months after the date of the enactment of the 21st Century Cures Act; and

(ii) final guidance not later than 12 months after the close of the public comment period for the draft guidance under clause (i).

PREMARKET APPROVAL

General Requirement

SEC. 515. (a) A class III device—

(1) which is subject to a an order issued under subsection (b) (or a regulation promulgated under such subsection prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act); or

(2) which is a class III device because of section 513(f),

is required to have, unless exempt under section 520(g), an approval under this section of an application for premarket approval or, as applicable, an approval under subsection (c)(2) of a report seeking premarket approval.

Order To Require Premarket Approval

(b)(1) In the case of a class III device which—

(A) was introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this section; or

(B) is (i) of a type so introduced or delivered, and (ii) is substantially equivalent to another device within that type;

the Secretary shall by administrative order following publication of a proposed order in the Federal Register, a meeting of a device classification panel described in section 513(b), and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of title 5, United States Code, require that such device have an approval under this section of an application for premarket approval. Authority to issue such administrative order shall not be delegated below the Director of the Center for Devices and Radiological Health, acting in consultation with the Commissioner.

(2) A proposed order required under paragraph (1) shall contain—

(A) the proposed order;

(B) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved application for premarket approval and the benefit to the public from use of the device;

(C) opportunity for the submission of comments on the proposed order and the proposed findings; and

(D) opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

(3) After the expiration of the period for comment on a proposed order and proposed findings published under paragraph (2), consideration of comments submitted on such proposed order and findings, and a meeting of a device classification panel described in section 513(b), the Secretary shall (A) issue an administrative order under paragraph (1) and publish in the Federal Register findings on the matters referred to in paragraph (2)(B), or (B) publish a notice terminating the proceeding for the issuance of the administrative order together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.

Application for Premarket Approval

(c)(1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain—

(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 514 which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets

such performance standard or adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;

(F) specimens of the labeling proposed to be used for such device;

(G) the certification required under section 402(j)(5)(B) of the Public Health Service Act (which shall not be considered an element of such application); and

(H) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 513, may require.

(2)(A) Any person may file with the Secretary a report seeking premarket approval for a class III device referred to in subsection (a) that is a reprocessed single-use device. Such a report shall contain the following:

(i) The device name, including both the trade or proprietary name and the common or usual name.

(ii) The establishment registration number of the owner or operator submitting the report.

(iii) Actions taken to comply with performance standards under section 514.

(iv) Proposed labels, labeling, and advertising sufficient to describe the device, its intended use, and directions for use.

(v) Full reports of all information, published or known to or which should be reasonably known to the applicant, concerning investigations which have been made to show whether or not the device is safe or effective.

(vi) A description of the device's components, ingredients, and properties.

(vii) A full description of the methods used in, and the facilities and controls used for, the reprocessing and packing of the device.

(viii) Such samples of the device that the Secretary may reasonably require.

(ix) A financial certification or disclosure statement or both, as required by part 54 of title 21, Code of Federal Regulations.

(x) A statement that the applicant believes to the best of the applicant's knowledge that all data and information submitted to the Secretary are truthful and accurate and that no material fact has been omitted in the report.

(xi) Any additional data and information, including information of the type required in paragraph (1) for an application under such paragraph, that the Secretary determines is necessary to determine whether there is reasonable assurance of safety and effectiveness for the reprocessed device.

(xii) Validation data described in section 510(o)(1)(A) that demonstrates that the reasonable assurance of the safety or effectiveness of the device will remain after the maximum num-

ber of times the device is reprocessed as intended by the person submitting such report.

(B) In the case of a class III device referred to in subsection (a) that is a reprocessed single-use device:

(i) Subparagraph (A) of this paragraph applies in lieu of paragraph (1).

(ii) Subject to clause (i), the provisions of this section apply to a report under subparagraph (A) to the same extent and in the same manner as such provisions apply to an application under paragraph (1).

(iii) Each reference in other sections of this Act to an application under this section, other than such a reference in section 737 or 738, shall be considered to be a reference to a report under subparagraph (A).

(iv) Each reference in other sections of this Act to a device for which an application under this section has been approved, or has been denied, suspended, or withdrawn, other than such a reference in section 737 or 738, shall be considered to be a reference to a device for which a report under subparagraph (A) has been approved, or has been denied, suspended, or withdrawn, respectively.

(3) Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

(A) may on the Secretary's own initiative, or

(B) shall, upon the request of an applicant unless the Secretary finds that the information in the application which would be reviewed by a panel substantially duplicates information which has previously been reviewed by a panel appointed under section 513,

refer such application to the appropriate panel under section 513 for study and for submission (within such period as he may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation. Where appropriate, the Secretary shall ensure that such panel includes, or consults with, one or more pediatric experts.

(4)(A) Prior to the submission of an application under this subsection, the Secretary shall accept and review any portion of the application that the applicant and the Secretary agree is complete, ready, and appropriate for review, except that such requirement does not apply, and the Secretary has discretion whether to accept and review such portion, during any period in which, under section 738(h), the Secretary does not have the authority to collect fees under section 738(a).

(B) Each portion of a submission reviewed under subparagraph (A) and found acceptable by the Secretary shall not be further reviewed after receipt of an application that satisfies the requirements of paragraph (1), unless a significant issue of safety or effectiveness provides the Secretary reason to review such accepted portion.

(C) Whenever the Secretary determines that a portion of a submission under subparagraph (A) is unacceptable, the Secretary shall, in writing, provide to the applicant a description of any deficiencies in such portion and identify the information that is re-

quired to correct these deficiencies, unless the applicant is no longer pursuing the application.

(5)(A) Whenever the Secretary requests additional information from an applicant regarding an application under paragraph (1), the Secretary shall consider the least burdensome appropriate means necessary to demonstrate device safety and effectiveness, and request information accordingly.

(B) For purposes of subparagraph (A), the term "necessary" means the minimum required information that would support a determination by the Secretary that an application provides a reasonable assurance of the safety and effectiveness of the device.

(C) Nothing in this paragraph alters the standards for premarket approval of a device.

Action on an Application for Premarket Approval

(d)(1)(A) As promptly as possible, but in no event later than one hundred and eighty days after the receipt of an application under subsection (c) (except as provided in section 520(l)(3)(D)(ii) or unless, in accordance with subparagraph (B)(i), an additional period as agreed upon by the Secretary and the applicant), the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall—

(i) issue an order approving the application if he finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or

(ii) deny approval of the application if he finds (and sets forth the basis for such finding as part of or accompanying such denial) that one or more grounds for denial specified in paragraph (2) of this subsection apply.

In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling.

(B)(i) The Secretary may not enter into an agreement to extend the period in which to take action with respect to an application submitted for a device subject to a regulation promulgated under subsection (b) unless he finds that the continued availability of the device is necessary for the public health.

(ii) An order approving an application for a device may require as a condition to such approval that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 520(e).

(iii) The Secretary shall accept and review statistically valid and reliable data and any other information from investigations conducted under the authority of regulations required by section 520(g) to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section if—

(I) the data or information is derived from investigations of an earlier version of the device, the device has been modified

during or after the investigations (but prior to submission of an application under subsection (c)) and such a modification of the device does not constitute a significant change in the design or in the basic principles of operation of the device that would invalidate the data or information; or

(II) the data or information relates to a device approved under this section, is available for use under this Act, and is relevant to the design and intended use of the device for which the application is pending.

(2) The Secretary shall deny approval of an application for a device if, upon the basis of the information submitted to the Secretary as part of the application and any other information before him with respect to such device, the Secretary finds that—

(A) there is a lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(B) there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(C) the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device do not conform to the requirements of section 520(f);

(D) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(E) such device is not shown to conform in all respects to a performance standard in effect under section 514 compliance with which is a condition to approval of the application and there is a lack of adequate information to justify the deviation from such standard.

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with one or more protocols prescribed by the Secretary).

(3)(A)(i) The Secretary shall, upon the written request of an applicant, meet with the applicant, not later than 100 days after the receipt of an application that has been filed as complete under subsection (c), to discuss the review status of the application.

(ii) The Secretary shall, in writing and prior to the meeting, provide to the applicant a description of any deficiencies in the application that, at that point, have been identified by the Secretary based on an interim review of the entire application and identify the information that is required to correct those deficiencies.

(iii) The Secretary shall notify the applicant promptly of—

(I) any additional deficiency identified in the application, or

(II) any additional information required to achieve completion of the review and final action on the application,

that was not described as a deficiency in the written description provided by the Secretary under clause (ii).

(B) The Secretary and the applicant may, by mutual consent, establish a different schedule for a meeting required under this paragraph.

(4) An applicant whose application has been denied approval may, by petition filed on or before the thirtieth day after the date

upon which he receives notice of such denial, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g), and any interested person may obtain review, in accordance with paragraph (1) or (2) of subsection (g), of an order of the Secretary approving an application.

[(5) In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, the Secretary shall provide review priority for devices—

[(A) representing breakthrough technologies,

[(B) for which no approved alternatives exist,

[(C) which offer significant advantages over existing approved alternatives, or

[(D) the availability of which is in the best interest of the patients.]

[(6)] *(5)*(A)(i) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness*, subject to section 524B*, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 520(f).

(ii) The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device may distribute the device 30 days after the date on which the Secretary receives the notice*, subject to section 524B*, unless the Secretary within such 30-day period notifies the holder that the notice is not adequate and describes such further information or action that is required for acceptance of such change. If the Secretary notifies the holder that a supplemental application is required, the Secretary shall review the supplement within 135 days after the receipt of the supplement. The time used by the Secretary to review the notice of the manufacturing change shall be deducted from the 135-day review period if the notice meets appropriate content requirements for premarket approval supplements.

(B)(i) Subject to clause (ii), in reviewing a supplement to an approved application, for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve such supplement if—

(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changed device.

(ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness.

Withdrawal and Temporary Suspension of Approval of Application

(e)(1) The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from a panel or panels under section 513, and after due notice and opportunity for informal hearing to the

holder of an approved application for a device, issue an order withdrawing approval of the application if the Secretary finds—

(A) that such device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(B) on the basis of new information before him with respect to such device, evaluated together with the evidence available to him when the application was approved, that there is a lack of a showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(C) that the application contained or was accompanied by an untrue statement of a material fact;

(D) that the applicant (i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 519(a), (ii) has refused to permit access to, or copying or verification of, such records as required by section 704, or (iii) has not complied with the requirements of section 510;

(E) on the basis of new information before him with respect to such device, evaluated together with the evidence before him when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such device do not conform with the requirements of section 520(f) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

(F) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that the labeling of such device, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

(G) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that such device is not shown to conform in all respects to a performance standard which is in effect under section 514 compliance with which was a condition to approval of the application and that there is a lack of adequate information to justify the deviation from such standard.

(2) The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such withdrawal, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g).

(3) If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a device under an approved application would cause serious, adverse health consequences or death, the Secretary shall by order temporarily suspend the approval of the application approved under this section. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

Product Development Protocol

(f)(1) In the case of a class III device which is required to have an approval of an application submitted under subsection (c), such device shall be considered as having such an approval if a notice of completion of testing conducted in accordance with a product development protocol approved under paragraph (4) has been declared completed under paragraph (6).

(2) Any person may submit to the Secretary a proposed product development protocol with respect to a device. Such a protocol shall be accompanied by data supporting it. If, within thirty days of the receipt of such a protocol, the Secretary determines that it appears to be appropriate to apply the requirements of this subsection to the device with respect to which the protocol is submitted, the Secretary—

(A) may, at the initiative of the Secretary, refer the proposed protocol to the appropriate panel under section 513 for its recommendation respecting approval of the protocol; or

(B) shall so refer such protocol upon the request of the submitter, unless the Secretary finds that the proposed protocol and accompanying data which would be reviewed by such panel substantially duplicate a product development protocol and accompanying data which have previously been reviewed by such a panel.

(3) A proposed product development protocol for a device may be approved only if—

(A) the Secretary determines that it is appropriate to apply the requirements of this subsection to the device in lieu of the requirement of approval of an application submitted under subsection (c); and

(B) the Secretary determines that the proposed protocol provides—

(i) a description of the device and the changes which may be made in the device,

(ii) a description of the preclinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the commencement of clinical trials of the device, and (II) any permissible variations in preclinical trials and the results therefrom,

(iii) a description of the clinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the filing of a notice of completion of the requirements of the protocol, and (II) any permissible variations in such trials and the results therefrom,

(iv) a description of the methods to be used in, and the facilities and controls to be used for, the manufacture, processing, and when relevant, packing and installation of the device,

(v) an identifying reference to any performance standard under section 514 to be applicable to any aspect of such device,

(vi) if appropriate, specimens of the labeling proposed to be used for such device,

(vii) such other information relevant to the subject matter of the protocol as the Secretary, with the concurrence

of the appropriate panel or panels under section 513, may require, and

(viii) a requirement for submission of progress reports and, when completed, records of the trials conducted under the protocol which records are adequate to show compliance with the protocol.

(4) The Secretary shall approve or disapprove a proposed product development protocol submitted under paragraph (2) within one hundred and twenty days of its receipt unless an additional period is agreed upon by the Secretary and the person who submitted the protocol. Approval of a protocol or denial of approval of a protocol is final agency action subject to judicial review under chapter 7 of title 5, United States Code.

(5) At any time after a product development protocol for a device has been approved pursuant to paragraph (4), the person for whom the protocol was approved may submit a notice of completion—

(A) stating (i) his determination that the requirements of the protocol have been fulfilled and that, to the best of his knowledge, there is no reason bearing on safety or effectiveness why the notice of completion should not become effective, and (ii) the data and other information upon which such determination was made, and

(B) setting forth the results of the trials required by the protocol and all the information required by subsection (c)(1).

(6)(A) The Secretary may, after providing the person who has an approved protocol an opportunity for an informal hearing and at any time prior to receipt of notice of completion of such protocol, issue a final order to revoke such protocol if he finds that—

(i) such person has failed substantially to comply with the requirements of the protocol,

(ii) the results of the trials obtained under the protocol differ so substantially from the results required by the protocol that further trials cannot be justified, or

(iii) the results of the trials conducted under the protocol or available new information do not demonstrate that the device tested under the protocol does not present an unreasonable risk to health and safety.

(B) After the receipt of a notice of completion of an approved protocol the Secretary shall, within the ninety-day period beginning on the date such notice is received, by order either declare the protocol completed or declare it not completed. An order declaring a protocol not completed may take effect only after the Secretary has provided the person who has the protocol opportunity for an informal hearing on the order. Such an order may be issued only if the Secretary finds—

(i) such person has failed substantially to comply with the requirements of the protocol,

(ii) the results of the trials obtained under the protocol differ substantially from the results required by the protocol, or

(iii) there is a lack of a showing of reasonable assurance of the safety and effectiveness of the device under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.

(C) A final order issued under subparagraph (A) or (B) shall be in writing and shall contain the reasons to support the conclusions thereof.

(7) At any time after a notice of completion has become effective, the Secretary may issue an order (after due notice and opportunity for an informal hearing to the person for whom the notice is effective) revoking the approval of a device provided by a notice of completion which has become effective as provided in subparagraph (B) if he finds that any of the grounds listed in subparagraphs (A) through (G) of subsection (e)(1) of this section apply. Each reference in such subparagraphs to an application shall be considered for purposes of this paragraph as a reference to a protocol and the notice of completion of such protocol, and each reference to the time when an application was approved shall be considered for purposes of this paragraph as a reference to the time when a notice of completion took effect.

(8) A person who has an approved protocol subject to an order issued under paragraph (6)(A) revoking such protocol, a person who has an approved protocol with respect to which an order under paragraph (6)(B) was issued declaring that the protocol had not been completed, or a person subject to an order issued under paragraph (7) revoking the approval of a device may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such order, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g).

Review

(g)(1) Upon petition for review of—

(A) an order under subsection (d) approving or denying approval of an application or an order under subsection (e) withdrawing approval of an application, or

(B) an order under subsection (f)(6)(A) revoking an approved protocol, under subsection (f)(6)(B) declaring that an approved protocol has not been completed, or under subsection (f)(7) revoking the approval of a device,

the Secretary shall, unless he finds the petition to be without good cause or unless a petition for review of such order has been submitted under paragraph (2), hold a hearing, in accordance with section 554 of title 5 of the United States Code, on the order. The panel or panels which considered the application, protocol, or device subject to such order shall designate a member to appear and testify at any such hearing upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this requirement does not preclude any other member of the panel or panels from appearing and testifying at any such hearing. Upon completion of such hearing and after considering the record established in such hearing, the Secretary shall issue an order either affirming the order subject to the hearing or reversing such order and, as appropriate, approving or denying approval of the application, reinstating the application's approval, approving the protocol, or placing in effect a notice of completion.

(2)(A) Upon petition for review of—

(i) an order under subsection (d) approving or denying approval of an application or an order under subsection (e) withdrawing approval of an application, or

(ii) an order under subsection (f)(6)(A) revoking an approved protocol, under subsection (f)(6)(B) declaring that an approved protocol has not been completed, or under subsection (f)(7) revoking the approval of a device,

the Secretary shall refer the application or protocol subject to the order and the basis for the order to an advisory committee of experts established pursuant to subparagraph (B) for a report and recommendation with respect to the order. The advisory committee shall, after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation, together with all underlying data and information and a statement of the reasons or basis for the recommendation. A copy of such report shall be promptly supplied by the Secretary to any person who petitioned for such referral to the advisory committee.

(B) The Secretary shall establish advisory committees (which may not be panels under section 513) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional backgrounds, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this Act. Members of an advisory committee (other than officers or employees of the United States), while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary which rates may not exceed the daily equivalent for grade GS–18 of the General Schedule for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate the chairman of an advisory committee from its members. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

(C) The Secretary shall make public the report and recommendation made by an advisory committee with respect to an application and shall by order, stating the reasons therefor, either affirm the order referred to the advisory committee or reverse such order and, if appropriate, approve or deny approval of the application, reinstate the application's approval, approve the protocol, or place in effect a notice of completion.

Service of Orders

(h) Orders of the Secretary under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary, or (2) by mailing the order by registered mail or certified mail addressed to the applicant at his last known address in the records of the Secretary.

Revision

(i)(1) Before December 1, 1995, the Secretary shall by order require manufacturers of devices, which were introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and which are subject to revision of classification under paragraph (2), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturer respecting such devices, including adverse safety or effectiveness information which has not been submitted under section 519. The Secretary may require the manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

(2) After the issuance of an order under paragraph (1) but before the date that is 2 years after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall issue an administrative order following publication of a proposed order in the Federal Register, a meeting of a device classification panel described in section 513(b), and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of title 5, United States Code, for each device—

(A) which the Secretary has classified as a class III device, and

(B) for which no administrative order has been issued under subsection (b) (or no regulation has been promulgated under such subsection prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act),

revising the classification of the device so that the device is classified into class I or class II, unless the administrative order issued under this paragraph requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 513(a).

(3) The Secretary shall, as promptly as is reasonably achievable, but not later than 12 months after the effective date of the order requiring a device to remain in class III, establish a schedule for the issuance of an administrative order under subsection (b) for each device which is subject to the order requiring the device to remain in class III.

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SEC. 515B. PRIORITY REVIEW FOR BREAKTHROUGH DEVICES.

(a) IN GENERAL.—In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, the Secretary shall establish a program to provide priority review for devices—

(1) representing breakthrough technologies;

(2) for which no approved alternatives exist;

(3) offering significant advantages over existing approved or cleared alternatives, including the potential to, compared to existing approved or cleared alternatives, reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through

self-directed personal assistance), or establish long-term clinical efficiencies; or

(4) the availability of which is in the best interest of patients.

(b) REQUEST FOR DESIGNATION.—A sponsor of a device may request that the Secretary designate the device for priority review under this section. Any such request for designation may be made at any time prior to the submission of an application under section 515(c), a petition for classification under section 513(f)(2), or a notification under section 510(k).

(c) DESIGNATION PROCESS.—

(1) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under subsection (b), the Secretary shall determine whether the device that is the subject of the request meets the criteria described in subsection (a). If the Secretary determines that the device meets the criteria, the Secretary shall designate the device for priority review.

(2) REVIEW.—Review of a request under subsection (b) shall be undertaken by a team that is composed of experienced staff and managers of the Food and Drug Administration and is chaired by a senior manager.

(3) DESIGNATION DETERMINATION.—A determination approving or denying a request under subsection (b) shall be considered a significant decision under section 517A and the Secretary shall provide a written, substantive summary of the basis for the determination in accordance with section 517A(a).

(4) RECONSIDERATION.—

(A) REQUEST FOR RECONSIDERATION.—Any person whose request under subsection (b) is denied may, within 30 days of the denial, request reconsideration of the denial in accordance with section 517A(b)—

(i) based upon the submission of documents by such person; or

(ii) based upon such documents and a meeting or teleconference.

(B) RESPONSE.—Reconsideration of a designation determination under this paragraph shall be conducted in accordance with section 517A(b).

(5) WITHDRAWAL.—If the Secretary approves a priority review designation for a device under this section, the Secretary may not withdraw the designation based on the fact that the criteria specified in subsection (a) are no longer met because of the subsequent clearance or approval of another device that was designated under—

(A) this section; or

(B) section 515(d)(5) (as in effect immediately prior to the enactment of the 21st Century Cures Act).

(d) PRIORITY REVIEW.—

(1) ACTIONS.—For purposes of expediting the development and review of devices designated under subsection (c), the Secretary shall—

(A) assign a team of staff, including a team leader with appropriate subject matter expertise and experience, for each device for which a request is submitted under subsection (b);

(B) provide for oversight of the team by senior agency personnel to facilitate the efficient development of the device and the efficient review of any submission described in subsection (b) for the device;

(C) adopt an efficient process for timely dispute resolution;

(D) provide for interactive communication with the sponsor of the device during the review process;

(E) expedite the Secretary's review of manufacturing and quality systems compliance, as applicable;

(F) disclose to the sponsor in advance the topics of any consultation concerning the sponsor's device that the Secretary intends to undertake with external experts or an advisory committee and provide the sponsor an opportunity to recommend such external experts;

(G) for applications submitted under section 515(c), provide for advisory committee input, as the Secretary determines appropriate (including in response to the request of the sponsor); and

(H) assign staff to be available within a reasonable time to address questions posed by institutional review committees concerning the conditions and clinical testing requirements applicable to the investigational use of the device pursuant to an exemption under section 520(g).

(2) ADDITIONAL ACTIONS.—In addition to the actions described in paragraph (1), for purposes of expediting the development and review of devices designated under subsection (c), the Secretary, in collaboration with the device sponsor, may, as appropriate—

(A) coordinate with the sponsor regarding early agreement on a data development plan;

(B) take steps to ensure that the design of clinical trials is as efficient as practicable, such as through adoption of shorter or smaller clinical trials, application of surrogate endpoints, and use of adaptive trial designs and Bayesian statistics, to the extent scientifically appropriate;

(C) facilitate, to the extent scientifically appropriate, expedited and efficient development and review of the device through utilization of timely postmarket data collection, with regard to applications for approval under section 515(c); and

(D) agree to clinical protocols that the Secretary will consider binding on the Secretary and the sponsor, subject to—

(i) changes agreed to by the sponsor and the Secretary;

(ii) changes that the Secretary determines are required to prevent an unreasonable risk to the public health; or

(iii) the identification of a substantial scientific issue determined by the Secretary to be essential to the safety or effectiveness of the device involved.

(e) PRIORITY REVIEW GUIDANCE.—

(1) CONTENT.—The Secretary shall issue guidance on the implementation of this section. Such guidance shall include the following:

(A) The process for a person to seek a priority review designation.

(B) A template for requests under subsection (b).

(C) The criteria the Secretary will use in evaluating a request for priority review.

(D) The standards the Secretary will use in assigning a team of staff, including team leaders, to review devices designated for priority review, including any training required for such personnel on effective and efficient review.

(2) PROCESS.—Prior to finalizing the guidance under paragraph (1), the Secretary shall propose such guidance for public comment.

(f) CONSTRUCTION.—

(1) PURPOSE.—This section is intended to encourage the Secretary and provide the Secretary sufficient authorities to apply efficient and flexible approaches to expedite the development of, and prioritize the agency's review of, devices that represent breakthrough technologies.

(2) CONSTRUCTION.— Nothing in this section shall be construed to alter the criteria and standards for evaluating an application pursuant to section 515(c), a report and request for classification under section 513(f)(2), or a report under section 510(k), including the recognition of valid scientific evidence as described in section 513(a)(3)(B), and consideration of the least burdensome means of evaluating device effectiveness or demonstrating substantial equivalence between devices with differing technological characteristics, as applicable. Nothing in this section alters the authority of the Secretary to act on an application pursuant to section 515(d) before completion of an establishment inspection, as the Secretary deems appropriate.

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SEC. 517A. AGENCY DOCUMENTATION AND REVIEW OF SIGNIFICANT DECISIONS REGARDING DEVICES.

(a) DOCUMENTATION OF RATIONALE FOR SIGNIFICANT DECISIONS.—

(1) IN GENERAL.—The Secretary shall provide a substantive summary of the scientific and regulatory rationale for any significant decision of the Center for Devices and Radiological Health regarding submission or review of a report under section 510(k), an application under section 515, *a request for designation under section 515B,* or an application for an exemption under section 520(g), including documentation of significant controversies or differences of opinion and the resolution of such controversies or differences of opinion.

(2) PROVISION OF DOCUMENTATION.—Upon request, the Secretary shall furnish such substantive summary to the person who is seeking to submit, or who has submitted, such report or application.

(b) REVIEW OF SIGNIFICANT DECISIONS.—

(1) REQUEST FOR SUPERVISORY REVIEW OF SIGNIFICANT DECISION.—Any person may request a supervisory review of the significant decision described in subsection (a)(1). Such review may be conducted at the next supervisory level or higher above the individual who made the significant decision.

(2) SUBMISSION OF REQUEST.—A person requesting a supervisory review under paragraph (1) shall submit such request to the Secretary not later than 30 days after such decision and shall indicate in the request whether such person seeks an in-person meeting or a teleconference review.

(3) TIMEFRAME.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall schedule an in-person or teleconference review, if so requested, not later than 30 days after such request is made. The Secretary shall issue a decision to the person requesting a review under this subsection not later than 45 days after the request is made under paragraph (1), or, in the case of a person who requests an in-person meeting or teleconference, 30 days after such meeting or teleconference.

(B) EXCEPTION.—Subparagraph (A) shall not apply in cases that are referred to experts outside of the Food and Drug Administration.

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GENERAL PROVISIONS RESPECTING CONTROL OF DEVICES INTENDED FOR HUMAN USE

General Rule

SEC. 520. (a) Any requirement authorized by or under section 501, 502, 510, or 519 applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed by action taken under section 513, 514, or 515 or under subsection (g) of this section, and any requirement established by or under section 501, 502, 510, or 519 which is inconsistent with a requirement imposed on such device under section 514 or 515 or under subsection (g) of this section shall not apply to such device.

(b) CUSTOM DEVICES.—

(1) IN GENERAL.—The requirements of sections 514 and 515 shall not apply to a device that—

(A) is created or modified in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing);

(B) in order to comply with an order described in subparagraph (A), necessarily deviates from an otherwise applicable performance standard under section 514 or requirement under section 515;

(C) is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution;

(D) is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat;

(E)(i) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such

physician or dentist (or other specially qualified person so designated); or

(ii) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated);

(F) is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of individuals described in clause (i) or (ii) of subparagraph (E); and

(G) may have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercially distributed devices.

(2) LIMITATIONS.—Paragraph (1) shall apply to a device only if—

(A) such device is for the purpose of treating a sufficiently rare condition, such that conducting clinical investigations on such device would be impractical;

(B) production of such device under paragraph (1) is limited to no more than 5 units per year of a particular device type, provided that such replication otherwise complies with this section; and

(C) the manufacturer of such device notifies the Secretary on an annual basis, in a manner prescribed by the Secretary, of the manufacture of such device.

(3) GUIDANCE.—Not later than 2 years after the date of enactment of this section, the Secretary shall issue final guidance on replication of multiple devices described in paragraph (2)(B).

Trade Secrets

(c) Any information reported to or otherwise obtained by the Secretary or his representative under section 513, 514, 515, 516, 518, 519, or 704 or under subsection (f) or (g) of this section which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section shall be considered confidential and shall not be disclosed and may not be used by the Secretary as the basis for the reclassification of a device from class III to class II or class I or as the basis for the establishment or amendment of a performance standard under section 514 for a device reclassified from class III to class II, except (1) in accordance with subsection (h), and (2) that such information may be disclosed to other officers or employees concerned with carrying out this Act or when relevant in any proceeding under this Act (other than section 513 or 514 thereof).

Notices and Findings

(d) Each notice of proposed rulemaking under section 513, 514, 515, 516, 518, or 519, or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

(1) the manner in which interested persons may examine data and other information on which the notice or findings is based, and

(2) the period within which interested persons may present their comments on the notice or findings (including the need therefor) orally or in writing, which period shall be at least sixty days but may not exceed ninety days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefor.

Restricted Devices

(e)(1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—

(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

(B) upon such other conditions as the Secretary may prescribe in such regulation,

if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. No condition prescribed under subparagraph (B) may restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device. No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board. A device subject to a regulation under this subsection is a restricted device.

(2) The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) as the Secretary may in such regulation prescribe.

Good Manufacturing Practice Requirements

(f)(1)(A) The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this Act.

(B) Before the Secretary may promulgate any regulation under subparagraph (A) he shall—

(i) afford the advisory committee established under paragraph (3) an opportunity to submit recommendations to him with respect to the regulation proposed to be promulgated;

(ii) afford opportunity for an oral hearing; and

(iii) ensure that such regulation conforms, to the extent practicable, with internationally recognized standards defining quality systems, or parts of the standards, for medical devices.

The Secretary shall provide the advisory committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A).

(2)(A) Any person subject to any requirement prescribed by regulations under paragraph (1) may petition the Secretary for an exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as he shall prescribe and shall—

(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this Act,

(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, facilities, and controls prescribed by the requirement, and

(iii) contain such other information as the Secretary shall prescribe.

(B) The Secretary may refer to the advisory committee established under paragraph (3) any petition submitted under subparagraph (A). The advisory committee shall report its recommendations to the Secretary with respect to a petition referred to it within sixty days of the date of the petition's referral. Within sixty days after—

(i) the date the petition was submitted to the Secretary under subparagraph (A), or

(ii) if the petition was referred to an advisory committee, the expiration of the sixty-day period beginning on the date the petition was referred to the advisory committee,

whichever occurs later, the Secretary shall by order either deny the petition or approve it.

(C) The Secretary may approve—

(i) a petition for an exemption for a device from a requirement if he determines that compliance with such requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this Act, and

(ii) a petition for a variance for a device from a requirement if he determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, controls, and facilities prescribed by the requirement are sufficient to assure that the device will be safe and effective and otherwise in compliance with this Act.

An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of the device to be granted the variance under the petition as may be necessary to assure that the device will be safe and effective and otherwise in compliance with this Act.

(D) After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

(3) The Secretary shall establish an advisory committee for the purpose of advising and making recommendations to him with respect to regulations proposed to be promulgated under paragraph (1)(A) and the approval or disapproval of petitions submitted under paragraph (2). The advisory committee shall be composed of nine members as follows:

(A) Three of the members shall be appointed from persons who are officers or employees of any State or local government or of the Federal Government.

(B) Two of the members shall be appointed from persons who are representative of interests of the device manufacturing industry; two of the members shall be appointed from persons who are representative of the interests of physicians and other health professionals; and two of the members shall be representative of the interests of the general public.

Members of the advisory committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule, for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate one of the members of the advisory committee to serve as its chairman. The Secretary shall furnish the advisory committee with clerical and other assistance. Section 14 of the Federal Advisory Committee Act shall not apply with respect to the duration of the advisory committee established under this paragraph.

Exemption for Devices for Investigational Use

(g)(1) It is the purpose of this subsection to encourage to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

(2)(A) The Secretary shall, within the one hundred and twenty-day period beginning on the date of the enactment of this section, by regulation prescribe procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 502, 510, 514, 515, 516, 519, or 721 or subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.

(B) The conditions prescribed pursuant to subparagraph (A) shall include the following:

(i) A requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify.

(ii) A requirement that the person applying for an exemption for a device assure the establishment and maintenance of such records, and the making of such reports to the Secretary of safety or effectiveness data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device.

(iii) Such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety.

(C) Procedures and conditions prescribed pursuant to subparagraph (A) for an exemption may appropriately vary depending on (i) the scope and duration of clinical testing to be conducted under such exemption, (ii) the number of human subjects that are to be involved in such testing, (iii) the need to permit changes to be made in the device subject to the exemption during testing conducted in accordance with a clinical testing plan required under paragraph (3)(A), and (iv) whether the clinical testing of such device is for the purpose of developing data to obtain approval for the commercial distribution of such device.

(3) Procedures and conditions prescribed pursuant to paragraph (2)(A) shall require, as a condition to the exemption of any device to be the subject of testing involving human subjects, that the person applying for the exemption—

(A) submit a plan for any proposed clinical testing of the device and a report of prior investigations of the device (including, where appropriate, tests on animals) adequate to justify the proposed clinical testing—

(i) to the [local] institutional review committee [which has been] established in accordance with regulations of the Secretary to supervise clinical testing of devices in the facilities where the proposed clinical testing is to be conducted, or

(ii) to the Secretary, if—

(I) no such committee exists, or

(II) the Secretary finds that the process of review by such committee is inadequate (whether or not the plan for such testing has been approved by such committee),

for review for adequacy to justify the commencement of such testing; and, unless the plan and report are submitted to the Secretary, submit to the Secretary a summary of the plan and a report of prior investigations of the device (including, where appropriate, tests on animals);

(B) promptly notify the Secretary (under such circumstances and in such manner as the Secretary prescribes) of approval by a [local] institutional review committee of any clinical testing plan submitted to it in accordance with subparagraph (A);

(C) in the case of a device to be distributed to investigators for testing, obtain signed agreements from each of such investigators that any testing of the device involving human subjects will be under such investigator's supervision and in accordance with subparagraph (D) and submit such agreements to the Secretary; and

(D) assure that informed consent will be obtained from each human subject (or his representative) of proposed clinical testing involving such device, [except where subject to such conditions as the Secretary may prescribe, the investigator] *except where, subject to such conditions as the Secretary may prescribe—*

(i) the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject; or

(ii) the investigator conducting or supervising the proposed clinical testing of the device determines in writing that there exists a life threatening situation involving the human subject of such testing which necessitates the use of such device and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain such consent from his representative.

The determination required by subparagraph [(D)] *(D)(ii)* shall be concurred in by a licensed physician who is not involved in the testing of the human subject with respect to which such determination is made unless immediate use of the device is required to save the life of the human subject of such testing and there is not sufficient time to obtain such concurrence.

(4)(A) An application, submitted in accordance with the procedures prescribed by regulations under paragraph (2), for an exemption for a device (other than an exemption from section 516) shall be deemed approved on the thirtieth day after the submission of the application to the Secretary unless on or before such day the Secretary by order disapproves the application and notifies the applicant of the disapproval of the application.

(B) The Secretary may disapprove an application only if he finds that the investigation with respect to which the application is submitted does not conform to procedures and conditions prescribed under regulations under paragraph (2). Such a notification shall contain the order of disapproval and a complete statement of the reasons for the Secretary's disapproval of the application and afford the applicant opportunity for an informal hearing on the disapproval order.

(C) Consistent with paragraph (1), the Secretary shall not disapprove an application under this subsection because the Secretary determines that—

(i) the investigation may not support a substantial equivalence or de novo classification determination or approval of the device;

(ii) the investigation may not meet a requirement, including a data requirement, relating to the approval or clearance of a device; or

(iii) an additional or different investigation may be necessary to support clearance or approval of the device.

(5) The Secretary may by order withdraw an exemption granted under this subsection for a device if the Secretary determines that the conditions applicable to the device under this subsection for such exemption are not met. Such an order may be issued only after opportunity for an informal hearing, except that such an order may be issued before the provision of an opportunity for an

informal hearing if the Secretary determines that the continuation of testing under the exemption with respect to which the order is to be issued will result in an unreasonable risk to the public health.

(6)(A) Not later than 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall by regulation establish, with respect to a device for which an exemption under this subsection is in effect, procedures and conditions that, without requiring an additional approval of an application for an exemption or the approval of a supplement to such an application, permit—

(i) developmental changes in the device (including manufacturing changes) that do not constitute a significant change in design or in basic principles of operation and that are made in response to information gathered during the course of an investigation; and

(ii) changes or modifications to clinical protocols that do not affect—

(I) the validity of data or information resulting from the completion of an approved protocol, or the relationship of likely patient risk to benefit relied upon to approve a protocol;

(II) the scientific soundness of an investigational plan submitted under paragraph (3)(A); or

(III) the rights, safety, or welfare of the human subjects involved in the investigation.

(B) Regulations under subparagraph (A) shall provide that a change or modification described in such subparagraph may be made if—

(i) the sponsor of the investigation determines, on the basis of credible information (as defined by the Secretary) that the applicable conditions under subparagraph (A) are met; and

(ii) the sponsor submits to the Secretary, not later than 5 days after making the change or modification, a notice of the change or modification.

(7)(A) In the case of a person intending to investigate the safety or effectiveness of a class III device or any implantable device, the Secretary shall ensure that the person has an opportunity, prior to submitting an application to the Secretary or to an institutional review committee, to submit to the Secretary, for review, an investigational plan (including a clinical protocol). If the applicant submits a written request for a meeting with the Secretary regarding such review, the Secretary shall, not later than 30 days after receiving the request, meet with the applicant for the purpose of reaching agreement regarding the investigational plan (including a clinical protocol). The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan (including a clinical protocol) for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device.

(B) Any agreement regarding the parameters of an investigational plan (including a clinical protocol) that is reached between the Secretary and a sponsor or applicant shall be reduced to writ-

ing and made part of the administrative record by the Secretary. Any such agreement shall not be changed, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (C) by the director of the office in which the device involved is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the device involved has been identified.

(C) A decision under subparagraph (B)(ii) by the director shall be in writing, and may be made only after the Secretary has provided to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the scientific issue involved.

(8)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is a determination that—

(i) the device involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the device, the design of the clinical investigation, the condition for which the device is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish.

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

Release of Safety and Effectiveness Information

(h)(1) The Secretary shall promulgate regulations under which a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the Secretary and which was the basis for—

(A) an order under section 515(d)(1)(A) approving an application for premarket approval for the device or denying approval of such an application or an order under section 515(e) withdrawing approval of such an application for the device,

(B) an order under section 515(f)(6)(A) revoking an approved protocol for the device, an order under section 515(f)(6)(B) declaring a protocol for the device completed or not completed, or an order under section 515(f)(7) revoking the approval of the device, or

(C) an order approving an application under subsection (g) for an exemption for the device from section 516 or an order

disapproving, or withdrawing approval of, an application for an exemption under such subsection for the device,

shall be made available to the public upon issuance of the order. Summaries of information made available pursuant to this paragraph respecting a device shall include information respecting any adverse effects on health of the device.

(2) The Secretary shall promulgate regulations under which each advisory committee established under section 515(g)(2)(B) shall make available to the public a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the advisory committee and which was the basis for its recommendation to the Secretary made pursuant to section 515(g)(2)(A). A summary of information upon which such a recommendation is based shall be made available pursuant to this paragraph only after the issuance of the order with respect to which the recommendation was made and each summary shall include information respecting any adverse effect on health of the device subject to such order.

(3) Except as provided in paragraph (4), any information respecting a device which is made available pursuant to paragraph (1) or (2) of this subsection (A) may not be used to establish the safety or effectiveness of another device for purposes of this Act by any person other than the person who submitted the information so made available, and (B) shall be made available subject to subsection (c) of this section.

(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) (including information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of a device, but excluding descriptions of methods of manufacture and product composition and other trade secrets) shall be available, 6 years after the application has been approved by the Secretary, for use by the Secretary in—

(i) approving another device;

(ii) determining whether a product development protocol has been completed, under section 515 for another device;

(iii) establishing a performance standard or special control under this Act; or

(iv) classifying or reclassifying another device under section 513 and subsection (l)(2).

(B) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the agency actions described in subparagraph (A).

Proceedings of Advisory Panels and Committees

(i) Each panel under section 513 and each advisory committee established under section 514(b)(5)(B) or 515(g) or under subsection (f) of this section shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made pursuant to this subsection information which under subsection (c) of this section is to be considered confidential.

Traceability Requirements

(j) Except as provided in section 519(e), no regulation under this Act may impose on a type or class of device requirements for the traceability of such type or class of device unless such requirements are necessary to assure the protection of the public health.

Research and Development

(k) The Secretary may enter into contracts for research, testing, and demonstrations respecting devices and may obtain devices for research, testing, and demonstration purposes without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 41 U.S.C. 5).

Transitional Provisions for Devices Considered as New Drugs

(l)(1) Any device intended for human use—

(A) for which on the date of enactment of the Medical Device Amendments of 1976 (hereinafter in this subsection referred to as the "enactment date") an approval of an application submitted under section 505(b) was in effect;

(B) for which such an application was filed on or before the enactment date and with respect to which application no order of approval or refusing to approve had been issued on such date under subsection (c) or (d) of such section;

(C) for which on the enactment date an exemption under subsection (i) of such section was in effect;

(D) which is within a type of device described in subparagraph (A), (B), or (C) and is substantially equivalent to another device within that type;

(E) which the Secretary in a notice published in the Federal Register before the enactment date has declared to be a new drug subject to section 505; or

(F) with respect to which on the enactment date an action is pending in a United States court under section 302, 303, or 304 for an alleged violation of a provision of section 301 which enforces a requirement of section 505 or for an alleged violation of section 505(a),

is classified in class III unless the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

(2) The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition. Except as provided in paragraph (3)(D)(ii), within one hundred and eighty days after the filing of a petition under this paragraph, the Secretary shall, after consultation with the appropriate panel under section 513, by order either deny the petition or order the classification, in accordance with the criteria prescribed by section 513(a)(1)(A) or 513(a)(1)(B), of the device in class I or class II.

(3)(A) In the case of a device which is described in paragraph (1)(A) and which is in class III—

(i) such device shall on the enactment date be considered a device with an approved application under section 515, and

(ii) the requirements applicable to such device before the enactment date under section 505 shall continue to apply to such device until changed by the Secretary as authorized by this Act.

(B) In the case of a device which is described in paragraph (1)(B) and which is in class III, an application for such device shall be considered as having been filed under section 515 on the enactment date. The period in which the Secretary shall act on such application in accordance with section 515(d)(1) shall be one hundred and eighty days from the enactment date (or such greater period as the Secretary and the applicant may agree upon after the Secretary has made the finding required by section 515(d)(1)(B)(i)) less the number of days in the period beginning on the date an application for such device was filed under section 505 and ending on the enactment date. After the expiration of such period such device is required, unless exempt under subsection (g), to have in effect an approved application under section 515.

(C) A device which is described in paragraph (1)(C) and which is in class III shall be considered a new drug until the expiration of the ninety-day period beginning on the date of the promulgation of regulations under subsection (g) of this section. After the expiration of such period such device is required, unless exempt under subsection (g), to have in effect an approved application under section 515.

(D)(i) Except as provided in clauses (ii) and (iii), a device which is described in subparagraph (D), (E), or (F) of paragraph (1) and which is in class III is required, unless exempt under subsection (g) of this section, to have on and after sixty days after the enactment date in effect an approved application under section 515.

(ii) If—

(I) a petition is filed under paragraph (2) for a device described in subparagraph (D), (E), or (F) of paragraph (1), or

(II) an application for premarket approval is filed under section 515 for such a device,

within the sixty-day period beginning on the enactment date (or within such greater period as the Secretary, after making the finding required under section 515(d)(1)(B), and the petitioner or applicant may agree upon), the Secretary shall act on such petition or application in accordance with paragraph (2) or section 515 except that the period within which the Secretary must act on the petition or application shall be within the one hundred and twenty-day period beginning on the date the petition or application is filed. If such a petition or application is filed within such sixty-day (or greater) period, clause (i) of this subparagraph shall not apply to such device before the expiration of such one hundred and twenty-day period, or if such petition is denied or such application is denied approval, before the date of such denial, whichever occurs first.

(iii) In the case of a device which is described in subparagraph (E) of paragraph (1), which the Secretary in a notice published in

the Federal Register after March 31, 1976, declared to be a new drug subject to section 505, and which is in class III—

(I) the device shall, after eighteen months after the enactment date, have in effect an approved application under section 515 unless exempt under subsection (g) of this section, and

(II) the Secretary may, during the period beginning one hundred and eighty days after the enactment date and ending eighteen months after such date, restrict the use of the device to investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of such device, and to investigational use in accordance with the requirements applicable under regulations under subsection (g) of this section to investigational use of devices granted an exemption under such subsection.

If the requirements under subsection (g) of this section are made applicable to the investigational use of such a device, they shall be made applicable in such a manner that the device shall be made reasonably available to physicians meeting appropriate qualifications prescribed by the Secretary.

(5)(A) Before December 1, 1991, the Secretary shall by order require manufacturers of devices described in paragraph (1), which are subject to revision of classification under subparagraph (B), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturers respecting the devices, including adverse safety or effectiveness information which has not been submitted under section 519. The Secretary may require a manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

(B) Except as provided in subparagraph (C), after the issuance of an order under subparagraph (A) but before December 1, 1992, the Secretary shall publish a regulation in the Federal Register for each device which is classified in class III under paragraph (1) revising the classification of the device so that the device is classified into class I or class II, unless the regulation requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 513(a). Before the publication of a regulation requiring a device to remain in class III or revising its classification, the Secretary shall publish a proposed regulation respecting the classification of a device under this subparagraph and provide an opportunity for the submission of comments on any such regulation. No regulation under this subparagraph requiring a device to remain in class III or revising its classification may take effect before the expiration of 90 days from the date of the publication in the Federal Register of the proposed regulation.

(C) The Secretary may by notice published in the Federal Register extend the period prescribed by subparagraph (B) for a device for an additional period not to exceed 1 year.

Humanitarian Device Exemption

(m)(1) To the extent consistent with the protection of the public health and safety and with ethical standards, it is the purpose of this subsection to encourage the discovery and use of devices in-

tended to benefit patients in the treatment and diagnosis of diseases or conditions that affect [fewer than 4,000] *not more than 8,000* individuals in the United States.

(2) The Secretary may grant a request for an exemption from the effectiveness requirements of sections 514 and 515 for a device for which the Secretary finds that—

(A) the device is designed to treat or diagnose a disease or condition that affects [fewer than 4,000] *not more than 8,000* individuals in the United States,

(B) the device would not be available to a person with a disease or condition referred to in subparagraph (A) unless the Secretary grants such an exemption and there is no comparable device, other than under this exemption, available to treat or diagnose such disease or condition, and

(C) the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devic or alternative forms of treatment.

The request shall be in the form of an application submitted to the Secretary and such application shall include the certification required under section 402(j)(5)(B) of the Public Health Service Act (which shall not be considered an element of such application). Not later than 75 days after the date of the receipt of the application, the Secretary shall issue an order approving or denying the application.

(3) Except as provided in paragraph (6), no person granted an exemption under paragraph (2) with respect to a device may sell the device for an amount that exceeds the costs of research and development, fabrication, and distribution of the device.

(4) Devices granted an exemption under paragraph (2) may only be used—

[(A) in facilities that have established, in accordance with regulations of the Secretary, a local institutional review committee to supervise clinical testing of devices in the facilities, and]

(A) in facilities in which clinical testing of devices is supervised by an institutional review committee established in accordance with the regulations of the Secretary, and

(B) if, before the use of a device, an institutional review committee approves the use in the treatment or diagnosis of a disease or condition referred to in paragraph (2)(A), unless a physician determines in an emergency situation that approval from a [local] institutional review committee can not be obtained in time to prevent serious harm or death to a patient.

In a case described in subparagraph (B) in which a physician uses a device without an approval from an institutional review committee, the physician shall, after the use of the device, notify the chairperson of the [local] institutional review committee of such use. Such notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use.

(5) The Secretary may require a person granted an exemption under paragraph (2) to demonstrate continued compliance with the

requirements of this subsection if the Secretary believes such demonstration to be necessary to protect the public health, if the Secretary has reason to believe that the requirements of paragraph (6) are no longer met, or if the Secretary has reason to believe that the criteria for the exemption are no longer met. If the person granted an exemption under paragraph (2) fails to demonstrate continued compliance with the requirements of this subsection, the Secretary may suspend or withdraw the exemption from the effectiveness requirements of sections 514 and 515 for a humanitarian device only after providing notice and an opportunity for an informal hearing.

(6)(A) Except as provided in subparagraph (D), the prohibition in paragraph (3) shall not apply with respect to a person granted an exemption under paragraph (2) if each of the following conditions apply:

(i) The device with respect to which the exemption is granted—

(I) is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or

(II) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.

(ii) During any calendar year, the number of such devices distributed during that year under each exemption granted under this subsection does not exceed the annual distribution number for such device. In this paragraph, the term "annual distribution number" means the number of such devices reasonably needed to treat, diagnose, or cure a population of [4,000] *8,000* individuals in the United States. The Secretary shall determine the annual distribution number when the Secretary grants such exemption.

(iii) Such person immediately notifies the Secretary if the number of such devices distributed during any calendar year exceeds the annual distribution number referred to in clause (ii).

(iv) The request for such exemption is submitted on or before October 1, 2017.

(B) The Secretary may inspect the records relating to the number of devices distributed during any calendar year of a person granted an exemption under paragraph (2) for which the prohibition in paragraph (3) does not apply.

(C) A person may petition the Secretary to modify the annual distribution number determined by the Secretary under subparagraph (A)(ii) with respect to a device if additional information arises, and the Secretary may modify such annual distribution number.

(D) If a person notifies the Secretary, or the Secretary determines through an inspection under subparagraph (B), that the number of devices distributed during any calendar year exceeds the annual distribution number, as required under subparagraph (A)(iii), and modified under subparagraph (C), if applicable, then

the prohibition in paragraph (3) shall apply with respect to such person for such device for any sales of such device after such notification.

(E)(i) In this subsection, the term "pediatric patients" means patients who are 21 years of age or younger at the time of the diagnosis or treatment.

(ii) In this subsection, the term "pediatric subpopulation" means 1 of the following populations:

(I) Neonates.

(II) Infants.

(III) Children.

(IV) Adolescents.

(7) The Secretary shall refer any report of an adverse event regarding a device described in paragraph (6)(A)(i)(I) for which the prohibition under paragraph (3) does not apply pursuant to paragraph (6)(A) that the Secretary receives to the Office of Pediatric Therapeutics, established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109). In considering the report, the Director of the Office of Pediatric Therapeutics, in consultation with experts in the Center for Devices and Radiological Health, shall provide for periodic review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this Act in response to the report.

(8) The Secretary, acting through the Office of Pediatric Therapeutics and the Center for Devices and Radiological Health, shall provide for an annual review by the Pediatric Advisory Committee of all devices described in paragraph (6)(A)(i)(I) to ensure that the exemption under paragraph (2) remains appropriate for the pediatric populations for which it is granted.

Regulation of Contact Lens as Devices

(n)(1) All contact lenses shall be deemed to be devices under section 201(h).

(2) Paragraph (1) shall not be construed as bearing on or being relevant to the question of whether any product other than a contact lens is a device as defined by section 201(h) or a drug as defined by section 201(g).

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SEC. 524B. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.

(a) ACCREDITATION AND ASSESSMENT.—

(1) IN GENERAL; CERTIFICATION OF DEVICE QUALITY SYSTEM.— The Secretary shall, in accordance with this section, establish a third-party quality system assessment program—

(A) to accredit persons to assess whether a requestor's quality system, including its design controls, can reasonably assure the safety and effectiveness of in-scope devices subject to device-related changes;

(B) under which accredited persons shall (as applicable) certify that a requestor's quality system meets the criteria included in the guidance issued under paragraph (5) with respect to the in-scope devices at issue; and

(C) under which the Secretary shall rely on such certifications for purposes of determining the safety and effective-

ness (or as applicable, substantial equivalence) of in-scope devices subject to the device-related changes involved, in lieu of compliance with the following submission requirements:

(i) A premarket notification.

(ii) A thirty-day notice.

(iii) A Special PMA supplement.

(2) DEFINITIONS.—For purposes of this section-

(A) the term "device-related changes" means changes made by a requestor with respect to in-scope devices, which are—

(i) changes to a device found to be substantially equivalent under sections 513(i) and 510(k) to a predicate device, that—

(I) would otherwise be subject to a premarket notification; and

(II) do not alter—

(aa) the intended use of the changed device; or

(bb) the fundamental scientific technology of such device;

(ii) manufacturing changes subject to a 30-day notice;

(iii) changes that qualify for a Special PMA Supplement; and

(iv) such other changes relating to the devices or the device manufacturing process as the Secretary determines appropriate;

(B) the term "in-scope device" means a device within the scope of devices agreed to by the requestor and the accredited person for purposes of a request for certification under this section;

(C) the term "premarket notification" means a premarket notification under section 510(k);

(D) the term "quality system" means the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of devices, as described in section 520(f);

(E) the term "requestor" means a device manufacturer that is seeking certification under this section of a quality system used by such manufacturer;

(F) the term "Special PMA" means a Special PMA supplement under section 814.39(d) of title 21, Code of Federal Regulations (or any successor regulations); and

(G) the term "thirty-day notice" means a notice described in section 515(d)(6).

(3) ACCREDITATION PROCESS; ACCREDITATION RENEWAL.—Except as inconsistent with this section, the process and qualifications for accreditation of persons and renewal of such accreditation under section 704(g) shall apply with respect to accreditation of persons and renewal of such accreditation under this section.

(4) USE OF ACCREDITED PARTIES TO CONDUCT ASSESSMENTS.—

(A) INITIATION OF ASSESSMENT SERVICES.—

(i) DATE ASSESSMENTS AUTHORIZED.—Beginning after the date on which the final guidance is issued under paragraph (5), an accredited person may conduct an assessment under this section.

(ii) INITIATION OF ASSESSMENTS.—Use of one or more accredited persons to assess a requestor's quality system under this section with respect to in-scope devices shall be at the initiation of the person who registers and lists the devices at issue under section 510.

(B) COMPENSATION.—Compensation for such accredited persons shall—

(i) be determined by agreement between the accredited person and the person who engages the services of the accredited person; and

(ii) be paid by the person who engages such services.

(C) ACCREDITED PERSON SELECTION.—Each person who chooses to use an accredited person to assess a requestor's quality system, as described in this section, shall select the accredited person from a list of such persons published by the Secretary in accordance with section 704(g)(4).

(5) GUIDANCE; CRITERIA FOR CERTIFICATION.—

(A) IN GENERAL.—The criteria for certification of a quality system under this section shall be as specified by the Secretary in guidance issued under this paragraph.

(B) CONTENTS; CERTIFICATION CRITERIA.—The guidance under this paragraph shall include specification of—

(i) evaluative criteria to be used by an accredited person to assess and, as applicable, certify a requestor's quality system under this section with respect to in-scope devices; and

(ii) criteria for accredited persons to apply for a waiver of, and exemptions from, the certification criteria under clause (i).

(C) TIMEFRAME FOR ISSUING GUIDANCE.—The Secretary shall issue under this paragraph—

(i) draft guidance not later than 12 months after the enactment of the 21st Century Cures Act; and

(ii) final guidance not later than 12 months after issuance of the draft guidance under clause (i).

(b) USE OF THIRD-PARTY ASSESSMENT.—

(1) ASSESSMENT SUMMARY; CERTIFICATION.—

(A) SUBMISSION OF ASSESSMENT TO SECRETARY.—An accredited person who assesses a requestor's quality system under subsection (a) shall submit to the Secretary a summary of the assessment—

(i) within 30 days of the assessment; and

(ii) which shall include (as applicable)—

(I) the accredited person's certification that the requestor has satisfied the criteria specified in the guidance issued under subsection (a)(5) for quality system certification with respect to the in-scope devices at issue; and

(II) any waivers or exemptions from such criteria applied by the accredited person.

(B) TREATMENT OF ASSESSMENTS.—Subject to action by the Secretary under subparagraph (C), with respect to assessments which include a certification under this section—

(i) the Secretary's review of the assessment summary shall be deemed complete on the day that is 30 days after the date on which the Secretary receives the summary under subparagraph (A); and

(ii) the assessment summary and certification of the quality system of a requestor shall be deemed accepted by the Secretary on such 30th day.

(C) ACTIONS BY SECRETARY.—

(i) IN GENERAL.—Within 30 days of receiving an assessment summary and certification under subparagraph (A), the Secretary may, by written notice to the accredited person submitting such assessment certification, deem any such certification to be provisional beyond such 30-day period, suspended pending further review by the Secretary, or otherwise qualified or cancelled, based on the Secretary's determination that (as applicable)—

(I) additional information is needed to support such certification;

(II) such assessment or certification is unwarranted; or

(III) such action with regard to the certification is otherwise justified according to such factors and criteria as the Secretary finds appropriate.

(ii) ACCEPTANCE OF CERTIFICATION.—If following action by the Secretary under clause (i) with respect to a certification, the Secretary determines that such certification is acceptable, the Secretary shall issue written notice to the applicable accredited person indicating such acceptance.

(2) NOTIFICATIONS TO SECRETARY BY CERTIFIED REQUESTORS OR ACCREDITED PERSONS FOR PROGRAM EVALUATION PURPOSES.—

(A) ANNUAL SUMMARY REPORT FOR DEVICE-RELATED CHANGES OTHERWISE SUBJECT TO PREMARKET NOTIFICATION.—A requestor whose quality system is certified under this section that effectuates device-related changes with respect to in-scope devices, without prior submission of a premarket notification, shall ensure that an annual summary report is submitted to the Secretary by the accredited person which—

(i) describes the changes made to the in-scope device; and

(ii) indicates the effective dates of such changes.

(B) PERIODIC NOTIFICATION FOR MANUFACTURING CHANGES OTHERWISE SUBJECT TO THIRTY-DAY NOTICE.—A requestor whose quality system is certified under this section that effectuates device-related changes with respect to in-scope devices, without prior submission of a thirty-day notice, shall provide notification to the Secretary of such changes in the requestor's next periodic report under section

814.84(b) of title 21, Code of Federal Regulations (or any successor regulation). Such notification shall—

(i) describe the changes made; and

(ii) indicate the effective dates of such changes.

(C) PERIODIC NOTIFICATION FOR DEVICE-RELATED CHANGES OTHERWISE SUBJECT TO SPECIAL PMA SUPPLEMENT.—A requestor whose quality system is certified under this section that effectuates device-related changes with respect to in-scope devices, without prior submission of a Special PMA Supplement, shall provide notification to the Secretary of such changes in the requestor's next periodic report under section 814.84(b) of title 21, Code of Federal Regulations (or any successor regulation). Such notification shall—

(i) describe the changes made, including a full explanation of the basis for the changes; and

(ii) indicate the effective dates of such changes.

(D) USE OF NOTIFICATIONS FOR PROGRAM EVALUATION PURPOSES.—Information submitted to the Secretary under subparagraphs (A) through (C) shall be used by the Secretary for purposes of the program evaluation under subsection (d).

(c) DURATION AND EFFECT OF CERTIFICATION.—A certification under this section—

(1) shall remain in effect for a period of 2 years from the date such certification is accepted by the Secretary, subject to paragraph (6);

(2) may be renewed through the process described in subsection (a)(3);

(3) shall continue to apply with respect to device-related changes made during such 2-year period, provided the certification remains in effect, irrespective of whether such certification is renewed after such 2-year period;

(4) shall have no effect on the need to comply with applicable submission requirements specified in subsection (a)(1)(C) with respect to any change pertaining to in-scope devices which is not a device-related change under subsection (a)(2);

(5) shall have no effect on the authority of the Secretary to conduct an inspection or otherwise determine whether the requestor has complied with the applicable requirements of this Act; and

(6) may be revoked by the Secretary upon a determination that the requestor's quality system no longer meets the certification criteria specified in the guidance issued under subsection (a)(5) with respect to the in-scope devices at issue.

(d) NOTICE OF REVOCATION.—The Secretary shall provide written notification to the requestor of a revocation pursuant to subsection (c)(6) not later than 10 business days after the determination described in such subsection. Upon receipt of the written notification, the requestor shall satisfy the applicable submission requirements specified in subsection (a)(1)(C) for any device-related changes effectuated after the date of such determination. After such revocation, such requestor is eligible to seek re-certification under this section of its quality system.

(e) PROGRAM EVALUATION; SUNSET.—

(1) PROGRAM EVALUATION AND REPORT.—

(A) EVALUATION.—The Secretary shall complete an evaluation of the third-party quality system assessment program under this section no later than January 31, 2021, based on—

(i) analysis of information from a representative group of device manufacturers obtained from notifications provided by certified requestors or accredited persons under subsection (b)(2); and

(ii) such other available information and data as the Secretary determines appropriate.

(B) REPORT.—No later than 1 year after completing the evaluation under subparagraph (A), the Secretary shall issue a report of the evaluation's findings on the website of the Food and Drug Administration, which shall include the Secretary's recommendations with respect to continuation and as applicable expansion of the program under this section to encompass—

(i) device submissions beyond those identified in subsection (a)(1)(C); and

(ii) device changes beyond those described in subsection (a)(2)(A).

(2) SUNSET.—This section shall cease to be effective October 1, 2022.

(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the authority of the Secretary to request and review the complete assessment of a certified requestor under this section on a for-cause basis.

SEC. 524C. HEALTH SOFTWARE.

(a) INAPPLICABILITY OF REGULATION TO HEALTH SOFTWARE.—Except as provided in subsection (b), health software shall not be subject to regulation under this Act.

(b) EXCEPTION.—

(1) IN GENERAL.—Subsection (a) shall not apply with respect to a software product—

(A) of a type described in subparagraph (F) of section 201(ss)(1); and

(B) that the Secretary determines poses a significant risk to patient safety.

(2) CONSIDERATIONS.—In making a determination under subparagraph (B) of paragraph (1) with respect to a product to which such paragraph applies, the Secretary shall consider the following:

(A) The likelihood and severity of patient harm if the product were to not perform as intended.

(B) The extent to which the product is intended to support the clinical judgment of a medical professional.

(C) Whether there is a reasonable opportunity for a medical professional to review the basis of the information or treatment recommendation provided by the product.

(D) The intended user and user environment, such as whether a medical professional will use a software product of a type described in subparagraph (F) of section 201(ss)(1).

(c) DELEGATION.—The Secretary shall delegate primary jurisdiction for regulating a software product determined under subsection (b) to be subject to regulation under this Act to the center at the Food and Drug Administration charged with regulating devices.

(d) REGULATION OF SOFTWARE.—

(1) IN GENERAL.—The Secretary shall review existing regulations and guidance regarding the regulation of software under this Act. The Secretary may implement a new framework for the regulation of software and shall, as appropriate, modify such regulations and guidance or issue new regulations or guidance.

(2) ISSUANCE BY ORDER.—Notwithstanding subchapter II of chapter 5 of title 5, United States Code, the Secretary may modify or issue regulations for the regulation of software under this Act by administrative order published in the Federal Register following the publication of a proposed order.

(3) AREAS UNDER REVIEW.—The review of existing regulations and guidance under paragraph (1) may include review of the following areas:

(A) Classification of software.

(B) Standards for development of software.

(C) Standards for validation and verification of software.

(D) Review of software.

(E) Modifications to software.

(F) Manufacturing of software.

(G) Quality systems for software.

(H) Labeling requirements for software.

(I) Postmarketing requirements for reporting of adverse events.

(4) PROCESS FOR ISSUING PROPOSED REGULATIONS, ADMINISTRATIVE ORDER, AND GUIDANCE.—Not later than 18 months after the date of enactment of this section, the Secretary shall consult with external stakeholders (including patients, industry, health care providers, academia, and government) to gather input before issuing regulations, an administrative order, and guidance under this subsection.

(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as providing the Secretary with the authority to regulate under this Act any health software product of the type described in subparagraph (F) of section 201(ss)(1) unless and until the Secretary has made a determination described in subsection (b)(1)(B) with respect to such product.

SUBCHAPTER B—DRUGS FOR RARE DISEASES OR CONDITIONS

* * * * * * *

SEC. 529. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR RARE PEDIATRIC DISEASES.

(a) DEFINITIONS.—In this section:

(1) PRIORITY REVIEW.—The term "priority review", with respect to a human drug application as defined in section 735(1), means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012.

(2) PRIORITY REVIEW VOUCHER.—The term "priority review voucher" means a voucher issued by the Secretary to the sponsor of a rare pediatric disease product application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 505(b)(1) or section 351(a) of the Public Health Service Act after the date of approval of the rare pediatric disease product application.

(3) RARE PEDIATRIC DISEASE.—The term "rare pediatric disease" means a disease that meets each of the following criteria:

[(A) The disease primarily affects individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents.**]**

(A) The disease is a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents.

(B) The disease is a rare disease or condition, within the meaning of section 526.

(4) RARE PEDIATRIC DISEASE PRODUCT APPLICATION.—The term "rare pediatric disease product application" means a human drug application, as defined in section 735(1), that—

(A) is for a drug or biological product—

(i) that is for the prevention or treatment of a rare pediatric disease; and

(ii) that contains no active ingredient (including any ester or salt of the active ingredient) that has been previously approved in any other application under section 505(b)(1), 505(b)(2), or 505(j) of this Act or section 351(a) or 351(k) of the Public Health Service Act;

(B) is submitted under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act;

(C) the Secretary deems eligible for priority review;

(D) that relies on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population;

(E) that does not seek approval for an adult indication in the original rare pediatric disease product application; **[**and**]**

(F) is approved after the date of the enactment of the Prescription Drug User Fee Amendments of 2012**[**.**]***; and*

(G) is for a drug or biological product for which a priority review voucher has not been issued under section 524 (relating to tropical disease products).

(b) PRIORITY REVIEW VOUCHER.—

(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a rare pediatric disease product application upon approval by the Secretary of such rare pediatric disease product application.

(2) TRANSFERABILITY.—

(A) IN GENERAL.—The sponsor of a rare pediatric disease product application that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher. There is no limit on the number

of times a priority review voucher may be transferred before such voucher is used.

(B) NOTIFICATION OF TRANSFER.—Each person to whom a voucher is transferred shall notify the Secretary of such change in ownership of the voucher not later than 30 days after such transfer.

(3) LIMITATION.—A sponsor of a rare pediatric disease product application may not receive a priority review voucher under this section if the rare pediatric disease product application was submitted to the Secretary prior to the date that is 90 days after the date of enactment of the Prescription Drug User Fee Amendments of 2012.

(4) NOTIFICATION.—

(A) IN GENERAL.—The sponsor of a human drug application shall notify the Secretary not later than 90 days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

(B) TRANSFER AFTER NOTICE.—The sponsor of a human drug application that provides notification of the intent of such sponsor to use the voucher for the human drug application under subparagraph (A) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application described in the notification.

[(5) TERMINATION OF AUTHORITY.—The Secretary may not award any priority review vouchers under paragraph (1) after the last day of the 1-year period that begins on the date that the Secretary awards the third rare pediatric disease priority voucher under this section.]

(5) TERMINATION OF AUTHORITY.—The Secretary may not award any priority review vouchers under paragraph (1) after December 31, 2018.

(c) PRIORITY REVIEW USER FEE.—

(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary, based on the difference between—

(A) the average cost incurred by the Food and Drug Administration in the review of a human drug application subject to priority review in the previous fiscal year; and

(B) the average cost incurred by the Food and Drug Administration in the review of a human drug application that is not subject to priority review in the previous fiscal year.

(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after Sep-

tember 30, 2012, the amount of the priority review user fee for that fiscal year.

(4) PAYMENT.—

(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the notification by a sponsor of the intent of such sponsor to use the voucher, as specified in subsection (b)(4)(A). All other user fees associated with the human drug application shall be due as required by the Secretary or under applicable law.

(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriations Acts.

(d) DESIGNATION PROCESS.—

(1) IN GENERAL.—Upon the request of the manufacturer or the sponsor of a new drug, the Secretary may designate—

(A) the new drug as a drug for a rare pediatric disease; and

(B) the application for the new drug as a rare pediatric disease product application.

(2) REQUEST FOR DESIGNATION.—The request for a designation under paragraph (1) shall be made at the same time a request for designation of orphan disease status under section 526 or fast-track designation under section 506 is made. Requesting designation under this subsection is not a prerequisite to receiving a priority review voucher under this section.

(3) DETERMINATION BY SECRETARY.—Not later than 60 days after a request is submitted under paragraph (1), the Secretary shall determine whether—

(A) the disease or condition that is the subject of such request is a rare pediatric disease; and

(B) the application for the new drug is a rare pediatric disease product application.

(e) MARKETING OF RARE PEDIATRIC DISEASE PRODUCTS.—

(1) REVOCATION.—The Secretary may revoke any priority review voucher awarded under subsection (b) if the rare pediatric disease product for which such voucher was awarded is not marketed in the United States within the 365-day period beginning on the date of the approval of such drug under section 505 of this Act or section 351 of the Public Health Service Act.

(2) POSTAPPROVAL PRODUCTION REPORT.—The sponsor of an approved rare pediatric disease product shall submit a report to the Secretary not later than 5 years after the approval of the applicable rare pediatric disease product application. Such report shall provide the following information, with respect to each of the first 4 years after approval of such product:

(A) The estimated population in the United States suffering from the rare pediatric disease.

(B) The estimated demand in the United States for such rare pediatric disease product.

(C) The actual amount of such rare pediatric disease product distributed in the United States.

(f) NOTICE AND REPORT.—

(1) NOTICE OF ISSUANCE OF VOUCHER AND APPROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary shall publish a notice in the Federal Register and on the Internet Web site of the Food and Drug Administration not later than 30 days after the occurrence of each of the following:

(A) The Secretary issues a priority review voucher under this section.

(B) The Secretary approves a drug pursuant to an application submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act for which the sponsor of the application used a priority review voucher under this section.

(2) NOTIFICATION.—If, after the last day of the 1-year period that begins on the date that the Secretary awards the third rare pediatric disease priority voucher under this section, a sponsor of an application submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act for a drug uses a priority review voucher under this section for such application, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a document—

(A) notifying such Committees of the use of such voucher; and

(B) identifying the drug for which such priority review voucher is used.

(g) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing in this section precludes a sponsor who seeks a priority review voucher under this section from participating in any other incentive program, including under this Act.

(h) RELATION TO OTHER PROVISIONS.—The provisions of this section shall supplement, not supplant, any other provisions of this Act or the Public Health Service Act that encourage the development of drugs for tropical diseases and rare pediatric diseases.

(i) GAO STUDY AND REPORT.—

(1) STUDY.—

(A) IN GENERAL.—Beginning on the date that the Secretary awards the third rare pediatric disease priority voucher under this section, the Comptroller General of the United States shall conduct a study of the effectiveness of awarding rare pediatric disease priority vouchers under

this section in the development of human drug products that treat or prevent such diseases.

(B) CONTENTS OF STUDY.—In conducting the study under subparagraph (A), the Comptroller General shall examine the following:

(i) The indications for which each rare disease product for which a priority review voucher was awarded was approved under section 505 or section 351 of the Public Health Service Act.

(ii) Whether, and to what extent, an unmet need related to the treatment or prevention of a rare pediatric disease was met through the approval of such a rare disease product.

(iii) The value of the priority review voucher if transferred.

(iv) Identification of each drug for which a priority review voucher was used.

(v) The length of the period of time between the date on which a priority review voucher was awarded and the date on which it was used.

(2) REPORT.—Not later than 1 year after the date under paragraph (1)(A), the Comptroller General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, a report containing the results of the study under paragraph (1).

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SUBCHAPTER E—GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES

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SEC. 561A. EXPANDED ACCESS POLICY REQUIRED FOR INVESTIGATIONAL DRUGS.

(a) IN GENERAL.—The manufacturer or distributor of one or more investigational drugs for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions shall make publicly available the policy of the manufacturer or distributor on evaluating and responding to requests submitted under section 561(b) for provision of such a drug. A manufacturer or distributor may satisfy the requirement of the preceding sentence by posting such policy as generally applicable to all of such manufacturer's or distributor's investigational drugs.

(b) CONTENT OF POLICY.—A policy described in subsection (a) shall include making publicly available—

(1) contact information for the manufacturer or distributor to facilitate communication about requests described in subsection (a);

(2) procedures for making such requests;

(3) the general criteria the manufacturer or distributor will consider or use to approve such requests; and

(4) the length of time the manufacturer or distributor anticipates will be necessary to acknowledge receipt of such requests.

(c) NO GUARANTEE OF ACCESS.—The posting of policies by manufacturers and distributors under subsection (a) shall not serve as a

guarantee of access to any specific investigational drug by any individual patient.

(d) REVISED POLICY.—A manufacturer or distributor that has made a policy publicly available as required by this section may revise the policy at any time.

(e) APPLICATION.—This section shall apply to a manufacturer or distributor with respect to an investigational drug beginning on the later of—

(1) the date that is 60 days after the date of enactment of the 21st Century Cures Act; or

(2) the first initiation of a phase 2 or phase 3 study (as such terms are defined in section 312.21(b) and (c) of title 21, Code of Federal Regulations (or any successor regulations)) with respect to such investigational new drug.

* * * * * * *

Subchapter J—Precision Medicine

SEC. 591. GENERAL AGENCY GUIDANCE ON PRECISION MEDICINE.

(a) IN GENERAL.—The Secretary shall issue and periodically update guidance to assist sponsors in the development of a precision drug or biological product. Such guidance shall—

(1) define the term "precision drug or biological product"; and

(2) address the topics described in subsection (b).

(b) CERTAIN ISSUES.—The topics to be addressed by guidance under subsection (a) are—

(1) the evidence needed to support the use of biomarkers (as defined in section 507(e)) that identify subsets of patients as likely responders to therapies in order to streamline the conduct of clinical trials;

(2) recommendations for the design of studies to demonstrate the validity of a biomarker as a predictor of drug or biological product response;

(3) the manner and extent to which a benefit-risk assessment may be affected when clinical trials are limited to patient population subsets that are identified using biomarkers;

(4) the development of companion diagnostics in the context of a drug development program; and

(5) considerations for developing biomarkers that inform prescribing decisions for a drug or biological product, and when information regarding a biomarker may be included in the approved prescription labeling for a precision drug or biological product.

(c) DATE CERTAIN FOR INITIAL GUIDANCE.—The Secretary shall issue guidance under subsection (a) not later than 18 months after the date of the enactment of the 21st Century Cures Act.

SEC. 592. PRECISION MEDICINE REGARDING ORPHAN-DRUG AND EXPEDITED-APPROVAL PROGRAMS.

(a) IN GENERAL.—In the case of a precision drug or biological product that is the subject of an application submitted under section 505(b)(1), or section 351(a) of the Public Health Service Act, for the treatment of a serious or life-threatening disease or condition and has been designated under section 526 as a drug for a rare disease or condition, the Secretary may—

(1) consistent with applicable standards for approval, rely upon data or information previously submitted by the sponsor of the precision drug or biological product, or another sponsor, provided that the sponsor of the precision drug or biological product has obtained a contractual right of reference to such other sponsor's data and information, in an application approved under section 505(c) or licensed under section 351(a) of the Public Health Service Act, as applicable—

(A) for a different drug or biological product; or

(B) for a different indication for such precision drug or biological product,

in order to expedite clinical development for a precision drug or biological product that is using the same or similar approach as that used to support approval of the prior approved application or license, as appropriate; and

(2) as appropriate, consider the application for approval of such precision drug or biological product to be eligible for expedited review and approval programs described in section 506, including accelerated approval in accordance with subsection (c) of such section.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

(1) limit the authority of the Secretary to approve products pursuant to this Act and the Public Health Service Act as authorized prior to the date of enactment of this section; or

(2) confer any new rights, beyond those authorized under this Act prior to enactment of this section, with respect to a sponsor's ability to reference information contained in another application submitted under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act.

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CHAPTER VII—GENERAL AUTHORITY

SUBCHAPTER A—GENERAL ADMINISTRATIVE PROVISIONS

* * * * * * *

SEC. 708A. COLLECTION OF CERTAIN VOLUNTARY INFORMATION EXEMPTED FROM PAPERWORK REDUCTION ACT.

Chapter 35 of title 44, United States Code, shall not apply to the collection from patients, industry, academia, and other stakeholders, of voluntary information such as through voluntary surveys or questionnaires, initiated by the Secretary.

* * * * * * *

SEC. 714A. ADDITIONAL HIRING AUTHORITY.

(a) IN GENERAL.—The Secretary may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, appoint qualified candidates to scientific, technical, or professional positions within the following centers of the Food and Drug Administration:

(1) The Center for Drug Evaluation and Research.

(2) The Center for Biologics Evaluation and Research.

(3) The Center for Devices and Radiological Health.

Such positions shall be within the competitive service.

(b) COMPENSATION.—

(1) IN GENERAL.—Notwithstanding any other provision of law, including any requirement with respect to General Schedule pay rates under subchapter III of chapter 53 of title 5, United States Code, and consistent with the requirements of paragraph (2), the Secretary may determine and fix—

(A) the annual rate of pay of any individual appointed under subsection (a); and

(B) for purposes of retaining qualified employees, the annual rate of pay for any highly qualified scientific, technical, or professional personnel appointed to a position at any of the centers listed under subsection (a) before the date of enactment of this section.

(2) LIMITATION.—The annual rate of pay established pursuant to paragraph (1) may not exceed the annual rate of pay of the President.

(c) SUNSET.—The authority to appoint employees under this section shall terminate on September 30, 2022.

(d) REPORT.—

(1) IN GENERAL.—Not later than September 30, 2021, the Secretary shall submit a report to Congress that examines the extent to which the authority to appoint and retain personnel under this section enhanced the Food and Drug Administration's ability to meet the agency's critical need for highly qualified individuals for scientific, technical, or professional positions.

(2) RECOMMENDATIONS.—The report under paragraph (1) shall include the recommendations of the Secretary on—

(A) whether the authority to appoint personnel under this section should be reauthorized; and

(B) other personnel authorities that would help the Food and Drug Administration to better recruit and retain highly qualified individuals for scientific, technical, or professional positions in the agency's medical product centers.

* * * * * * *

Subchapter I—Reagan-Udall Foundation for the Food and Drug Administration

SEC. 770. ESTABLISHMENT AND FUNCTIONS OF THE FOUNDATION.

(a) IN GENERAL.—A nonprofit corporation to be known as the Reagan-Udall Foundation for the Food and Drug Administration (referred to in this subchapter as the "Foundation") shall be established in accordance with this section. The Foundation shall be headed by an Executive Director, appointed by the members of the Board of Directors under subsection (e). The Foundation shall not be an agency or instrumentality of the United States Government.

(b) PURPOSE OF FOUNDATION.—The purpose of the Foundation is to advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.

(c) DUTIES OF THE FOUNDATION.—The Foundation shall—

(1) taking into consideration the Critical Path reports and priorities published by the Food and Drug Administration,

identify unmet needs in the development, manufacture, and evaluation of the safety and effectiveness, including post-approval, of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics, and including the incorporation of more sensitive and predictive tools and devices to measure safety;

(2) establish goals and priorities in order to meet the unmet needs identified in paragraph (1);

(3) in consultation with the Secretary, identify existing and proposed Federal intramural and extramural research and development programs relating to the goals and priorities established under paragraph (2), coordinate Foundation activities with such programs, and minimize Foundation duplication of existing efforts;

(4) award grants to, or enter into contracts, memoranda of understanding, or cooperative agreements with, scientists and entities, which may include the Food and Drug Administration, university consortia, public-private partnerships, institutions of higher education, entities described in section 501(c)(3) of the Internal Revenue Code (and exempt from tax under section 501(a) of such Code), and industry, to efficiently and effectively advance the goals and priorities established under paragraph (2);

(5) recruit meeting participants and hold or sponsor (in whole or in part) meetings as appropriate to further the goals and priorities established under paragraph (2);

(6) release and publish information and data and, to the extent practicable, license, distribute, and release material, reagents, and techniques to maximize, promote, and coordinate the availability of such material, reagents, and techniques for use by the Food and Drug Administration, nonprofit organizations, and academic and industrial researchers to further the goals and priorities established under paragraph (2);

(7) ensure that—

(A) action is taken as necessary to obtain patents for inventions developed by the Foundation or with funds from the Foundation;

(B) action is taken as necessary to enable the licensing of inventions developed by the Foundation or with funds from the Foundation; and

(C) executed licenses, memoranda of understanding, material transfer agreements, contracts, and other such instruments, promote, to the maximum extent practicable, the broadest conversion to commercial and noncommercial applications of licensed and patented inventions of the Foundation to further the goals and priorities established under paragraph (2);

(8) provide objective clinical and scientific information to the Food and Drug Administration and, upon request, to other Federal agencies to assist in agency determinations of how to ensure that regulatory policy accommodates scientific advances and meets the agency's public health mission;

(9) conduct annual assessments of the unmet needs identified in paragraph (1); and

(10) carry out such other activities consistent with the purposes of the Foundation as the Board determines appropriate.

(d) BOARD OF DIRECTORS.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—The Foundation shall have a Board of Directors (referred to in this subchapter as the "Board"), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

(B) EX OFFICIO MEMBERS.—The ex officio members of the Board shall be the following individuals or their designees:

(i) The Commissioner.

(ii) The Director of the National Institutes of Health.

(iii) The Director of the Centers for Disease Control and Prevention.

(iv) The Director of the Agency for Healthcare Research and Quality.

(C) APPOINTED MEMBERS.—

(i) IN GENERAL.—The ex officio members of the Board under subparagraph (B) shall, by majority vote, appoint to the Board 14 individuals, of which 9 shall be from a list of candidates to be provided by the National Academy of Sciences and 5 shall be from lists of candidates provided by patient and consumer advocacy groups, professional scientific and medical societies, and industry trade organizations. Of such appointed members—

(I) 4 shall be representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries;

(II) 3 shall be representatives of academic research organizations;

(III) 2 shall be representatives of patient or consumer advocacy organizations;

(IV) 1 shall be a representative of health care providers; and

(V) 4 shall be at-large members with expertise or experience relevant to the purpose of the Foundation.

(ii) ADDITIONAL MEMBERS.—The Board, through amendments to the bylaws of the Foundation, may provide that the number of voting members of the Board shall be a number (to be specified in such amendment) greater than 14. Any Board positions that are established by any such amendment shall be appointed (by majority vote) by the individuals who, as of the date of such amendment, are voting members of the Board and persons so appointed may represent any of the categories specified in subclauses (I) through (V) of clause (i), so long as no more than 30 percent of the total voting members of the Board (including members whose positions are established by such amendment) are representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries.

[(ii)**]** *(iii)* REQUIREMENTS.—

(I) EXPERTISE.—[The ex officio members shall ensure] *The ex officio members, acting pursuant to clause (i), and the Board, acting pursuant to clause (ii), shall ensure* the Board membership includes individuals with expertise in areas including the sciences of developing, manufacturing, and evaluating the safety and effectiveness of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics.

(II) FEDERAL EMPLOYEES.—No employee of the Federal Government shall be appointed as a member of the Board under this subparagraph or under paragraph (3)(B). *For purposes of this section, the term "employee of the Federal Government" does not include a "special Government employee", as that term is defined in section 202(a) of title 18, United States Code.*

(D) INITIAL MEETING.—

(i) IN GENERAL.—Not later than 30 days after the date of the enactment of this subchapter, the Secretary shall convene a meeting of the ex officio members of the Board to—

(I) incorporate the Foundation; and

(II) appoint the members of the Board in accordance with subparagraph (C).

(ii) SERVICE OF EX OFFICIO MEMBERS.—Upon the appointment of the members of the Board under clause (i)(II)—

(I) the terms of service of the Director of the Centers for Disease Control and Prevention and of the Director of the Agency for Healthcare Research and Quality as ex officio members of the Board shall terminate; and

(II) the Commissioner and the Director of the National Institutes of Health shall continue to serve as ex officio members of the Board, but shall be nonvoting members.

(iii) CHAIR.—The ex officio members of the Board under subparagraph (B) shall designate an appointed member of the Board to serve as the Chair of the Board.

(2) DUTIES OF BOARD.—The Board shall—

(A) establish bylaws for the Foundation that—

(i) are published in the Federal Register and available for public comment;

(ii) establish policies for the selection of the officers, employees, agents, and contractors of the Foundation;

(iii) establish policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the disposition of the assets of the Foundation, including appropriate limits on the ability of donors to designate, by stipulation or restriction, the use or recipient of donated funds;

(iv) establish policies that would subject all employees, fellows, and trainees of the Foundation to the conflict of interest standards under section 208 of title 18, United States Code;

(v) establish licensing, distribution, and publication policies that support the widest and least restrictive use by the public of information and inventions developed by the Foundation or with Foundation funds to carry out the duties described in paragraphs (6) and (7) of subsection (c), and may include charging cost-based fees for published material produced by the Foundation;

(vi) specify principles for the review of proposals and awarding of grants and contracts that include peer review and that are consistent with those of the Foundation for the National Institutes of Health, to the extent determined practicable and appropriate by the Board;

(vii) specify a cap on administrative expenses for recipients of a grant, contract, or cooperative agreement from the Foundation;

(viii) establish policies for the execution of memoranda of understanding and cooperative agreements between the Foundation and other entities, including the Food and Drug Administration;

(ix) establish policies for funding training fellowships, whether at the Foundation, academic or scientific institutions, or the Food and Drug Administration, for scientists, doctors, and other professionals who are not employees of regulated industry, to foster greater understanding of and expertise in new scientific tools, diagnostics, manufacturing techniques, and potential barriers to translating basic research into clinical and regulatory practice;

(x) specify a process for annual Board review of the operations of the Foundation; and

(xi) establish specific duties of the Executive Director;

(B) prioritize and provide overall direction to the activities of the Foundation;

(C) evaluate the performance of the Executive Director; and

(D) carry out any other necessary activities regarding the functioning of the Foundation.

(3) TERMS AND VACANCIES.—

[(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C) shall be 4 years, except that the terms of offices for the initial appointed members of the Board shall expire on a staggered basis as determined by the ex officio members.]

(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C)(i), and the term of office of any member of the Board whose position is established pursuant to paragraph (1)(C)(ii), shall be 4 years, except that—

(i) the terms of offices for the members of the Board initially appointed under paragraph (1)(C)(i) shall expire on a staggered basis as determined by the ex officio members; and

(ii) the terms of office for the persons initially appointed to positions established pursuant to paragraph (1)(C)(ii) may be made to expire on a staggered basis, as determined by the individuals who, as of the date of the amendment establishing such positions, are members of the Board.

(B) VACANCY.—Any vacancy in the membership of the Board—

(i) shall not affect the power of the remaining members to execute the duties of the Board; and

(ii) shall be filled by appointment by the appointed members described in paragraph (1)(C) by majority vote.

(C) PARTIAL TERM.—If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed under subparagraph (B) to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(D) SERVING PAST TERM.—A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

(4) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.

(e) INCORPORATION.—The ex officio members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.

(f) NONPROFIT STATUS.—In carrying out subsection (b), the Board shall establish such policies and bylaws under subsection (d), and the Executive Director shall carry out such activities under subsection (g), as may be necessary to ensure that the Foundation maintains status as an organization that—

(1) is described in subsection (c)(3) of section 501 of the Internal Revenue Code of 1986; and

(2) is, under subsection (a) of such section, exempt from taxation.

(g) EXECUTIVE DIRECTOR.—

(1) IN GENERAL.—The Board shall appoint an Executive Director who shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

(2) COMPENSATION.—The compensation of the Executive Director shall be fixed by the Board [but shall not be greater than the compensation of the Commissioner].

(h) ADMINISTRATIVE POWERS.—In carrying out this subchapter, the Board, acting through the Executive Director, may—

(1) adopt, alter, and use a corporate seal, which shall be judicially noticed;

(2) hire, promote, compensate, and discharge 1 or more officers, employees, and agents, as may be necessary, and define their duties;

(3) prescribe the manner in which—

(A) real or personal property of the Foundation is acquired, held, and transferred;

(B) general operations of the Foundation are to be conducted; and

(C) the privileges granted to the Board by law are exercised and enjoyed;

(4) with the consent of the applicable executive department or independent agency, use the information, services, and facilities of such department or agencies in carrying out this section;

(5) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

(6) hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation under subsection (i);

(7) enter into such other contracts, leases, cooperative agreements, and other transactions as the Board considers appropriate to conduct the activities of the Foundation;

(8) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this subchapter;

(9) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;

(10) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;

(11) appoint other groups of advisors as may be determined necessary to carry out the functions of the Foundation; and

(12) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this subchapter.

(i) ACCEPTANCE OF FUNDS FROM OTHER SOURCES.—The Executive Director may solicit and accept on behalf of the Foundation, any funds, gifts, grants, devises, or bequests of real or personal property made to the Foundation, including from private entities, for the purposes of carrying out the duties of the Foundation.

(j) SERVICE OF FEDERAL EMPLOYEES.—Federal Government employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its functions, so long as such employees do not direct or control Foundation activities.

(k) DETAIL OF GOVERNMENT EMPLOYEES; FELLOWSHIPS.—

(1) DETAIL FROM FEDERAL AGENCIES.—Federal Government employees may be detailed from Federal agencies with or without reimbursement to those agencies to the Foundation at any time, and such detail shall be without interruption or loss of civil service status or privilege. Each such employee shall abide by the statutory, regulatory, ethical, and procedural standards

applicable to the employees of the agency from which such employee is detailed and those of the Foundation.

(2) VOLUNTARY SERVICE; ACCEPTANCE OF FEDERAL EMPLOYEES.—

(A) FOUNDATION.—The Executive Director of the Foundation may accept the services of employees detailed from Federal agencies with or without reimbursement to those agencies.

(B) FOOD AND DRUG ADMINISTRATION.—The Commissioner may accept the uncompensated services of Foundation fellows or trainees. Such services shall be considered to be undertaking an activity under contract with the Secretary as described in section 708.

(l) ANNUAL REPORTS.—

(1) REPORTS TO FOUNDATION.—Any recipient of a grant, contract, fellowship, memorandum of understanding, or cooperative agreement from the Foundation under this section shall submit to the Foundation a report on an annual basis for the duration of such grant, contract, fellowship, memorandum of understanding, or cooperative agreement, that describes the activities carried out under such grant, contract, fellowship, memorandum of understanding, or cooperative agreement.

(2) REPORT TO CONGRESS AND THE FDA.—Beginning with fiscal year 2009, the Executive Director shall submit to Congress and the Commissioner an annual report that—

(A) describes the activities of the Foundation and the progress of the Foundation in furthering the goals and priorities established under subsection (c)(2), including the practical impact of the Foundation on regulated product development;

(B) provides a specific accounting of the source and use of all funds used by the Foundation to carry out such activities; and

(C) provides information on how the results of Foundation activities could be incorporated into the regulatory and product review activities of the Food and Drug Administration.

(m) SEPARATION OF FUNDS.—The Executive Director shall ensure that the funds received from the Treasury [are held in separate accounts from funds received from entities under subsection (i)] *are managed as individual programmatic funds under subsection (i), according to best accounting practices*.

(n) FUNDING.—From amounts appropriated to the Food and Drug Administration for each fiscal year, the Commissioner shall transfer not less than $500,000 and not more than $1,250,000, to the Foundation to carry out subsections (a), (b), and (d) through (m).

FOOD AND DRUG ADMINISTRATION AMENDMENTS ACT OF 2007

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SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

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TITLE XI—OTHER PROVISIONS

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Subtitle B—Antibiotic Access and Innovation

[Sec. 1111. Identification of clinically susceptible concentrations of antimicrobials.]

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TITLE XI—OTHER PROVISIONS

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Subtitle B—Antibiotic Access and Innovation

[SEC. 1111. IDENTIFICATION OF CLINICALLY SUSCEPTIBLE CONCENTRATIONS OF ANTIMICROBIALS.

[(a) DEFINITION.—In this section, the term "clinically susceptible concentrations" means specific values which characterize bacteria as clinically susceptible, intermediate, or resistant to the drug (or drugs) tested.

[(b) IDENTIFICATION.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), through the Commissioner of Food and Drugs, shall identify (where such information is reasonably available) and periodically update clinically susceptible concentrations.

[(c) PUBLIC AVAILABILITY.—The Secretary, through the Commissioner of Food and Drugs, shall make such clinically susceptible concentrations publicly available, such as by posting on the Internet, not later than 30 days after the date of identification and any update under this section.

[(d) EFFECT.—Nothing in this section shall be construed to restrict, in any manner, the prescribing of antibiotics by physicians, or to limit the practice of medicine, including for diseases such as Lyme and tick-borne diseases.]

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SOCIAL SECURITY ACT

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TITLE XI—GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

PART A—GENERAL PROVISIONS

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SEC. 1128G. TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS.

(a) TRANSPARENCY REPORTS.—

(1) PAYMENTS OR OTHER TRANSFERS OF VALUE.—

(A) IN GENERAL.—On March 31, 2013, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer that provides a payment or other

transfer of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient), shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information with respect to the preceding calendar year:

(i) The name of the covered recipient.

(ii) The business address of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and National Provider Identifier of the covered recipient.

(iii) The amount of the payment or other transfer of value.

(iv) The dates on which the payment or other transfer of value was provided to the covered recipient.

(v) A description of the form of the payment or other transfer of value, indicated (as appropriate for all that apply) as—

(I) cash or a cash equivalent;

(II) in-kind items or services;

(III) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or

(IV) any other form of payment or other transfer of value (as defined by the Secretary).

(vi) A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as—

(I) consulting fees;

(II) compensation for services other than consulting;

(III) honoraria;

(IV) gift;

(V) entertainment;

(VI) food;

(VII) travel (including the specified destinations);

(VIII) education;

(IX) research;

(X) charitable contribution;

(XI) royalty or license;

(XII) current or prospective ownership or investment interest;

(XIII) direct compensation for serving as faculty or as a speaker for a medical education program;

(XIV) grant; or

(XV) any other nature of the payment or other transfer of value (as defined by the Secretary).

(vii) If the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of that covered drug, device, biological, or medical supply.

(viii) Any other categories of information regarding the payment or other transfer of value the Secretary determines appropriate.

(B) SPECIAL RULE FOR CERTAIN PAYMENTS OR OTHER TRANSFERS OF VALUE.—In the case where an applicable manufacturer provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the applicable manufacturer shall disclose that payment or other transfer of value under the name of the covered recipient.

(2) PHYSICIAN OWNERSHIP.—In addition to the requirement under paragraph (1)(A), on March 31, 2013, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer or applicable group purchasing organization shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information regarding any ownership or investment interest (other than an ownership or investment interest in a publicly traded security and mutual fund, as described in section 1877(c)) held by a physician (or an immediate family member of such physician (as defined for purposes of section 1877(a))) in the applicable manufacturer or applicable group purchasing organization during the preceding year:

(A) The dollar amount invested by each physician holding such an ownership or investment interest.

(B) The value and terms of each such ownership or investment interest.

(C) Any payment or other transfer of value provided to a physician holding such an ownership or investment interest (or to an entity or individual at the request of or designated on behalf of a physician holding such an ownership or investment interest), including the information described in clauses (i) through (viii) of paragraph (1)(A), except that in applying such clauses, "physician" shall be substituted for "covered recipient" each place it appears.

(D) Any other information regarding the ownership or investment interest the Secretary determines appropriate.

(b) PENALTIES FOR NONCOMPLIANCE.—

(1) FAILURE TO REPORT.—

(A) IN GENERAL.—Subject to subparagraph (B) except as provided in paragraph (2), any applicable manufacturer or applicable group purchasing organization that fails to submit information required under subsection (a) in a timely manner in accordance with rules or regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $1,000, but not more than $10,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

(B) LIMITATION.—The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection

(a) by an applicable manufacturer or applicable group purchasing organization shall not exceed $150,000.

(2) KNOWING FAILURE TO REPORT.—

(A) IN GENERAL.—Subject to subparagraph (B), any applicable manufacturer or applicable group purchasing organization that knowingly fails to submit information required under subsection (a) in a timely manner in accordance with rules or regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $10,000, but not more than $100,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

(B) LIMITATION.—The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by an applicable manufacturer or applicable group purchasing organization shall not exceed $1,000,000.

(3) USE OF FUNDS.—Funds collected by the Secretary as a result of the imposition of a civil money penalty under this subsection shall be used to carry out this section.

(c) PROCEDURES FOR SUBMISSION OF INFORMATION AND PUBLIC AVAILABILITY.—

(1) IN GENERAL.—

(A) ESTABLISHMENT.—Not later than October 1, 2011, the Secretary shall establish procedures—

(i) for applicable manufacturers and applicable group purchasing organizations to submit information to the Secretary under subsection (a); and

(ii) for the Secretary to make such information submitted available to the public.

(B) DEFINITION OF TERMS.—The procedures established under subparagraph (A) shall provide for the definition of terms (other than those terms defined in subsection (e)), as appropriate, for purposes of this section.

(C) PUBLIC AVAILABILITY.—Except as provided in subparagraph (E), the procedures established under subparagraph (A)(ii) shall ensure that, not later than September 30, 2013, and on June 30 of each calendar year beginning thereafter, the information submitted under subsection (a) with respect to the preceding calendar year is made available through an Internet website that—

(i) is searchable and is in a format that is clear and understandable;

(ii) contains information that is presented by the name of the applicable manufacturer or applicable group purchasing organization, the name of the covered recipient, the business address of the covered recipient, the specialty of the covered recipient, the value of the payment or other transfer of value, the date on which the payment or other transfer of value was provided to the covered recipient, the form of the

payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(A)(v), the nature of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(A)(vi), and the name of the covered drug, device, biological, or medical supply, as applicable;

(iii) contains information that is able to be easily aggregated and downloaded;

(iv) contains a description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (b), during the preceding year;

(v) contains background information on industry-physician relationships;

(vi) in the case of information submitted with respect to a payment or other transfer of value described in subparagraph (E)(i), lists such information separately from the other information submitted under subsection (a) and designates such separately listed information as funding for clinical research;

(vii) contains any other information the Secretary determines would be helpful to the average consumer;

(viii) does not contain the National Provider Identifier of the covered recipient, and

(ix) subject to subparagraph (D), provides the applicable manufacturer, applicable group purchasing organization, or covered recipient an opportunity to review and submit corrections to the information submitted with respect to the applicable manufacturer, applicable group purchasing organization, or covered recipient, respectively, for a period of not less than 45 days prior to such information being made available to the public.

(D) CLARIFICATION OF TIME PERIOD FOR REVIEW AND CORRECTIONS.—In no case may the 45-day period for review and submission of corrections to information under subparagraph (C)(ix) prevent such information from being made available to the public in accordance with the dates described in the matter preceding clause (i) in subparagraph (C).

(E) DELAYED PUBLICATION FOR PAYMENTS MADE PURSUANT TO PRODUCT RESEARCH OR DEVELOPMENT AGREEMENTS AND CLINICAL INVESTIGATIONS.—

(i) IN GENERAL.—In the case of information submitted under subsection (a) with respect to a payment or other transfer of value made to a covered recipient by an applicable manufacturer pursuant to a product research or development agreement for services furnished in connection with research on a potential new medical technology or a new application of an existing medical technology or the development of a new drug, device, biological, or medical supply, or by an applicable manufacturer in connection with a clinical investigation regarding a new drug, device, biological, or medical supply, the procedures established under sub-

paragraph (A)(ii) shall provide that such information is made available to the public on the first date described in the matter preceding clause (i) in subparagraph (C) after the earlier of the following:

(I) The date of the approval or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration.

(II) Four calendar years after the date such payment or other transfer of value was made.

(ii) CONFIDENTIALITY OF INFORMATION PRIOR TO PUBLICATION.—Information described in clause (i) shall be considered confidential and shall not be subject to disclosure under section 552 of title 5, United States Code, or any other similar Federal, State, or local law, until on or after the date on which the information is made available to the public under such clause.

(2) CONSULTATION.—In establishing the procedures under paragraph (1), the Secretary shall consult with the Inspector General of the Department of Health and Human Services, affected industry, consumers, consumer advocates, and other interested parties in order to ensure that the information made available to the public under such paragraph is presented in the appropriate overall context.

(d) ANNUAL REPORTS AND RELATION TO STATE LAWS.—

(1) ANNUAL REPORT TO CONGRESS.—Not later than April 1 of each year beginning with 2013, the Secretary shall submit to Congress a report that includes the following:

(A) The information submitted under subsection (a) during the preceding year, aggregated for each applicable manufacturer and applicable group purchasing organization that submitted such information during such year (except, in the case of information submitted with respect to a payment or other transfer of value described in subsection (c)(1)(E)(i), such information shall be included in the first report submitted to Congress after the date on which such information is made available to the public under such subsection).

(B) A description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (b), during the preceding year.

(2) ANNUAL REPORTS TO STATES.—Not later than September 30, 2013 and on June 30 of each calendar year thereafter, the Secretary shall submit to States a report that includes a summary of the information submitted under subsection (a) during the preceding year with respect to covered recipients in the State (except, in the case of information submitted with respect to a payment or other transfer of value described in subsection (c)(1)(E)(i), such information shall be included in the first report submitted to States after the date on which such information is made available to the public under such subsection).

(3) RELATION TO STATE LAWS.—

(A) IN GENERAL.—In the case of a payment or other transfer of value provided by an applicable manufacturer that is received by a covered recipient (as defined in subsection (e)) on or after January 1, 2012, subject to subpara-

graph (B), the provisions of this section shall preempt any statute or regulation of a State or of a political subdivision of a State that requires an applicable manufacturer (as so defined) to disclose or report, in any format, the type of information (as described in subsection (a)) regarding such payment or other transfer of value.

(B) NO PREEMPTION OF ADDITIONAL REQUIREMENTS.—Subparagraph (A) shall not preempt any statute or regulation of a State or of a political subdivision of a State that requires the disclosure or reporting of information—

(i) not of the type required to be disclosed or reported under this section;

(ii) described in subsection (e)(10)(B), except in the case of information described in clause (i) of such subsection;

(iii) by any person or entity other than an applicable manufacturer (as so defined) or a covered recipient (as defined in subsection (e)); or

(iv) to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes.

(C) Nothing in subparagraph (A) shall be construed to limit the discovery or admissibility of information described in such subparagraph in a criminal, civil, or administrative proceeding.

(4) CONSULTATION.—The Secretary shall consult with the Inspector General of the Department of Health and Human Services on the implementation of this section.

(e) DEFINITIONS.—In this section:

(1) APPLICABLE GROUP PURCHASING ORGANIZATION.—The term "applicable group purchasing organization" means a group purchasing organization (as defined by the Secretary) that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States.

(2) APPLICABLE MANUFACTURER.—The term "applicable manufacturer" means a manufacturer of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States.

(3) CLINICAL INVESTIGATION.—The term "clinical investigation" means any experiment involving 1 or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed, or used.

(4) COVERED DEVICE.—The term "covered device" means any device for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

(5) COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY.—The term "covered drug, device, biological, or medical supply" means any drug, biological product, device, or medical supply for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

(6) COVERED RECIPIENT.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the term "covered recipient" means the following:

(i) A physician.

(ii) A teaching hospital.

(B) EXCLUSION.—Such term does not include a physician who is an employee of the applicable manufacturer that is required to submit information under subsection (a).

(7) EMPLOYEE.—The term "employee" has the meaning given such term in section 1877(h)(2).

(8) KNOWINGLY.—The term "knowingly" has the meaning given such term in section 3729(b) of title 31, United States Code.

(9) MANUFACTURER OF A COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY.—The term "manufacturer of a covered drug, device, biological, or medical supply" means any entity which is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply (or any entity under common ownership with such entity which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply).

(10) PAYMENT OR OTHER TRANSFER OF VALUE.—

(A) IN GENERAL.—The term "payment or other transfer of value" means a transfer of anything of value. Such term does not include a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient.

(B) EXCLUSIONS.—An applicable manufacturer shall not be required to submit information under subsection (a) with respect to the following:

(i) A transfer of anything the value of which is less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient by the applicable manufacturer during the calendar year exceeds $100. For calendar years after 2012, the dollar amounts specified in the preceding sentence shall be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year.

(ii) Product samples that are not intended to be sold and are intended for patient use.

(iii) Educational materials that directly benefit patients or are intended for patient use*, including peer-reviewed journals, journal reprints, journal supplements, medical conference reports, and medical textbooks*.

(iv) The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.

(v) Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

(vi) A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.

(vii) Discounts (including rebates).

(viii) In-kind items used for the provision of charity care.

(ix) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund (as described in section 1877(c)).

(x) In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.

(xi) In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional.

(xii) In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.

(xiii) In the case of a covered recipient who is a physician, an indirect payment or transfer of value to the covered recipient—

(I) for speaking at, or preparing educational materials for, an educational event for physicians or other health care professionals that does not commercially promote a covered drug, device, biological, or medical supply; or

(II) that serves the sole purpose of providing the covered recipient with medical education, such as by providing the covered recipient with the tuition required to attend an educational event or with materials provided to physicians at an educational event.

(11) PHYSICIAN.—The term "physician" has the meaning given that term in section 1861(r).

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TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

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PROVISIONS RELATING TO ADMINISTRATION

SEC. 1808. (a) COORDINATED ADMINISTRATION OF MEDICARE PRESCRIPTION DRUG AND MEDICARE ADVANTAGE PROGRAMS.—

(1) IN GENERAL.—There is within the Centers for Medicare & Medicaid Services a center to carry out the duties described in paragraph (3).

(2) DIRECTOR.—Such center shall be headed by a director who shall report directly to the Administrator of the Centers for Medicare & Medicaid Services.

(3) DUTIES.—The duties described in this paragraph are the following:

(A) The administration of parts C and D.

(B) The provision of notice and information under section 1804.

(C) Such other duties as the Secretary may specify.

(4) DEADLINE.—The Secretary shall ensure that the center is carrying out the duties described in paragraph (3) by not later than January 1, 2008.

(b) EMPLOYMENT OF MANAGEMENT STAFF.—

(1) IN GENERAL.—The Secretary may employ, within the Centers for Medicare & Medicaid Services, such individuals as management staff as the Secretary determines to be appropriate. With respect to the administration of parts C and D, such individuals shall include individuals with private sector expertise in negotiations with health benefits plans.

(2) ELIGIBILITY.—To be eligible for employment under paragraph (1) an individual shall be required to have demonstrated, by their education and experience (either in the public or private sector), superior expertise in at least one of the following areas:

(A) The review, negotiation, and administration of health care contracts.

(B) The design of health care benefit plans.

(C) Actuarial sciences.

(D) Compliance with health plan contracts.

(E) Consumer education and decision making.

(F) Any other area specified by the Secretary that requires specialized management or other expertise.

(3) RATES OF PAYMENT.—

(A) PERFORMANCE-RELATED PAY.—Subject to subparagraph (B), the Secretary shall establish the rate of pay for an individual employed under paragraph (1). Such rate shall take into account expertise, experience, and performance.

(B) LIMITATION.—In no case may the rate of compensation determined under subparagraph (A) exceed the highest rate of basic pay for the Senior Executive Service under section 5382(b) of title 5, United States Code.

(c) MEDICARE BENEFICIARY OMBUDSMAN.—

(1) IN GENERAL.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Beneficiary Ombudsman who shall have expertise and experience in the fields of health care and education of (and assistance to) individuals entitled to benefits under this title.

(2) DUTIES.—The Medicare Beneficiary Ombudsman shall—

(A) receive complaints, grievances, and requests for information submitted by individuals entitled to benefits

under part A or enrolled under part B, or both, with respect to any aspect of the medicare program;

(B) provide assistance with respect to complaints, grievances, and requests referred to in subparagraph (A), including—

(i) assistance in collecting relevant information for such individuals, to seek an appeal of a decision or determination made by a fiscal intermediary, carrier, MA organization, or the Secretary;

(ii) assistance to such individuals with any problems arising from disenrollment from an MA plan under part C; and

(iii) assistance to such individuals in presenting information under section 1839(i)(4)(C) (relating to income-related premium adjustment; and

(C) submit annual reports to Congress and the Secretary that describe the activities of the Office and that include such recommendations for improvement in the administration of this title as the Ombudsman determines appropriate.

The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.

(3) WORKING WITH HEALTH INSURANCE COUNSELING PROGRAMS.—To the extent possible, the Ombudsman shall work with health insurance counseling programs (receiving funding under section 4360 of Omnibus Budget Reconciliation Act of 1990) to facilitate the provision of information to individuals entitled to benefits under part A or enrolled under part B, or both regarding MA plans and changes to those plans. Nothing in this paragraph shall preclude further collaboration between the Ombudsman and such programs.

(4) PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN.—Not later than 12 months after the date of the enactment of this paragraph, the Secretary shall provide for a pharmaceutical and technology ombudsman within the Centers for Medicare & Medicaid Services who shall receive and respond to complaints, grievances, and requests that—

(A) are from entities that manufacture pharmaceutical, biotechnology, medical device, or diagnostic products that are covered or for which coverage is being sought under this title; and

(B) are with respect to coverage, coding, or payment under this title for such products.

(5) MONITORING DME REIMBURSEMENT UNDER MEDICAID.—The ombudsmen under each of paragraphs (1) and (4) shall evaluate the impact of the competitive acquisition program under section 1847, including as applied under section 1903(i)(27), on beneficiary health status and health outcomes.

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PART B—SUPPLEMENTARY MEDICAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

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PAYMENT OF BENEFITS

SEC. 1833. (a) Except as provided in section 1876, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to—

(1) in the case of services described in section 1832(a)(1)—80 percent of the reasonable charges for the services; except that (A) an organization which provides medical and other health services (or arranges for their availability) on a prepayment basis (and either is sponsored by a union or employer, or does not provide, or arrange for the provision of, any inpatient hospital services) may elect to be paid 80 percent of the reasonable cost of services for which payment may be made under this part on behalf of individuals enrolled in such organization in lieu of 80 percent of the reasonable charges for such services if the organization undertakes to charge such individuals no more than 20 percent of such reasonable cost plus any amounts payable by them as a result of subsection (b), (B) with respect to items and services described in section 1861(s)(10)(A), the amounts paid shall be 100 percent of the reasonable charges for such items and services, (C) with respect to expenses incurred for those physicians' services for which payment may be made under this part that are described in section 1862(a)(4), the amounts paid shall be subject to such limitations as may be prescribed by regulations, (D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i)(I) on the basis of a fee schedule under subsection (h)(1) (for tests furnished before January 1, 2017) or section 1834(d)(1), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B), or the amount of the charges billed for the tests, or (II) undersection 1834A (for tests furnished on or after January1, 2017), the amount paid shall be equal to 80 percent(or 100 percent, in the case of such tests for whichpayment is made on an assignment-related basis) ofthe lesser of the amount determined under such sectionor the amount of the charges billed for the tests, or(ii) for tests furnished before January 1, 2017,on the basis of a negotiated rate established under subsection (h)(6), the amount paid shall be equal to 100 percent of such negotiated rate,, (E) with respect to services furnished to individuals who have been determined to have end stage renal disease, the amounts paid shall be determined subject to the provisions of section 1881, (F) with respect to clinical social worker services under section 1861(s)(2)(N), the amounts paid shall be 80 percent of the lesser of (i) the actual charge for the services or (ii) 75 percent of the amount determined for payment of a psychologist under clause (L),

(G) with respect to facility services furnished in connection with a surgical procedure specified pursuant to subsection (i)(1)(A) and furnished to an individual in an ambulatory surgical center described in such subsection, for services furnished beginning with the implementation date of a revised payment system for such services in such facilities specified in subsection (i)(2)(D), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under such revised payment system,

(H) with respect to services of a certified registered nurse anesthetist under section 1861(s)(11), the amounts paid shall be 80 percent of the least of the actual charge, the prevailing charge that would be recognized (or, for services furnished on or after January 1, 1992, the fee schedule amount provided under section 1848) if the services had been performed by an anesthesiologist, or the fee schedule for such services established by the Secretary in accordance with subsection (l), (I) with respect to covered items (described in section 1834(a)(13)), the amounts paid shall be the amounts described in section 1834(a)(1), and (J) with respect to expenses incurred for radiologist services (as defined in section 1834(b)(6)), subject to section 1848, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount provided under the fee schedule established under section 1834(b), (K) with respect to certified nurse-midwife services under section 1861(s)(2)(L), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph (but in no event shall such fee schedule exceed 65 percent of the prevailing charge that would be allowed for the same service performed by a physician, or, for services furnished on or after January 1, 1992, 65 percent (or 100 percent for services furnished on or after January 1, 2011) of the fee schedule amount provided under section 1848 for the same service performed by a physician), (L) with respect to qualified psychologist services under section 1861(s)(2)(M), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph, (M) with respect to prosthetic devices and orthotics and prosthetics (as defined in section 1834(h)(4)), the amounts paid shall be the amounts described in section 1834(h)(1), (N) with respect to expenses incurred for physicians' services (as defined in section 1848(j)(3)) other than personalized prevention plan services (as defined in section 1861(hhh)(1)), the amounts paid shall be 80 percent of the payment basis determined under section 1848(a)(1), (O) with respect to services described in section 1861(s)(2)(K) (relating to services furnished by physician assistants, nurse practitioners, or clinic nurse specialists), the amounts paid shall be equal to 80 percent of (i) the lesser of the actual charge or 85 percent of the fee schedule amount provided under section 1848, or (ii) in the case of services as an assistant at surgery, the lesser of the actual charge or 85 percent of the amount that would oth-

erwise be recognized if performed by a physician who is serving as an assistant at surgery, (P) with respect to surgical dressings, the amounts paid shall be the amounts determined under section 1834(i), (Q) with respect to items or services for which fee schedules are established pursuant to section 1842(s), the amounts paid shall be 80 percent of the lesser of the actual charge or the fee schedule established in such section, (R) with respect to ambulance services, (i) the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary under section 1834(l) and (ii) with respect to ambulance services described in section 1834(l)(8), the amounts paid shall be the amounts determined under section 1834(g) for outpatient critical access hospital services, (S) with respect to drugs and biologicals (including intravenous immune globulin (as defined in section 1861(zz))) not paid on a cost or prospective payment basis as otherwise provided in this part (other than items and services described in subparagraph (B)), the amounts paid shall be 80 percent of the lesser of the actual charge or the payment amount established in section 1842(o) (or, if applicable, under section 1847, 1847A, or 1847B), (T) with respect to medical nutrition therapy services (as defined in section 1861(vv)), the amount paid shall be 80 percent (or 100 percent if such services are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual) of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) for the same services if furnished by a physician, (U) with respect to facility fees described in section 1834(m)(2)(B), the amounts paid shall be 80 percent of the lesser of the actual charge or the amounts specified in such section, (V) notwithstanding subparagraphs (I) (relating to durable medical equipment), (M) (relating to prosthetic devices and orthotics and prosthetics), and (Q) (relating to 1842(s) items), with respect to competitively priced items and services (described in section 1847(a)(2)) that are furnished in a competitive area, the amounts paid shall be the amounts described in section 1847(b)(5), (W) with respect to additional preventive services (as defined in section 1861(ddd)(1)), the amount paid shall be (i) in the case of such services which are clinical diagnostic laboratory tests, the amount determined under subparagraph (D) (if such subparagraph were applied, by substituting "100 percent" for "80 percent"), and (ii) in the case of all other such services, 100 percent of the lesser of the actual charge for the service or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph, (X) with respect to personalized prevention plan services (as defined in section 1861(hhh)(1)), the amount paid shall be 100 percent of the lesser of the actual charge for the services or the amount determined under the payment basis determined under section 1848, (Y) with respect to preventive services described in subparagraphs (A) and (B) of section 1861(ddd)(3) that are appropriate for the individual and, in the case of such services de-

scribed in subparagraph (A), are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population, the amount paid shall be 100 percent of (i) except as provided in clause (ii), the lesser of the actual charge for the services or the amount determined under the fee schedule that applies to such services under this part, and (ii) in the case of such services that are covered OPD services (as defined in subsection (t)(1)(B)), the amount determined under subsection (t), and (Z) with respect to Federally qualified health center services for which payment is made under section 1834(o), the amounts paid shall be 80 percent of the lesser of the actual charge or the amount determined under such section;

(2) in the case of services described in section 1832(a)(2) (except those services described in subparagraphs (C), (D), (E), (F), (G), (H), and (I) of such section and unless otherwise specified in section 1881)—

(A) with respect to home health services (other than a covered osteoporosis drug) (as defined in section 1861(kk)), the amount determined under the prospective payment system under section 1895;

(B) with respect to other items and services (except those described in subparagraph (C), (D), or (E) of this paragraph and except as may be provided in section 1886 or section 1888(e)(9))—

(i) furnished before January 1, 1999, the lesser of—

(I) the reasonable cost of such services, as determined under section 1861(v), or

(II) the customary charges with respect to such services,—less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A), but in no case may the payment for such other services exceed 80 percent of such reasonable cost, or

(ii) if such services are furnished before January 1, 1999, by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this clause), free of charge or at nominal charges to the public, 80 percent of the amount determined in accordance with section 1814(b)(2), or

(iii) if such services are furnished on or after January 1, 1999, the amount determined under subsection (t), or

(iv) if (and for so long as) the conditions described in section 1814(b)(3) are met, the amounts determined under the reimbursement system described in such section;

(C) with respect to services described in the second sentence of section 1861(p), 80 percent of the reasonable charges for such services;

(D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i)(I)on the basis of a fee schedule determined under subsection(h)(1) (for

tests furnished before January 1, 2017) or section 1834(d)(1), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1866) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B), or the amount of the charges billed for the tests, or (II) under section 1834A (for tests furnished on or after January 1, 2017), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1866) of the lesser of the amount determined under such section or the amount of the charges billed for the tests, or (ii) for tests furnished before January 1, 2017, on the basis of a negotiated rate established under subsection (h)(6), the amount paid shall be equal to 100 percent of such negotiated rate for such tests;

(E) with respect to—

(i) outpatient hospital radiology services (including diagnostic and therapeutic radiology, nuclear medicine and CAT scan procedures, magnetic resonance imaging, and ultrasound and other imaging services, but excluding screening mammography and, for services furnished on or after January 1, 2005, diagnostic mammography), and

(ii) effective for procedures performed on or after October 1, 1989, diagnostic procedures (as defined by the Secretary) described in section 1861(s)(3) (other than diagnostic x-ray tests and diagnostic laboratory tests),

the amount determined under subsection (n) or, for services or procedures performed on or after January 1, 1999, subsection (t);

(F) with respect to a covered osteoporosis drug (as defined in section 1861(kk)) furnished by a home health agency, 80 percent of the reasonable cost of such service, as determined under section 1861(v);

(G) with respect to items and services described in section 1861(s)(10)(A), the lesser of—

(i) the reasonable cost of such services, as determined under section 1861(v), or

(ii) the customary charges with respect to such services; and

(H) with respect to personalized prevention plan services (as defined in section 1861(hhh)(1)) furnished by an outpatient department of a hospital, the amount determined under paragraph (1)(X),

or, if such services are furnished by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this provision), free of charge or at nominal charges to the public, the amount determined in accordance with section 1814(b)(2);

(3) in the case of services described in section 1832(a)(2)(D)—

(A) except as provided in subparagraph (B), the costs which are reasonable and related to the cost of furnishing such services or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations, including those authorized under section 1861(v)(1)(A), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A), but in no case may the payment for such services (other than for items and services described in section 1861(s)(10)(A)) exceed 80 percent of such costs; or

(B) with respect to the services described in clause (ii) of section 1832(a)(2)(D) that are furnished to an individual enrolled with a MA plan under part C pursuant to a written agreement described in section 1853(a)(4), the amount (if any) by which—

(i) the amount of payment that would have otherwise been provided (I) under subparagraph (A) (calculated as if "100 percent" were substituted for "80 percent" in such subparagraph) for such services if the individual had not been so enrolled, or (II) in the case of such services furnished on or after the implementation date of the prospective payment system under section 1834(o), under such section (calculated as if "100 percent" were substituted for "80 percent" in such section) for such services if the individual had not been so enrolled; exceeds

(ii) the amount of the payments received under such written agreement for such services (not including any financial incentives provided for in such agreement such as risk pool payments, bonuses, or withholds),

less the amount the federally qualified health center may charge as described in section 1857(e)(3)(B);

(4) in the case of facility services described in section 1832(a)(2)(F), and outpatient hospital facility services furnished in connection with surgical procedures specified by the Secretary pursuant to section 1833(i)(1)(A), the applicable amount as determined under paragraph (2) or (3) of subsection (i) or subsection (t);

(5) in the case of covered items (described in section 1834(a)(13)) the amounts described in section 1834(a)(1);

(6) in the case of outpatient critical access hospital services, the amounts described in section 1834(g);

(7) in the case of prosthetic devices and orthotics and prosthetics (as described in section 1834(h)(4)), the amounts described in section 1834(h);

(8) in the case of—

(A) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services furnished—

(i) by a rehabilitation agency, public health agency, clinic, comprehensive outpatient rehabilitation facility, or skilled nursing facility,

(ii) by a home health agency to an individual who is not homebound, or

(iii) by another entity under an arrangement with an entity described in clause (i) or (ii); and

(B) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services furnished—

(i) by a hospital to an outpatient or to a hospital inpatient who is entitled to benefits under part A but has exhausted benefits for inpatient hospital services during a spell of illness or is not so entitled to benefits under part A, or

(ii) by another entity under an arrangement with a hospital described in clause (i),

the amounts described in section 1834(k); and

(9) in the case of services described in section 1832(a)(2)(E) that are not described in paragraph (8), the amounts described in section 1834(k).

Paragraph (3)(A) shall not apply to Federally qualified health center services furnished on or after the implementation date of the prospective payment system under section 1834(0).

(b) Before applying subsection (a) with respect to expenses incurred by an individual during any calendar year, the total amount of the expenses incurred by such individual during such year (which would, except for this subsection, constitute incurred expenses from which benefits payable under subsection (a) are determinable) shall be reduced by a deductible of $75 for calendar years before 1991, $100 for 1991 through 2004, $110 for 2005, and for a subsequent year the amount of such deductible for the previous year increased by the annual percentage increase in the monthly actuarial rate under section 1839(a)(1) ending with such subsequent year (rounded to the nearest $1); except that (1) such total amount shall not include expenses incurred for preventive services described in subparagraph (A) of section 1861(ddd)(3) that are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual., (2) such deductible shall not apply with respect to home health services (other than a covered osteoporosis drug (as defined in section 1861(kk))), (3) such deductible shall not apply with respect to clinical diagnostic laboratory tests for which payment is made under this part (A) under subsection (a)(1)(D)(i) or (a)(2)(D)(i) on an assignment-related basis, or to a provider having an agreement under section 1866, or (B) for tests furnished before January 1, 2017,on the basis of a negotiated rate determined under subsection (h)(6), (4) such deductible shall not apply to Federally qualified health center services, (5) such deductible shall not apply with respect to screening mammography (as described in section 1861(jj)), (6) such deductible shall not apply with respect to screening pap smear and screening pelvic exam (as described in section 1861(nn)), (7) such deductible shall not apply with respect to ultrasound screening for abdominal aortic aneurysm (as defined in section 1861(bbb)), (8) such deductible shall not apply with respect to colorectal cancer screening tests (as described in section 1861(pp)(1)), (9) such deductible shall not apply with respect to an initial preventive physical examination (as defined in section 1861(ww)), and (10) such deductible shall not apply with respect to personalized prevention plan services (as defined in section

1861(hhh)(1)). The total amount of the expenses incurred by an individual as determined under the preceding sentence shall, after the reduction specified in such sentence, be further reduced by an amount equal to the expenses incurred for the first three pints of whole blood (or equivalent quantities of packed red blood cells, as defined under regulations) furnished to the individual during the calendar year, except that such deductible for such blood shall in accordance with regulations be appropriately reduced to the extent that there has been a replacement of such blood (or equivalent quantities of packed red blood cells, as so defined); and for such purposes blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual shall be deemed replaced when the institution or other person furnishing such blood (or such equivalent quantities of packed red blood cells, as so defined) is given one pint of blood for each pint of blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual with respect to which a deduction is made under this sentence. The deductible under the previous sentence for blood or blood cells furnished an individual in a year shall be reduced to the extent that a deductible has been imposed under section 1813(a)(2) to blood or blood cells furnished the individual in the year. Paragraph (1) of the first sentence of this subsection shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

(c)(1) Notwithstanding any other provision of this part, with respect to expenses incurred in a calendar year in connection with the treatment of mental, psychoneurotic, and personality disorders of an individual who is not an inpatient of a hospital at the time such expenses are incurred, there shall be considered as incurred expenses for purposes of subsections (a) and (b)—

(A) for expenses incurred in years prior to 2010, only 62½ percent of such expenses;

(B) for expenses incurred in 2010 or 2011, only 68¾ percent of such expenses;

(C) for expenses incurred in 2012, only 75 percent of such expenses;

(D) for expenses incurred in 2013, only 81¼ percent of such expenses; and

(E) for expenses incurred in 2014 or any subsequent calendar year, 100 percent of such expenses.

(2) For purposes of subparagraphs (A) through (D) of paragraph (1), the term "treatment" does not include brief office visits (as defined by the Secretary) for the sole purpose of monitoring or changing drug prescriptions used in the treatment of such disorders or partial hospitalization services that are not directly provided by a physician

(d) No payment may be made under this part with respect to any services furnished an individual to the extent that such individual is entitled (or would be entitled except for section 1813) to have payment made with respect to such services under part A.

(e) No payment shall be made to any provider of services or other person under this part unless there has been furnished such infor-

mation as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

(f) In establishing limits under subsection (a) on payment for rural health clinic services provided by rural health clinics (other than such clinics in hospitals with less than 50 beds), the Secretary shall establish such limit, for services provided—

(1) in 1988, after March 31, at $46 per visit, and

(2) in a subsequent year, at the limit established under this subsection for the previous year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) applicable to primary care services (as defined in section 1842(i)(4)) furnished as of the first day of that year.

(g)(1) Subject to paragraphs (4) and (5), in the case of physical therapy services of the type described in section 1861(p) and speech-language pathology services of the type described in such section through the application of section 1861(ll)(2), but (except as provided in paragraph (6)) not described in subsection (a)(8)(B), and physical therapy services and speech-language pathology services of such type which are furnished by a physician or as incident to physicians' services, with respect to expenses incurred in any calendar year, no more than the amount specified in paragraph (2) for the year shall be considered as incurred expenses for purposes of subsections (a) and (b).

(2) The amount specified in this paragraph—

(A) for 1999, 2000, and 2001, is $1,500, and

(B) for a subsequent year is the amount specified in this paragraph for the preceding year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year;

except that if an increase under subparagraph (B) for a year is not a multiple of $10, it shall be rounded to the nearest multiple of $10.

(3) Subject to paragraphs (4) and (5), in the case of occupational therapy services (of the type that are described in section 1861(p) (but (except as provided in paragraph (6)) not described in subsection (a)(8)(B)) through the operation of section 1861(g) and of such type which are furnished by a physician or as incident to physicians' services), with respect to expenses incurred in any calendar year, no more than the amount specified in paragraph (2) for the year shall be considered as incurred expenses for purposes of subsections (a) and (b).

(4) This subsection shall not apply to expenses incurred with respect to services furnished during 2000, 2001, 2002, 2004, and 2005.

(5)(A) With respect to expenses incurred during the period beginning on January 1, 2006, and ending on December 31, 2017, for services, the Secretary shall implement a process under which an individual enrolled under this part may, upon request of the individual or a person on behalf of the individual, obtain an exception from the uniform dollar limitation specified in paragraph (2), for services described in paragraphs (1) and (3) if the provision of such services is determined to be medically necessary and if the requirement of subparagraph (B) is met. Under such process, if the Sec-

retary does not make a decision on such a request for an exception within 10 business days of the date of the Secretary's receipt of the request made in accordance with such requirement, the Secretary shall be deemed to have found the services to be medically necessary.

(B) In the case of outpatient therapy services for which an exception is requested under the first sentence of subparagraph (A), the claim for such services shall contain an appropriate modifier (such as the KX modifier used as of the date of the enactment of this subparagraph) indicating that such services are medically necessary as justified by appropriate documentation in the medical record involved.

(C)(i) In applying this paragraph with respect to a request for an exception with respect to expenses that would be incurred for outpatient therapy services (including services described in subsection (a)(8)(B)) that would exceed the threshold described in clause (ii) for a year, the request for such an exception, for services furnished on or after October 1, 2012, shall be subject to a manual medical review process that, subject to subparagraph (E), is similar to the manual medical review process used for certain exceptions under this paragraph in 2006.

(ii) The threshold under this clause for a year is $3,700. Such threshold shall be applied separately—

(I) for physical therapy services and speech-language pathology services; and

(II) for occupational therapy services.

(D) With respect to services furnished on or after January 1, 2013, where payment may not be made as a result of application of paragraphs (1) and (3), section 1879 shall apply in the same manner as such section applies to a denial that is made by reason of section 1862(a)(1).

(E)(i) In place of the manual medical review process under subparagraph (C)(i), the Secretary shall implement a process for medical review under this subparagraph under which the Secretary shall identify and conduct medical review for services described in subparagraph (C)(i) furnished by a provider of services or supplier (in this subparagraph referred to as a "therapy provider") using such factors as the Secretary determines to be appropriate.

(ii) Such factors may include the following:

(I) The therapy provider has had a high claims denial percentage for therapy services under this part or is less compliant with applicable requirements under this title.

(II) The therapy provider has a pattern of billing for therapy services under this part that is aberrant compared to peers or otherwise has questionable billing practices for such services, such as billing medically unlikely units of services in a day.

(III) The therapy provider is newly enrolled under this title or has not previously furnished therapy services under this part.

(IV) The services are furnished to treat a type of medical condition.

(V) The therapy provider is part of group that includes another therapy provider identified using the factors determined under this subparagraph.

(iii) For purposes of carrying out this subparagraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of $5,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for fiscal years 2015 and 2016, to remain available until expended. Such funds may not be used by a contractor under section 1893(h) for medical reviews under this subparagraph.

(iv) The targeted review process under this subparagraph shall not apply to services for which expenses are incurred beyond the period for which the exceptions process under subparagraph (A) is implemented.

(6)(A) In applying paragraphs (1) and (3) to services furnished during the period beginning not later than October 1, 2012, and ending on December 31, 2017, the exclusion of services described in subsection (a)(8)(B) from the uniform dollar limitation specified in paragraph (2) shall not apply to such services furnished during 2012 through 2017.

(B)(i) With respect to outpatient therapy services furnished beginning on or after January 1, 2013, and before January 1, 2014, for which payment is made under section 1834(g), the Secretary shall count toward the uniform dollar limitations described in paragraphs (1) and (3) and the threshold described in paragraph (5)(C) the amount that would be payable under this part if such services were paid under section 1834(k)(1)(B) instead of being paid under section 1834(g).

(ii) Nothing in clause (i) shall be construed as changing the method of payment for outpatient therapy services under section 1834(g).

(h)(1)(A) Subject to section 1834(d)(1), the Secretary shall establish fee schedules for clinical diagnostic laboratory tests (including prostate cancer screening tests under section 1861(oo) consisting of prostate-specific antigen blood tests) for which payment is made under this part, other than such tests performed by a provider of services for an inpatient of such provider.

(B) In the case of clinical diagnostic laboratory tests performed by a physician or by a laboratory (other than tests performed by a qualified hospital laboratory (as defined in subparagraph (D)) for outpatients of such hospital), the fee schedules established under subparagraph (A) shall be established on a regional, statewide, or carrier service area basis (as the Secretary may determine to be appropriate) for tests furnished on or after July 1, 1984.

(C) In the case of clinical diagnostic laboratory tests performed by a qualified hospital laboratory (as defined in subparagraph (D)) for outpatients of such hospital, the fee schedules established under subparagraph (A) shall be established on a regional, statewide, or carrier service area basis (as the Secretary may determine to be appropriate) for tests furnished on or after July 1, 1984.

(D) In this subsection, the term "qualified hospital laboratory" means a hospital laboratory, in a sole community hospital (as defined in section 1886(d)(5)(D)(iii)), which provides some clinical diagnostic laboratory tests 24 hours a day in order to serve a hospital emergency room which is available to provide services 24 hours a day and 7 days a week.

(2)(A)(i) Except as provided in clause (v), subparagraph (B), and paragraph (4), the Secretary shall set the fee schedules at 60 percent (or, in the case of a test performed by a qualified hospital laboratory (as defined in paragraph (1)(D)) for outpatients of such hospital, 62 percent) of the prevailing charge level determined pursuant to the third and fourth sentences of section 1842(b)(3) for similar clinical diagnostic laboratory tests for the applicable region, State, or area for the 12-month period beginning July 1, 1984, adjusted annually (to become effective on January 1 of each year) by, subject to clause (iv), a percentage increase or decrease equal to the percentage increase or decrease in the Consumer Price Index for All Urban Consumers (United States city average) minus, for each of the years 2009 and 2010, 0.5 percentage points, and, for tests furnished before the dateof enactment of section 1834A, subject to such other adjustments as the Secretary determines are justified by technological changes.

(ii) Notwithstanding clause (i)—

(I) any change in the fee schedules which would have become effective under this subsection for tests furnished on or after January 1, 1988, shall not be effective for tests furnished during the 3-month period beginning on January 1, 1988,

(II) the Secretary shall not adjust the fee schedules under clause (i) to take into account any increase in the consumer price index for 1988,

(III) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1991, 1992, and 1993 shall be 2 percent, and

(IV) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1994 and 1995, 1998 through 2002, and 2004 through 2008 shall be 0 percent.

(iii) In establishing fee schedules under clause (i) with respect to automated tests and tests (other than cytopathology tests) which before July 1, 1984, the Secretary made subject to a limit based on lowest charge levels under the sixth sentence of section 1842(b)(3) performed after March 31, 1988, the Secretary shall reduce by 8.3 percent the fee schedules otherwise established for 1988, and such reduced fee schedules shall serve as the base for 1989 and subsequent years.

(iv) After determining the adjustment to the fee schedules under clause (i), the Secretary shall reduce such adjustment—

(I) for 2011 and each subsequent year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(II) for each of 2011 through 2015, by 1.75 percentage points.

Subclause (I) shall not apply in a year where the adjustment to the fee schedules determined under clause (i) is 0.0 or a percentage decrease for a year. The application of the productivity adjustment under subclause (I) shall not result in an adjustment to the fee schedules under clause (i) being less than 0.0 for a year. The application of subclause (II) may result in an adjustment to the fee schedules under clause (i) being less than 0.0 for a year, and may result in payment rates for a year being less than such payment rates for the preceding year.

(v) The Secretary shall reduce by 2 percent the fee schedules otherwise determined under clause (i) for 2013, and such reduced fee schedules shall serve as the base for 2014 and subsequent years.

(B) The Secretary may make further adjustments or exceptions to the fee schedules to assure adequate reimbursement of (i) emergency laboratory tests needed for the provision of bona fide emergency services, and (ii) certain low volume high-cost tests where highly sophisticated equipment or extremely skilled personnel are necessary to assure quality.

(3) In addition to the amounts provided under the fee schedules (for tests furnished before January 1, 2017)or under section 1834A (for tests furnished on or afterJanuary 1, 2017), subject to subsection (b)(5) of such section, the Secretary shall provide for and establish (A) a nominal fee to cover the appropriate costs in collecting the sample on which a clinical diagnostic laboratory test was performed and for which payment is made under this part, except that not more than one such fee may be provided under this paragraph with respect to samples collected in the same encounter, and (B) a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample, except that such a fee may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital). In establishing a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a sample, the Secretary shall provide a method for computing the fee based on the number of miles traveled and the personnel costs associated with the collection of each individual sample, but the Secretary shall only be required to apply such method in the case of tests furnished during the period beginning on April 1, 1989, and ending on December 31, 1990, by a laboratory that establishes to the satisfaction of the Secretary (based on data for the 12-month period ending June 30, 1988) that (i) the laboratory is dependent upon payments under this title for at least 80 percent of its collected revenues for clinical diagnostic laboratory tests, (ii) at least 85 percent of its gross revenues for such tests are attributable to tests performed with respect to individuals who are homebound or who are residents in a nursing facility, and (iii) the laboratory provided such tests for residents in nursing facilities representing at least 20 percent of the number of such facilities in the State in which the laboratory is located.

(4)(A) In establishing any fee schedule under this subsection, the Secretary may provide for an adjustment to take into account, with respect to the portion of the expenses of clinical diagnostic laboratory tests attributable to wages, the relative difference between a region's or local area's wage rates and the wage rate presumed in the data on which the schedule is based.

(B) For purposes of subsections (a)(1)(D)(i) and (a)(2)(D)(i), the limitation amount for a clinical diagnostic laboratory test performed—

(i) on or after July 1, 1986, and before April 1, 1988, is equal to 115 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(ii) after March 31, 1988, and before January 1, 1990, is equal to the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iii) after December 31, 1989, and before January 1, 1991, is equal to 93 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iv) after December 31, 1990, and before January 1, 1994, is equal to 88 percent of such median,

(v) after December 31, 1993, and before January 1, 1995, is equal to 84 percent of such median,

(vi) after December 31, 1994, and before January 1, 1996, is equal to 80 percent of such median,

(vii) after December 31, 1995, and before January 1, 1998, is equal to 76 percent of such median, and

(viii) after December 31, 1997, is equal to 74 percent of such median (or 100 percent of such median in the case of a clinical diagnostic laboratory test performed on or after January 1, 2001, that the Secretary determines is a new test for which no limitation amount has previously been established under this subparagraph).

(5)(A) In the case of a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part on an assignment-related basis or under a provider agreement under section 1866, payment may be made only to the person or entity which performed or supervised the performance of such test; except that—

(i) if a physician performed or supervised the performance of such test, payment may be made to another physician with whom he shares his practice,

(ii) in the case of a test performed at the request of a laboratory by another laboratory, payment may be made to the referring laboratory but only if—

(I) the referring laboratory is located in, or is part of, a rural hospital,

(II) the referring laboratory is wholly owned by the entity performing such test, the referring laboratory wholly owns the entity performing such test, or both the referring laboratory and the entity performing such test are wholly-owned by a third entity, or

(III) not more than 30 percent of the clinical diagnostic laboratory tests for which such referring laboratory (but not including a laboratory described in subclause (II)), receives requests for testing during the year in which the test is performed are performed by another laboratory, and

(iii) in the case of a clinical diagnostic laboratory test provided under an arrangement (as defined in section 1861(w)(1)) made by a hospital, critical access hospital, or skilled nursing facility, payment shall be made to the hospital or skilled nursing facility.

(B) In the case of such a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part, and which is not described in subparagraph (A), payment may be made to the beneficiary only on the basis of the itemized bill of the person or entity which performed or supervised the performance of the test.

(C) Payment for a clinical diagnostic laboratory test, including a test performed in a physician's office but excluding a test per-

formed by a rural health clinic may only be made on an assignment-related basis or to a provider of services with an agreement in effect under section 1866.

(D) A person may not bill for a clinical diagnostic laboratory test, including a test performed in a physician's office but excluding a test performed by a rural health clinic, other than on an assignment-related basis. If a person knowingly and willfully and on a repeated basis bills for a clinical diagnostic laboratory test in violation of the previous sentence, the Secretary may apply sanctions against the person in the same manner as the Secretary may apply sanctions against a physician in accordance with paragraph (2) of section 1842(j) in the same manner such paragraphs apply with respect to a physician. Paragraph (4) of such section shall apply in this subparagraph in the same manner as such paragraph applies to such section.

(6) For tests furnished before January 1, 2017, inthe case of any diagnostic laboratory test payment for which is not made on the basis of a fee schedule under paragraph (1), the Secretary may establish a payment rate which is acceptable to the person or entity performing the test and which would be considered the full charge for such tests. Such negotiated rate shall be limited to an amount not in excess of the total payment that would have been made for the services in the absence of such rate.

(7) Notwithstanding paragraphs (1) and (4)and section 1834A, the Secretary shall establish a national minimum payment amount under this part for a diagnostic or screening pap smear laboratory test (including all cervical cancer screening technologies that have been approved by the Food and Drug Administration as a primary screening method for detection of cervical cancer) equal to $14.60 for tests furnished in 2000. For such tests furnished in subsequent years, such national minimum payment amount shall be adjusted annually as provided in paragraph (2).

(8)(A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005 (in this paragraph referred to as "new tests").

(B) Determinations under subparagraph (A) shall be made only after the Secretary—

(i) makes available to the public (through an Internet website and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount under this subsection is being considered for a year;

(ii) on the same day such list is made available, causes to have published in the Federal Register notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis under this subsection for establishing payment amounts for the tests on such list;

(iii) not less than 30 days after publication of such notice convenes a meeting, that includes representatives of officials of the Centers for Medicare & Medicaid Services involved in determining payment amounts, to receive such comments and

recommendations (and data on which the recommendations are based);

(iv) taking into account the comments and recommendations (and accompanying data) received at such meeting, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under this subsection for each such code, together with an explanation of the reasons for each such determination, the data on which the determinations are based, and a request for public written comments on the proposed determination; and

(v) taking into account the comments received during the public comment period, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of final determinations of the payment amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

(C) Under the procedures established pursuant to subparagraph (A), the Secretary shall—

(i) set forth the criteria for making determinations under subparagraph (A); and

(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary deems appropriate.

(E) For purposes of this paragraph:

(i) The term "HCPCS" refers to the Health Care Procedure Coding System.

(ii) A code shall be considered to be "substantially revised" if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test).

(9) Notwithstanding any other provision in this part, in the case of any diagnostic laboratory test for HbA1c that is labeled by the Food and Drug Administration for home use and is furnished on or after April 1, 2008, the payment rate for such test shall be the payment rate established under this part for a glycated hemoglobin test (identified as of October 1, 2007, by HCPCS code 83036 (and any succeeding codes)).

(i)(1) The Secretary shall, in consultation with appropriate medical organizations—

(A) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in an ambulatory surgical center (meeting the standards specified under section 1832(a)(2)(F)(i)), critical access hospital, or hospital outpatient department, and

(B) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital

inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in a physician's office.

The lists of procedures established under subparagraphs (A) and (B) shall be reviewed and updated not less often than every 2 years, in consultation with appropriate trade and professional organizations.

(2)(A) For services furnished prior to the implementation of the system described in subparagraph (D), subject to subparagraph (E), the amount of payment to be made for facility services furnished in connection with a surgical procedure specified pursuant to paragraph (1)(A) and furnished to an individual in an ambulatory surgical center described in such paragraph shall be equal to 80 percent of a standard overhead amount established by the Secretary (with respect to each such procedure) on the basis of the Secretary's estimate of a fair fee which—

(i) takes into account the costs incurred by such centers, or classes of centers, generally in providing services furnished in connection with the performance of such procedure, as determined in accordance with a survey (based upon a representative sample of procedures and facilities) of the actual audited costs incurred by such centers in providing such services,

(ii) takes such costs into account in such a manner as will assure that the performance of the procedure in such a center will result in substantially less amounts paid under this title than would have been paid if the procedure had been performed on an inpatient basis in a hospital, and

(iii) in the case of insertion of an intraocular lens during or subsequent to cataract surgery includes payment which is reasonable and related to the cost of acquiring the class of lens involved.

Each amount so established shall be reviewed and updated not later than July 1, 1987, and annually thereafter to take account of varying conditions in different areas.

(B) The amount of payment to be made under this part for facility services furnished, in connection with a surgical procedure specified pursuant to paragraph (1)(B), in a physician's office shall be equal to 80 percent of a standard overhead amount established by the Secretary (with respect to each such procedure) on the basis of the Secretary's estimate of a fair fee which—

(i) takes into account additional costs, not usually included in the professional fee, incurred by physicians in securing, maintaining, and staffing the facilities and ancillary services appropriate for the performance of such procedure in the physician's office, and

(ii) takes such items into account in such a manner which will assure that the performance of such procedure in the physician's office will result in substantially less amounts paid under this title than would have been paid if the services had been furnished on an inpatient basis in a hospital.

Each amount so established shall be reviewed and updated not later than July 1, 1987, and annually thereafter to take account of varying conditions in different areas.

(C)(i) Notwithstanding the second sentence of each of subparagraphs (A) and (B), except as otherwise specified in clauses (ii),

(iii), and (iv), if the Secretary has not updated amounts established under such subparagraphs or under subparagraph (D), with respect to facility services furnished during a fiscal year (beginning with fiscal year 1986 or a calendar year (beginning with 2006)), such amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(ii) In each of the fiscal years 1998 through 2002, the increase under this subparagraph shall be reduced (but not below zero) by 2.0 percentage points.

(iii) In fiscal year 2004, beginning with April 1, 2004, the increase under this subparagraph shall be the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with March 31, 2003, minus 3.0 percentage points.

(iv) In fiscal year 2005, the last quarter of calendar year 2005, and each of calendar years 2006 through 2009, the increase under this subparagraph shall be 0 percent.

(D)(i) Taking into account the recommendations in the report under section 626(d) of Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Secretary shall implement a revised payment system for payment of surgical services furnished in ambulatory surgical centers.

(ii) In the year the system described in clause (i) is implemented, such system shall be designed to result in the same aggregate amount of expenditures for such services as would be made if this subparagraph did not apply, as estimated by the Secretary and taking into account reduced expenditures that would apply if subparagraph (E) were to continue to apply, as estimated by the Secretary.

(iii) The Secretary shall implement the system described in clause (i) for periods in a manner so that it is first effective beginning on or after January 1, 2006, and not later than January 1, 2008.

(iv) The Secretary may implement such system in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).

(v) In implementing the system described in clause (i) for 2011 and each subsequent year, any annual update under such system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II). The application of the preceding sentence may result in such update being less than 0.0 for a year, and may result in payment rates under the system described in clause (i) for a year being less than such payment rates for the preceding year.

(vi) There shall be no administrative or judicial review under section 1869, 1878, or otherwise, of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, under this subparagraph.

(E) With respect to surgical procedures furnished on or after January 1, 2007, and before the effective date of the implementation of a revised payment system under subparagraph (D), if—

(i) the standard overhead amount under subparagraph (A) for a facility service for such procedure, without the application of any geographic adjustment, exceeds

(ii) the Medicare OPD fee schedule amount established under the prospective payment system for hospital outpatient department services under paragraph (3)(D) of section 1833(t) for such service for such year, determined without regard to geographic adjustment under paragraph (2)(D) of such section,

the Secretary shall substitute under subparagraph (A) the amount described in clause (ii) for the standard overhead amount for such service referred to in clause (i).

(3)(A) The aggregate amount of the payments to be made under this part for outpatient hospital facility services or critical access hospital services furnished before January 1, 1999, in connection with surgical procedures specified under paragraph (1)(A) shall be equal to the lesser of—

(i) the amount determined with respect to such services under subsection (a)(2)(B); or

(ii) the blend amount (described in subparagraph (B)).

(B)(i) The blend amount for a cost reporting period is the sum of—

(I) the cost proportion (as defined in clause (ii)(I)) of the amount described in subparagraph (A)(i), and

(II) the ASC proportion (as defined in clause (ii)(II)) of the standard overhead amount payable with respect to the same surgical procedure as if it were provided in an ambulatory surgical center in the same area, as determined under paragraph (2)(A), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A).

(ii) Subject to paragraph (4), in this paragraph:

(I) The term "cost proportion" means 75 percent for cost reporting periods beginning in fiscal year 1988, 50 percent for portions of cost reporting periods beginning on or after October 1, 1988, and ending on or before December 31, 1990, and 42 percent for portions of cost reporting periods beginning on or after January 1, 1991.

(II) The term "ASC proportion" means 25 percent for cost reporting periods beginning in fiscal year 1988, 50 percent for portions of cost reporting periods beginning on or after October 1, 1988, and ending on or before December 31, 1990, and 58 percent for portions of cost reporting periods beginning on or after January 1, 1991.

(4)(A) In the case of a hospital that—

(i) makes application to the Secretary and demonstrates that it specializes in eye services or eye and ear services (as determined by the Secretary),

(ii) receives more than 30 percent of its total revenues from outpatient services, and

(iii) on October 1, 1987—

(I) was an eye specialty hospital or an eye and ear specialty hospital, or

(II) was operated as an eye or eye and ear unit (as defined in subparagraph (B)) of a general acute care hospital which, on the date of the application described in clause (i), operates less than 20 percent of the beds that the hos-

pital operated on October 1, 1987, and has sold or otherwise disposed of a substantial portion of the hospital's other acute care operations,

the cost proportion and ASC proportion in effect under subclauses (I) and (II) of paragraph (3)(B)(ii) for cost reporting periods beginning in fiscal year 1988 shall remain in effect for cost reporting periods beginning on or after October 1, 1988, and before January 1, 1995.

(B) For purposes of this subparagraph (A)(iii)(II), the term "eye or eye and ear unit" means a physically separate or distinct unit containing separate surgical suites devoted solely to eye or eye and ear services.

(5)(A) The Secretary is authorized to provide by regulations that in the case of a surgical procedure, specified by the Secretary pursuant to paragraph (1)(A), performed in an ambulatory surgical center described in such paragraph, there shall be paid (in lieu of any amounts otherwise payable under this part) with respect to the facility services furnished by such center and with respect to all related services (including physicians' services, laboratory, X-ray, and diagnostic services) a single all-inclusive fee established pursuant to subparagraph (B), if all parties furnishing all such services agree to accept such fee (to be divided among the parties involved in such manner as they shall have previously agreed upon) as full payment for the services furnished.

(B) In implementing this paragraph, the Secretary shall establish with respect to each surgical procedure specified pursuant to paragraph (1)(A) the amount of the all-inclusive fee for such procedure, taking into account such factors as may be appropriate. The amount so established with respect to any surgical procedure shall be reviewed periodically and may be adjusted by the Secretary, when appropriate, to take account of varying conditions in different areas.

(6) Any person, including a facility having an agreement under section 1832(a)(2)(F)(i), who knowingly and willfully presents, or causes to be presented, a bill or request for payment, for an intraocular lens inserted during or subsequent to cataract surgery for which payment may be made under paragraph (2)(A)(iii), is subject to a civil money penalty of not to exceed $2,000. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(7)(A) For purposes of paragraph (2)(D)(iv), the Secretary may provide, in the case of an ambulatory surgical center that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to a year, any annual increase provided under the system established under paragraph (2)(D) for such year shall be reduced by 2.0 percentage points. A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take into account such reduction in computing any annual increase factor for a subsequent year.

(B) Except as the Secretary may otherwise provide, the provisions of subparagraphs (B), (C), (D), and (E) of paragraph (17) of section 1833(t) shall apply with respect to services of ambulatory

surgical centers under this paragraph in a similar manner to the manner in which they apply under such paragraph and, for purposes of this subparagraph, any reference to a hospital, outpatient setting, or outpatient hospital services is deemed a reference to an ambulatory surgical center, the setting of such a center, or services of such a center, respectively.

(j) Whenever a final determination is made that the amount of payment made under this part either to a provider of services or to another person pursuant to an assignment under section 1842(b)(3)(B)(ii) was in excess of or less than the amount of payment that is due, and payment of such excess or deficit is not made (or effected by offset) within 30 days of the date of the determination, interest shall accrue on the balance of such excess or deficit not paid or offset (to the extent that the balance is owed by or owing to the provider) at a rate determined in accordance with the regulations of the Secretary of the Treasury applicable to charges for late payments.

(k) With respect to services described in section 1861(s)(10)(B), the Secretary may provide, instead of the amount of payment otherwise provided under this part, for payment of such an amount or amounts as reasonably reflects the general cost of efficiently providing such services.

(l)(1)(A) The Secretary shall establish a fee schedule for services of certified registered nurse anesthetists under section 1861(s)(11).

(B) In establishing the fee schedule under this paragraph the Secretary may utilize a system of time units, a system of base and time units, or any appropriate methodology.

(C) The provisions of this subsection shall not apply to certain services furnished in certain hospitals in rural areas under the provisions of section 9320(k) of the Omnibus Budget Reconciliation Act of 1986, as amended by section 6132 of the Omnibus Budget Reconciliation Act of 1989.

(2) Except as provided in paragraph (3), the fee schedule established under paragraph (1) shall be initially based on audited data from cost reporting periods ending in fiscal year 1985 and such other data as the Secretary determines necessary.

(3)(A) In establishing the initial fee schedule for those services, the Secretary shall adjust the fee schedule to the extent necessary to ensure that the estimated total amount which will be paid under this title for those services plus applicable coinsurance in 1989 will equal the estimated total amount which would be paid under this title for those services in 1989 if the services were included as inpatient hospital services and payment for such services was made under part A in the same manner as payment was made in fiscal year 1987, adjusted to take into account changes in prices and technology relating to the administration of anesthesia.

(B) The Secretary shall also reduce the prevailing charge of physicians for medical direction of a certified registered nurse anesthetist, or the fee schedule for services of certified registered nurse anesthetists, or both, to the extent necessary to ensure that the estimated total amount which will be paid under this title plus applicable coinsurance for such medical direction and such services in 1989 and 1990 will not exceed the estimated total amount which would have been paid plus applicable coinsurance but for the enactment of the amendments made by section 9320 of the Omnibus

Budget Reconciliation Act of 1986. A reduced prevailing charge under this subparagraph shall become the prevailing charge but for subsequent years for purposes of applying the economic index under the fourth sentence of section 1842(b)(3).

(4)(A) Except as provided in subparagraphs (C) and (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, by a certified registered nurse anesthetist who is not medically directed—

(i) the conversion factor shall be—

(I) for services furnished in 1991, $15.50,

(II) for services furnished in 1992, $15.75,

(III) for services furnished in 1993, $16.00,

(IV) for services furnished in 1994, $16.25,

(V) for services furnished in 1995, $16.50,

(VI) for services furnished in 1996, $16.75, and

(VII) for services furnished in calendar years after 1996, the previous year's conversion factor increased by the update determined under section 1848(d) for physician anesthesia services for that year;

(ii) the payment areas to be used shall be the fee schedule areas used under section 1848 (or, in the case of services furnished during 1991, the localities used under section 1842(b)) for purposes of computing payments for physicians' services that are anesthesia services;

(iii) the geographic adjustment factors to be applied to the conversion factor under clause (i) for services in a fee schedule area or locality is—

(I) in the case of services furnished in 1991, the geographic work index value and the geographic practice cost index value specified in section 1842(q)(1)(B) for physicians' services that are anesthesia services furnished in the area or locality, and

(II) in the case of services furnished after 1991, the geographic work index value, the geographic practice cost index value, and the geographic malpractice index value used for determining payments for physicians' services that are anesthesia services under section 1848,

with 70 percent of the conversion factor treated as attributable to work and 30 percent as attributable to overhead for services furnished in 1991 (and the portions attributable to work, practice expenses, and malpractice expenses in 1992 and thereafter being the same as is applied under section 1848).

(B)(i) Except as provided in clause (ii) and subparagraph (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, and before January 1, 1994, by a certified registered nurse anesthetist who is medically directed, the Secretary shall apply the same methodology specified in subparagraph (A).

(ii) The conversion factor used under clause (i) shall be—

(I) for services furnished in 1991, $10.50,

(II) for services furnished in 1992, $10.75, and

(III) for services furnished in 1993, $11.00.

(iii) In the case of services of a certified registered nurse anesthetist who is medically directed or medically supervised by a physician which are furnished on or after January 1, 1994, the fee

schedule amount shall be one-half of the amount described in section 1848(a)(5)(B) with respect to the physician.

(C) Notwithstanding subclauses (I) through (V) of subparagraph (A)(i)—

(i) in the case of a 1990 conversion factor that is greater than $16.50, the conversion factor for a calendar year after 1990 and before 1996 shall be the 1990 conversion factor reduced by the product of the last digit of the calendar year and one-fifth of the amount by which the 1990 conversion factor exceeds $16.50; and

(ii) in the case of a 1990 conversion factor that is greater than $15.49 but less than $16.51, the conversion factor for a calendar year after 1990 and before 1996 shall be the greater of—

(I) the 1990 conversion factor, or

(II) the conversion factor specified in subparagraph (A)(i) for the year involved.

(D) Notwithstanding subparagraph (C), in no case may the conversion factor used to determine payment for services in a fee schedule area or locality under this subsection, as adjusted by the adjustment factors specified in subparagraphs (A)(iii), exceed the conversion factor used to determine the amount paid for physicians' services that are anesthesia services in the area or locality.

(5)(A) Payment for the services of a certified registered nurse anesthetist (for which payment may otherwise be made under this part) may be made on the basis of a claim or request for payment presented by the certified registered nurse anesthetist furnishing such services, or by a hospital, critical access hospital, physician, group practice, or ambulatory surgical center with which the certified registered nurse anesthetist furnishing such services has an employment or contractual relationship that provides for payment to be made under this part for such services to such hospital, critical access hospital, physician, group practice, or ambulatory surgical center.

(B) No hospital or critical access hospital that presents a claim or request for payment for services of a certified nurse anesthetist under this part may treat any uncollected coinsurance amount imposed under this part with respect to such services as a bad debt of such hospital or critical access hospital for purposes of this title.

(6) If an adjustment under paragraph (3)(B) results in a reduction in the reasonable charge for a physicians' service and a nonparticipating physician furnishes the service to an individual entitled to benefits under this part after the effective date of the reduction, the physician's actual charge is subject to a limit under section 1842(j)(1)(D).

(m)(1) In the case of physicians' services furnished in a year to an individual, who is covered under the insurance program established by this part and who incurs expenses for such services, in an area that is designated (under section 332(a)(1)(A) of the Public Health Service Act) as a health professional shortage area as identified by the Secretary prior to the beginning of such year, in addition to the amount otherwise paid under this part, there also shall be paid to the physician (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6)) (on a monthly or quarterly basis) from the Federal Supplementary Medical Insurance

Trust Fund an amount equal to 10 percent of the payment amount for the service under this part.

(2) For each health professional shortage area identified in paragraph (1) that consists of an entire county, the Secretary shall provide for the additional payment under paragraph (1) without any requirement on the physician to identify the health professional shortage area involved. The Secretary may implement the previous sentence using the method specified in subsection (u)(4)(C).

(3) The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a list of the health professional shortage areas identified in paragraph (1) that consist of a partial county to facilitate the additional payment under paragraph (1) in such areas.

(4) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, respecting—

(A) the identification of a county or area;

(B) the assignment of a specialty of any physician under this paragraph;

(C) the assignment of a physician to a county under this subsection; or

(D) the assignment of a postal ZIP Code to a county or other area under this subsection.

(n)(1)(A) The aggregate amount of the payments to be made for all or part of a cost reporting period for services described in subsection (a)(2)(E)(i) furnished under this part on or after October 1, 1988, and before January 1, 1999, and for services described in subsection (a)(2)(E)(ii) furnished under this part on or after October 1, 1989, and before January 1, 1999, shall be equal to the lesser of—

(i) the amount determined with respect to such services under subsection (a)(2)(B), or

(ii) the blend amount for radiology services and diagnostic procedures determined in accordance with subparagraph (B).

(B)(i) The blend amount for radiology services and diagnostic procedures for a cost reporting period is the sum of—

(I) the cost proportion (as defined in clause (ii)) of the amount described in subparagraph (A)(i); and

(II) the charge proportion (as defined in clause (ii)(II)) of 62 percent (for services described in subsection (a)(2)(E)(i)), or (for procedures described in subsection (a)(2)(E)(ii)), 42 percent or such other percent established by the Secretary (or carriers acting pursuant to guidelines issued by the Secretary) based on prevailing charges established with actual charge data, of the prevailing charge or (for services described in subsection (a)(2)(E)(i) furnished on or after January 1, 1989) the fee schedule amount established for participating physicians for the same services as if they were furnished in a physician's office in the same locality as determined under section 1842(b), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A).

(ii) In this subparagraph:

(I) The term "cost proportion" means 50 percent, except that such term means 65 percent in the case of outpatient radiology services for portions of cost reporting periods which occur in fiscal year 1989 and in the case of diagnostic procedures de-

scribed in subsection (a)(2)(E)(ii) for portions of cost reporting periods which occur in fiscal year 1990, and such term means 42 percent in the case of outpatient radiology services for portions of cost reporting periods beginning on or after January 1, 1991.

(II) The term "charge proportion" means 100 percent minus the cost proportion.

(o)(1) In the case of shoes described in section 1861(s)(12)—

(A) no payment may be made under this part, with respect to any individual for any year, for the furnishing of—

(i) more than one pair of custom molded shoes (including inserts provided with such shoes) and 2 additional pairs of inserts for such shoes, or

(ii) more than one pair of extra-depth shoes (not including inserts provided with such shoes) and 3 pairs of inserts for such shoes, and

(B) with respect to expenses incurred in any calendar year, no more than the amount of payment applicable under paragraph (2) shall be considered as incurred expenses for purposes of subsections (a) and (b).

Payment for shoes (or inserts) under this part shall be considered to include payment for any expenses for the fitting of such shoes (or inserts).

(2)(A) Except as provided by the Secretary under subparagraphs (B) and (C), the amount of payment under this paragraph for custom molded shoes, extra-depth shoes, and inserts shall be the amount determined for such items by the Secretary under section 1834(h).

(B) The Secretary may establish payment amounts for shoes and inserts that are lower than the amount established under section 1834(h) if the Secretary finds that shoes and inserts of an appropriate quality are readily available at or below the amount established under such section.

(C) In accordance with procedures established by the Secretary, an individual entitled to benefits with respect to shoes described in section 1861(s)(12) may substitute modification of such shoes instead of obtaining one (or more, as specified by the Secretary) pair of inserts (other than the original pair of inserts with respect to such shoes). In such case, the Secretary shall substitute, for the payment amount established under section 1834(h), a payment amount that the Secretary estimates will assure that there is no net increase in expenditures under this subsection as a result of this subparagraph.

(3) In this title, the term "shoes" includes, except for purposes of subparagraphs (A)(ii) and (B) of paragraph (2), inserts for extra-depth shoes.

(q)(1) Each request for payment, or bill submitted, for an item or service furnished by an entity for which payment may be made under this part and for which the entity knows or has reason to believe there has been a referral by a referring physician (within the meaning of section 1877) shall include the name and unique physician identification number for the referring physician.

(2)(A) In the case of a request for payment for an item or service furnished by an entity under this part on an assignment-related basis and for which information is required to be provided under

paragraph (1) but not included, payment may be denied under this part.

(B) In the case of a request for payment for an item or service furnished by an entity under this part not submitted on an assignment-related basis and for which information is required to be provided under paragraph (1) but not included—

(i) if the entity knowingly and willfully fails to provide such information promptly upon request of the Secretary or a carrier, the entity may be subject to a civil money penalty in an amount not to exceed $2,000, and

(ii) if the entity knowingly, willfully, and in repeated cases fails, after being notified by the Secretary of the obligations and requirements of this subsection to provide the information required under paragraph (1), the entity may be subject to exclusion from participation in the programs under this Act for a period not to exceed 5 years, in accordance with the procedures of subsections (c), (f), and (g) of section 1128.

The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under clause (i) in the same manner as they apply to a penalty or proceeding under section 1128A(a).

(r)(1) With respect to services described in section 1861(s)(2)(K)(ii) (relating to nurse practitioner or clinical nurse specialist services), payment may be made on the basis of a claim or request for payment presented by the nurse practitioner or clinical nurse specialist furnishing such services, or by a hospital, critical access hospital, skilled nursing facility or nursing facility (as defined in section 1919(a)), physician, group practice, or ambulatory surgical center with which the nurse practitioner or clinical nurse specialist has an employment or contractual relationship that provides for payment to be made under this part for such services to such hospital, physician, group practice, or ambulatory surgical center.

(2) No hospital or critical access hospital that presents a claim or request for payment under this part for services described in section 1861(s)(2)(K)(ii) may treat any uncollected coinsurance amount imposed under this part with respect to such services as a bad debt of such hospital for purposes of this title.

(s) The Secretary may not provide for payment under subsection (a)(1)(A) with respect to an organization unless the organization provides assurances satisfactory to the Secretary that the organization meets the requirement of section 1866(f) (relating to maintaining written policies and procedures respecting advance directives).

(t) PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES.—

(1) AMOUNT OF PAYMENT.—

(A) IN GENERAL.—With respect to covered OPD services (as defined in subparagraph (B)) furnished during a year beginning with 1999, the amount of payment under this part shall be determined under a prospective payment system established by the Secretary in accordance with this subsection.

(B) DEFINITION OF COVERED OPD SERVICES.—For purposes of this subsection, the term "covered OPD services"—

(i) means hospital outpatient services designated by the Secretary;

(ii) subject to clause (iv), includes inpatient hospital services designated by the Secretary that are covered under this part and furnished to a hospital inpatient who (I) is entitled to benefits under part A but has exhausted benefits for inpatient hospital services during a spell of illness, or (II) is not so entitled;

(iii) includes implantable items described in paragraph (3), (6), or (8) of section 1861(s); but

(iv) does not include any therapy services described in subsection (a)(8) or ambulance services, for which payment is made under a fee schedule described in section 1834(k) or section 1834(l) and does not include screening mammography (as defined in section 1861(jj)), diagnostic mammography, or personalized prevention plan services (as defined in section 1861(hhh)(1)).

(2) SYSTEM REQUIREMENTS.—Under the payment system—

(A) the Secretary shall develop a classification system for covered OPD services;

(B) the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified to the group that includes the service to which the item relates;

(C) the Secretary shall, using data on claims from 1996 and using data from the most recent available cost reports, establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs and shall determine projections of the frequency of utilization of each such service (or group of services) in 1999;

(D) subject to paragraph (19), the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner;

(E) the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals;

(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services;

(G) the Secretary shall create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those that do not; and

(H) with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices and for stranded and non-stranded devices furnished on or after July 1, 2007.

For purposes of subparagraph (B), items and services within a group shall not be treated as "comparable with respect to the use of resources" if the highest median cost (or mean cost, if elected by the Secretary under subparagraph (C)) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the group; except that the Secretary may make exceptions in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act.

(3) CALCULATION OF BASE AMOUNTS.—

(A) AGGREGATE AMOUNTS THAT WOULD BE PAYABLE IF DEDUCTIBLES WERE DISREGARDED.—The Secretary shall estimate the sum of—

(i) the total amounts that would be payable from the Trust Fund under this part for covered OPD services in 1999, determined without regard to this subsection, as though the deductible under section 1833(b) did not apply, and

(ii) the total amounts of copayments estimated to be paid under this subsection by beneficiaries to hospitals for covered OPD services in 1999, as though the deductible under section 1833(b) did not apply.

(B) UNADJUSTED COPAYMENT AMOUNT.—

(i) IN GENERAL.—For purposes of this subsection, subject to clause (ii), the "unadjusted copayment amount" applicable to a covered OPD service (or group of such services) is 20 percent of the national median of the charges for the service (or services within the group) furnished during 1996, updated to 1999 using the Secretary's estimate of charge growth during the period.

(ii) ADJUSTED TO BE 20 PERCENT WHEN FULLY PHASED IN.—If the pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year would be equal to or exceed 80 percent, then the unadjusted copayment amount shall be 20 percent of amount determined under subparagraph (D).

(iii) RULES FOR NEW SERVICES.—The Secretary shall establish rules for establishment of an unadjusted copayment amount for a covered OPD service not fur-

nished during 1996, based upon its classification within a group of such services.

(C) CALCULATION OF CONVERSION FACTORS.—

(i) FOR 1999.—

(I) IN GENERAL.—The Secretary shall establish a 1999 conversion factor for determining the medicare OPD fee schedule amounts for each covered OPD service (or group of such services) furnished in 1999. Such conversion factor shall be established on the basis of the weights and frequencies described in paragraph (2)(C) and in such a manner that the sum for all services and groups of the products (described in subclause (II) for each such service or group) equals the total projected amount described in subparagraph (A).

(II) PRODUCT DESCRIBED.—The Secretary shall determine for each service or group the product of the medicare OPD fee schedule amounts (taking into account appropriate adjustments described in paragraphs (2)(D) and (2)(E)) and the estimated frequencies for such service or group.

(ii) SUBSEQUENT YEARS.—Subject to paragraph (8)(B), the Secretary shall establish a conversion factor for covered OPD services furnished in subsequent years in an amount equal to the conversion factor established under this subparagraph and applicable to such services furnished in the previous year increased by the OPD fee schedule increase factor specified under clause (iv) for the year involved.

(iii) ADJUSTMENT FOR SERVICE MIX CHANGES.—Insofar as the Secretary determines that the adjustments for service mix under paragraph (2) for a previous year (or estimates that such adjustments for a future year) did (or are likely to) result in a change in aggregate payments under this subsection during the year that are a result of changes in the coding or classification of covered OPD services that do not reflect real changes in service mix, the Secretary may adjust the conversion factor computed under this subparagraph for subsequent years so as to eliminate the effect of such coding or classification changes.

(iv) OPD FEE SCHEDULE INCREASE FACTOR.—For purposes of this subparagraph, subject to paragraph (17) and subparagraph (F) of this paragraph, the "OPD fee schedule increase factor" for services furnished in a year is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) to hospital discharges occurring during the fiscal year ending in such year, reduced by 1 percentage point for such factor for services furnished in each of 2000 and 2002. In applying the previous sentence for years beginning with 2000, the Secretary may substitute for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same

manner as the market basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year.

(D) CALCULATION OF MEDICARE OPD FEE SCHEDULE AMOUNTS.—The Secretary shall compute a medicare OPD fee schedule amount for each covered OPD service (or group of such services) furnished in a year, in an amount equal to the product of—

(i) the conversion factor computed under subparagraph (C) for the year, and

(ii) the relative payment weight (determined under paragraph (2)(C)) for the service or group.

(E) PRE-DEDUCTIBLE PAYMENT PERCENTAGE.—The pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year is equal to the ratio of—

(i) the medicare OPD fee schedule amount established under subparagraph (D) for the year, minus the unadjusted copayment amount determined under subparagraph (B) for the service or group, to

(ii) the medicare OPD fee schedule amount determined under subparagraph (D) for the year for such service or group.

(F) PRODUCTIVITY AND OTHER ADJUSTMENT.—After determining the OPD fee schedule increase factor under subparagraph (C)(iv), the Secretary shall reduce such increase factor—

(i) for 2012 and subsequent years, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(ii) for each of 2010 through 2019, by the adjustment described in subparagraph (G).

The application of this subparagraph may result in the increase factor under subparagraph (C)(iv) being less than 0.0 for a year, and may result in payment rates under the payment system under this subsection for a year being less than such payment rates for the preceding year.

(G) OTHER ADJUSTMENT.—For purposes of subparagraph (F)(ii), the adjustment described in this subparagraph is—

(i) for each of 2010 and 2011, 0.25 percentage point;

(ii) for each of 2012 and 2013, 0.1 percentage point;

(iii) for 2014, 0.3 percentage point;

(iv) for each of 2015 and 2016, 0.2 percentage point; and

(v) for each of 2017, 2018, and 2019, 0.75 percentage point.

(4) MEDICARE PAYMENT AMOUNT.—The amount of payment made from the Trust Fund under this part for a covered OPD service (and such services classified within a group) furnished in a year is determined, subject to paragraph (7), as follows:

(A) FEE SCHEDULE ADJUSTMENTS.—The medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service or group and year is adjusted for relative differences in the cost of labor and other factors deter-

mined by the Secretary, as computed under paragraphs (2)(D) and (2)(E).

(B) SUBTRACT APPLICABLE DEDUCTIBLE.—Reduce the adjusted amount determined under subparagraph (A) by the amount of the deductible under section 1833(b), to the extent applicable.

(C) APPLY PAYMENT PROPORTION TO REMAINDER.—The amount of payment is the amount so determined under subparagraph (B) multiplied by the pre-deductible payment percentage (as determined under paragraph (3)(E)) for the service or group and year involved, plus the amount of any reduction in the copayment amount attributable to paragraph (8)(C).

(5) OUTLIER ADJUSTMENT.—

(A) IN GENERAL.—Subject to subparagraph (D), the Secretary shall provide for an additional payment for each covered OPD service (or group of services) for which a hospital's charges, adjusted to cost, exceed—

(i) a fixed multiple of the sum of—

(I) the applicable medicare OPD fee schedule amount determined under paragraph (3)(D), as adjusted under paragraph (4)(A) (other than for adjustments under this paragraph or paragraph (6)); and

(II) any transitional pass-through payment under paragraph (6); and

(ii) at the option of the Secretary, such fixed dollar amount as the Secretary may establish.

(B) AMOUNT OF ADJUSTMENT.—The amount of the additional payment under subparagraph (A) shall be determined by the Secretary and shall approximate the marginal cost of care beyond the applicable cutoff point under such subparagraph.

(C) LIMIT ON AGGREGATE OUTLIER ADJUSTMENTS.—

(i) IN GENERAL.—The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year.

(ii) APPLICABLE PERCENTAGE.—For purposes of clause (i), the term "applicable percentage" means a percentage specified by the Secretary up to (but not to exceed)—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, 3.0 percent.

(D) TRANSITIONAL AUTHORITY.—In applying subparagraph (A) for covered OPD services furnished before January 1, 2002, the Secretary may—

(i) apply such subparagraph to a bill for such services related to an outpatient encounter (rather than for a specific service or group of services) using OPD fee schedule amounts and transitional pass-through payments covered under the bill; and

(ii) use an appropriate cost-to-charge ratio for the hospital involved (as determined by the Secretary), rather than for specific departments within the hospital.

(E) EXCLUSION OF SEPARATE DRUG AND BIOLOGICAL APCS FROM OUTLIER PAYMENTS.—No additional payment shall be made under subparagraph (A) in the case of ambulatory payment classification groups established separately for drugs or biologicals.

(6) TRANSITIONAL PASS-THROUGH FOR ADDITIONAL COSTS OF INNOVATIVE MEDICAL DEVICES, DRUGS, AND BIOLOGICALS.—

(A) IN GENERAL.—The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services):

(i) CURRENT ORPHAN DRUGS.—A drug or biological that is used for a rare disease or condition with respect to which the drug or biological has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act if payment for the drug or biological as an outpatient hospital service under this part was being made on the first date that the system under this subsection is implemented.

(ii) CURRENT CANCER THERAPY DRUGS AND BIOLOGICALS AND BRACHYTHERAPY.—A drug or biological that is used in cancer therapy, including (but not limited to) a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and a device of brachytherapy or temperature monitored cryoablation, if payment for such drug, biological, or device as an outpatient hospital service under this part was being made on such first date.

(iii) CURRENT RADIOPHARMACEUTICAL DRUGS AND BIOLOGICAL PRODUCTS.—A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine procedures if payment for the drug or biological as an outpatient hospital service under this part was being made on such first date.

(iv) NEW MEDICAL DEVICES, DRUGS, AND BIOLOGICALS.—A medical device, drug, or biological not described in clause (i), (ii), or (iii) if—

(I) payment for the device, drug, or biological as an outpatient hospital service under this part was not being made as of December 31, 1996; and

(II) the cost of the drug or biological or the average cost of the category of devices is not insignificant in relation to the OPD fee schedule amount

(as calculated under paragraph (3)(D)) payable for the service (or group of services) involved.

(B) USE OF CATEGORIES IN DETERMINING ELIGIBILITY OF A DEVICE FOR PASS-THROUGH PAYMENTS.—The following provisions apply for purposes of determining whether a medical device qualifies for additional payments under clause (ii) or (iv) of subparagraph (A):

(i) ESTABLISHMENT OF INITIAL CATEGORIES.—

(I) IN GENERAL.—The Secretary shall initially establish under this clause categories of medical devices based on type of device by April 1, 2001. Such categories shall be established in a manner such that each medical device that meets the requirements of clause (ii) or (iv) of subparagraph (A) as of January 1, 2001, is included in such a category and no such device is included in more than one category. For purposes of the preceding sentence, whether a medical device meets such requirements as of such date shall be determined on the basis of the program memoranda issued before such date.

(II) AUTHORIZATION OF IMPLEMENTATION OTHER THAN THROUGH REGULATIONS.—The categories may be established under this clause by program memorandum or otherwise, after consultation with groups representing hospitals, manufacturers of medical devices, and other affected parties.

(ii) ESTABLISHING CRITERIA FOR ADDITIONAL CATEGORIES.—

(I) IN GENERAL.—The Secretary shall establish criteria that will be used for creation of additional categories (other than those established under clause (i)) through rulemaking (which may include use of an interim final rule with comment period).

(II) STANDARD.—Such categories shall be established under this clause in a manner such that no medical device is described by more than one category. Such criteria shall include a test of whether the average cost of devices that would be included in a category and are in use at the time the category is established is not insignificant, as described in subparagraph (A)(iv)(II).

(III) DEADLINE.—Criteria shall first be established under this clause by July 1, 2001. The Secretary may establish in compelling circumstances categories under this clause before the date such criteria are established.

(IV) ADDING CATEGORIES.—The Secretary shall promptly establish a new category of medical devices under this clause for any medical device that meets the requirements of subparagraph (A)(iv) and for which none of the categories in effect (or that were previously in effect) is appropriate.

(iii) PERIOD FOR WHICH CATEGORY IS IN EFFECT.—A category of medical devices established under clause

(i) or (ii) shall be in effect for a period of at least 2 years, but not more than 3 years, that begins—

(I) in the case of a category established under clause (i), on the first date on which payment was made under this paragraph for any device described by such category (including payments made during the period before April 1, 2001); and

(II) in the case of any other category, on the first date on which payment is made under this paragraph for any medical device that is described by such category.

(iv) REQUIREMENTS TREATED AS MET.—A medical device shall be treated as meeting the requirements of subparagraph (A)(iv), regardless of whether the device meets the requirement of subclause (I) of such subparagraph, if—

(I) the device is described by a category established and in effect under clause (i); or

(II) the device is described by a category established and in effect under clause (ii) and an application under section 515 of the Federal Food, Drug, and Cosmetic Act has been approved with respect to the device, or the device has been cleared for market under section 510(k) of such Act, or the device is exempt from the requirements of section 510(k) of such Act pursuant to subsection (l) or (m) of section 510 of such Act or section 520(g) of such Act.

Nothing in this clause shall be construed as requiring an application or prior approval (other than that described in subclause (II)) in order for a covered device described by a category to qualify for payment under this paragraph.

(C) LIMITED PERIOD OF PAYMENT.—

(i) DRUGS AND BIOLOGICALS.—The payment under this paragraph with respect to a drug or biological shall only apply during a period of at least 2 years, but not more than 3 years, that begins—

(I) on the first date this subsection is implemented in the case of a drug or biological described in clause (i), (ii), or (iii) of subparagraph (A) and in the case of a drug or biological described in subparagraph (A)(iv) and for which payment under this part is made as an outpatient hospital service before such first date; or

(II) in the case of a drug or biological described in subparagraph (A)(iv) not described in subclause (I), on the first date on which payment is made under this part for the drug or biological as an outpatient hospital service.

(ii) MEDICAL DEVICES.—Payment shall be made under this paragraph with respect to a medical device only if such device—

(I) is described by a category of medical devices established and in effect under subparagraph (B); and

(II) is provided as part of a service (or group of services) paid for under this subsection and provided during the period for which such category is in effect under such subparagraph.

(D) AMOUNT OF ADDITIONAL PAYMENT.—Subject to subparagraph (E)(iii), the amount of the payment under this paragraph with respect to a device, drug, or biological provided as part of a covered OPD service is—

(i) in the case of a drug or biological, the amount by which the amount determined under section 1842(o) (or if the drug or biological is covered under a competitive acquisition contract under section 1847B, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary for purposes of this paragraph) for the drug or biological exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the drug or biological; or

(ii) in the case of a medical device, the amount by which the hospital's charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the device.

(E) LIMIT ON AGGREGATE ANNUAL ADJUSTMENT.—

(i) IN GENERAL.—The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year.

(ii) APPLICABLE PERCENTAGE.—For purposes of clause (i), the term "applicable percentage" means—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, a percentage specified by the Secretary up to (but not to exceed) 2.0 percent.

(iii) UNIFORM PROSPECTIVE REDUCTION IF AGGREGATE LIMIT PROJECTED TO BE EXCEEDED.—If the Secretary estimates before the beginning of a year that the amount of the additional payments under this paragraph for the year (or portion thereof) as determined under clause (i) without regard to this clause will exceed the limit established under such clause, the Secretary shall reduce pro rata the amount of each of the additional payments under this paragraph for that

year (or portion thereof) in order to ensure that the aggregate additional payments under this paragraph (as so estimated) do not exceed such limit.

(F) LIMITATION OF APPLICATION OF FUNCTIONAL EQUIVALENCE STANDARD.—

(i) IN GENERAL.—The Secretary may not publish regulations that apply a functional equivalence standard to a drug or biological under this paragraph.

(ii) APPLICATION.—Clause (i) shall apply to the application of a functional equivalence standard to a drug or biological on or after the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 unless—

(I) such application was being made to such drug or biological prior to such date of enactment; and

(II) the Secretary applies such standard to such drug or biological only for the purpose of determining eligibility of such drug or biological for additional payments under this paragraph and not for the purpose of any other payments under this title.

(iii) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed to effect the Secretary's authority to deem a particular drug to be identical to another drug if the 2 products are pharmaceutically equivalent and bioequivalent, as determined by the Commissioner of Food and Drugs.

(7) TRANSITIONAL ADJUSTMENT TO LIMIT DECLINE IN PAYMENT.—

(A) BEFORE 2002.—Subject to subparagraph (D), for covered OPD services furnished before January 1, 2002, for which the PPS amount (as defined in subparagraph (E)) is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount (as defined in subparagraph (F)), the amount of payment under this subsection shall be increased by 80 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.71 and the pre-BBA amount, exceeds (II) the product of 0.70 and the PPS amount;

(iii) at least 70 percent, but less than 80 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.63 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iv) less than 70 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 21 percent of the pre-BBA amount.

(B) 2002.—Subject to subparagraph (D), for covered OPD services furnished during 2002, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 70 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.61 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iii) less than 80 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 13 percent of the pre-BBA amount.

(C) 2003.—Subject to subparagraph (D), for covered OPD services furnished during 2003, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 60 percent of the amount of such difference; or

(ii) less than 90 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 6 percent of the pre-BBA amount.

(D) HOLD HARMLESS PROVISIONS.—

(i) TEMPORARY TREATMENT FOR CERTAIN RURAL HOSPITALS.—(I) In the case of a hospital located in a rural area and that has not more than 100 beds or a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) located in a rural area, for covered OPD services furnished before January 1, 2006, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(II) In the case of a hospital located in a rural area and that has not more than 100 beds and that is not a sole community hospital (as defined in section 1886(d)(5)(D)(iii)), for covered OPD services furnished on or after January 1, 2006, and before January 1, 2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the applicable percentage of the amount of such difference. For purposes of the preceding sentence, the applicable percentage shall be 95 percent with respect to covered OPD services furnished in 2006, 90 percent with respect to such services furnished in 2007, and 85 percent with respect to such services furnished in 2008, 2009, 2010, 2011, or 2012.

(III) In the case of a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) that has not more than 100 beds, for covered OPD services furnished on or after January 1, 2009, and before January 1, 2013,

for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by 85 percent of the amount of such difference. In the case of covered OPD services furnished on or after January 1, 2010, and before March 1, 2012, the preceding sentence shall be applied without regard to the 100-bed limitation.

(ii) PERMANENT TREATMENT FOR CANCER HOSPITALS AND CHILDREN'S HOSPITALS.—In the case of a hospital described in clause (iii) or (v) of section 1886(d)(1)(B), for covered OPD services for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(E) PPS AMOUNT DEFINED.—In this paragraph, the term "PPS amount" means, with respect to covered OPD services, the amount payable under this title for such services (determined without regard to this paragraph), including amounts payable as copayment under paragraph (8), coinsurance under section 1866(a)(2)(A)(ii), and the deductible under section 1833(b).

(F) PRE-BBA AMOUNT DEFINED.—

(i) IN GENERAL.—In this paragraph, the "pre-BBA amount" means, with respect to covered OPD services furnished by a hospital in a year, an amount equal to the product of the reasonable cost of the hospital for such services for the portions of the hospital's cost reporting period (or periods) occurring in the year and the base OPD payment-to-cost ratio for the hospital (as defined in clause (ii)).

(ii) BASE PAYMENT-TO-COST-RATIO DEFINED.—For purposes of this subparagraph, the "base payment-to-cost ratio" for a hospital means the ratio of—

(I) the hospital's reimbursement under this part for covered OPD services furnished during the cost reporting period ending in 1996 (or in the case of a hospital that did not submit a cost report for such period, during the first subsequent cost reporting period ending before 2001 for which the hospital submitted a cost report), including any reimbursement for such services through cost-sharing described in subparagraph (E), to

(II) the reasonable cost of such services for such period.

The Secretary shall determine such ratios as if the amendments made by section 4521 of the Balanced Budget Act of 1997 were in effect in 1996.

(G) INTERIM PAYMENTS.—The Secretary shall make payments under this paragraph to hospitals on an interim basis, subject to retrospective adjustments based on settled cost reports.

(H) NO EFFECT ON COPAYMENTS.—Nothing in this paragraph shall be construed to affect the unadjusted copayment amount described in paragraph (3)(B) or the copayment amount under paragraph (8).

(I) APPLICATION WITHOUT REGARD TO BUDGET NEUTRALITY.—The additional payments made under this paragraph—

(i) shall not be considered an adjustment under paragraph (2)(E); and

(ii) shall not be implemented in a budget neutral manner.

(8) COPAYMENT AMOUNT.—

(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), the copayment amount under this subsection is the amount by which the amount described in paragraph (4)(B) exceeds the amount of payment determined under paragraph (4)(C).

(B) ELECTION TO OFFER REDUCED COPAYMENT AMOUNT.—The Secretary shall establish a procedure under which a hospital, before the beginning of a year (beginning with 1999), may elect to reduce the copayment amount otherwise established under subparagraph (A) for some or all covered OPD services to an amount that is not less than 20 percent of the medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service involved. Under such procedures, such reduced copayment amount may not be further reduced or increased during the year involved and the hospital may disseminate information on the reduction of copayment amount effected under this subparagraph.

(C) LIMITATION ON COPAYMENT AMOUNT.—

(i) TO INPATIENT HOSPITAL DEDUCTIBLE AMOUNT.—In no case shall the copayment amount for a procedure performed in a year exceed the amount of the inpatient hospital deductible established under section 1813(b) for that year.

(ii) TO SPECIFIED PERCENTAGE.—The Secretary shall reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed the following percentage:

(I) For procedures performed in 2001, on or after April 1, 2001, 57 percent.

(II) For procedures performed in 2002 or 2003, 55 percent.

(III) For procedures performed in 2004, 50 percent.

(IV) For procedures performed in 2005, 45 percent.

(V) For procedures performed in 2006 and thereafter, 40 percent.

(D) NO IMPACT ON DEDUCTIBLES.—Nothing in this paragraph shall be construed as affecting a hospital's authority to waive the charging of a deductible under section 1833(b).

(E) COMPUTATION IGNORING OUTLIER AND PASS-THROUGH ADJUSTMENTS.—The copayment amount shall be computed

under subparagraph (A) as if the adjustments under paragraphs (5) and (6) (and any adjustment made under paragraph (2)(E) in relation to such adjustments) had not occurred.

(9) PERIODIC REVIEW AND ADJUSTMENTS COMPONENTS OF PROSPECTIVE PAYMENT SYSTEM.—

(A) PERIODIC REVIEW.—The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.

(B) BUDGET NEUTRALITY ADJUSTMENT.—If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made. In determining adjustments under the preceding sentence for 2004 and 2005, the Secretary shall not take into account under this subparagraph or paragraph (2)(E) any expenditures that would not have been made but for the application of paragraph (14).

(C) UPDATE FACTOR.—If the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year.

(10) SPECIAL RULE FOR AMBULANCE SERVICES.—The Secretary shall pay for hospital outpatient services that are ambulance services on the basis described in section 1861(v)(1)(U), or, if applicable, the fee schedule established under section 1834(l).

(11) SPECIAL RULES FOR CERTAIN HOSPITALS.—In the case of hospitals described in clause (iii) or (v) of section 1886(d)(1)(B)—

(A) the system under this subsection shall not apply to covered OPD services furnished before January 1, 2000; and

(B) the Secretary may establish a separate conversion factor for such services in a manner that specifically takes into account the unique costs incurred by such hospitals by virtue of their patient population and service intensity.

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

(A) the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F);

(B) the calculation of base amounts under paragraph (3);

(C) periodic adjustments made under paragraph (6);

(D) the establishment of a separate conversion factor under paragraph (8)(B); and

(E) the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under paragraph (6).

(13) AUTHORIZATION OF ADJUSTMENT FOR RURAL HOSPITALS.—

(A) STUDY.—The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals located in rural areas by ambulatory payment classification groups (APCs) exceed those costs incurred by hospitals located in urban areas.

(B) AUTHORIZATION OF ADJUSTMENT.—Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals located in rural areas exceed those costs incurred by hospitals located in urban areas, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs by January 1, 2006.

(14) DRUG APC PAYMENT RATES.—

(A) IN GENERAL.—The amount of payment under this subsection for a specified covered outpatient drug (defined in subparagraph (B)) that is furnished as part of a covered OPD service (or group of services)—

(i) in 2004, in the case of—

(I) a sole source drug shall in no case be less than 88 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug;

(ii) in 2005, in the case of—

(I) a sole source drug shall in no case be less than 83 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug; or

(iii) in a subsequent year, shall be equal, subject to subparagraph (E)—

(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or

(II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

(B) SPECIFIED COVERED OUTPATIENT DRUG DEFINED.—

(i) IN GENERAL.—In this paragraph, the term "specified covered outpatient drug" means, subject to clause (ii), a covered outpatient drug (as defined in section 1927(k)(2)) for which a separate ambulatory payment classification group (APC) has been established and that is—

(I) a radiopharmaceutical; or

(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

(ii) EXCEPTION.—Such term does not include—

(I) a drug or biological for which payment is first made on or after January 1, 2003, under paragraph (6);

(II) a drug or biological for which a temporary HCPCS code has not been assigned; or

(III) during 2004 and 2005, an orphan drug (as designated by the Secretary).

(C) PAYMENT FOR DESIGNATED ORPHAN DRUGS DURING 2004 AND 2005.—The amount of payment under this subsection for an orphan drug designated by the Secretary under subparagraph (B)(ii)(III) that is furnished as part of a covered OPD service (or group of services) during 2004 and 2005 shall equal such amount as the Secretary may specify.

(D) ACQUISITION COST SURVEY FOR HOSPITAL OUTPATIENT DRUGS.—

(i) ANNUAL GAO SURVEYS IN 2004 AND 2005.—

(I) IN GENERAL.—The Comptroller General of the United States shall conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each specified covered outpatient drug. Not later than April 1, 2005, the Comptroller General shall furnish data from such sur-

veys to the Secretary for use in setting the payment rates under subparagraph (A) for 2006.

(II) RECOMMENDATIONS.—Upon the completion of such surveys, the Comptroller General shall recommend to the Secretary the frequency and methodology of subsequent surveys to be conducted by the Secretary under clause (ii).

(ii) SUBSEQUENT SECRETARIAL SURVEYS.—The Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates under subparagraph (A).

(iii) SURVEY REQUIREMENTS.—The surveys conducted under clauses (i) and (ii) shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug. With respect to the surveys conducted under clause (i), the Comptroller General shall report to Congress on the justification for the size of the sample used in order to assure the validity of such estimates.

(iv) DIFFERENTIATION IN COST.—In conducting surveys under clause (i), the Comptroller General shall determine and report to Congress if there is (and the extent of any) variation in hospital acquisition costs for drugs among hospitals based on the volume of covered OPD services performed by such hospitals or other relevant characteristics of such hospitals (as defined by the Comptroller General).

(v) COMMENT ON PROPOSED RATES.—Not later than 30 days after the date the Secretary promulgated proposed rules setting forth the payment rates under subparagraph (A) for 2006, the Comptroller General shall evaluate such proposed rates and submit to Congress a report regarding the appropriateness of such rates based on the surveys the Comptroller General has conducted under clause (i).

(E) ADJUSTMENT IN PAYMENT RATES FOR OVERHEAD COSTS.—

(i) MEDPAC REPORT ON DRUG APC DESIGN.—The Medicare Payment Advisory Commission shall submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Such report shall include—

(I) a description and analysis of the data available with regard to such expenses;

(II) a recommendation as to whether such a payment adjustment should be made; and

(III) if such adjustment should be made, a recommendation regarding the methodology for making such an adjustment.

(ii) ADJUSTMENT AUTHORIZED.—The Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account the recommendations contained in the report submitted under clause (i).

(F) CLASSES OF DRUGS.—For purposes of this paragraph:

(i) SOLE SOURCE DRUGS.—The term "sole source drug" means—

(I) a biological product (as defined under section 1861(t)(1)); or

(II) a single source drug (as defined in section 1927(k)(7)(A)(iv)).

(ii) INNOVATOR MULTIPLE SOURCE DRUGS.—The term "innovator multiple source drug" has the meaning given such term in section 1927(k)(7)(A)(ii).

(iii) NONINNOVATOR MULTIPLE SOURCE DRUGS.—The term "noninnovator multiple source drug" has the meaning given such term in section 1927(k)(7)(A)(iii).

(G) REFERENCE AVERAGE WHOLESALE PRICE.—The term "reference average wholesale price" means, with respect to a specified covered outpatient drug, the average wholesale price for the drug as determined under section 1842(o) as of May 1, 2003.

(H) INAPPLICABILITY OF EXPENDITURES IN DETERMINING CONVERSION, WEIGHTING, AND OTHER ADJUSTMENT FACTORS.—Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.

(15) PAYMENT FOR NEW DRUGS AND BIOLOGICALS UNTIL HCPCS CODE ASSIGNED.—With respect to payment under this part for an outpatient drug or biological that is covered under this part and is furnished as part of covered OPD services for which a HCPCS code has not been assigned, the amount provided for payment for such drug or biological under this part shall be equal to 95 percent of the average wholesale price for the drug or biological.

(16) MISCELLANEOUS PROVISIONS.—

(A) APPLICATION OF RECLASSIFICATION OF CERTAIN HOSPITALS.—If a hospital is being treated as being located in a rural area under section 1886(d)(8)(E), that hospital shall be treated under this subsection as being located in that rural area.

(B) THRESHOLD FOR ESTABLISHMENT OF SEPARATE APCS FOR DRUGS.—The Secretary shall reduce the threshold for the establishment of separate ambulatory payment classification groups (APCs) with respect to drugs or biologicals to $50 per administration for drugs and biologicals furnished in 2005 and 2006.

(C) PAYMENT FOR DEVICES OF BRACHYTHERAPY AND THERAPEUTIC RADIOPHARMACEUTICALS AT CHARGES ADJUSTED TO COST.—Notwithstanding the preceding provisions of this subsection, for a device of brachytherapy consisting of a seed or seeds (or radioactive source) furnished

on or after January 1, 2004, and before January 1, 2010, and for therapeutic radiopharmaceuticals furnished on or after January 1, 2008, and before January 1, 2010, the payment basis for the device or therapeutic radiopharmaceutical under this subsection shall be equal to the hospital's charges for each device or therapeutic radiopharmaceutical furnished, adjusted to cost. Charges for such devices or therapeutic radiopharmaceuticals shall not be included in determining any outlier payment under this subsection.

(D) SPECIAL PAYMENT RULE.—

(i) IN GENERAL.—In the case of covered OPD services furnished on or after April 1, 2013, in a hospital described in clause (ii), if—

(I) the payment rate that would otherwise apply under this subsection for stereotactic radiosurgery, complete course of treatment of cranial lesion(s) consisting of 1 session that is multisource Cobalt 60 based (identified as of January 1, 2013, by HCPCS code 77371 (and any succeeding code) and reimbursed as of such date under APC 0127 (and any succeeding classification group)); exceeds

(II) the payment rate that would otherwise apply under this subsection for linear accelerator based stereotactic radiosurgery, complete course of therapy in one session (identified as of January 1, 2013, by HCPCS code G0173 (and any succeeding code) and reimbursed as of such date under APC 0067 (and any succeeding classification group)),

the payment rate for the service described in subclause (I) shall be reduced to an amount equal to the payment rate for the service described in subclause (II).

(ii) HOSPITAL DESCRIBED.—A hospital described in this clause is a hospital that is not—

(I) located in a rural area (as defined in section 1886(d)(2)(D));

(II) classified as a rural referral center under section 1886(d)(5)(C); or

(III) a sole community hospital (as defined in section 1886(d)(5)(D)(iii)).

(iii) NOT BUDGET NEUTRAL.—In making any budget neutrality adjustments under this subsection for 2013 (with respect to covered OPD services furnished on or after April 1, 2013, and before January 1, 2014) or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

(E) APPLICATION OF APPROPRIATE USE CRITERIA FOR CERTAIN IMAGING SERVICES.—For provisions relating to the application of appropriate use criteria for certain imaging services, see section 1834(q).

(F) PAYMENT INCENTIVE FOR THE TRANSITION FROM TRADITIONAL X-RAY IMAGING TO DIGITAL RADIOGRAPHY.—Notwithstanding the previous provisions of this subsection:

(i) LIMITATION ON PAYMENT FOR FILM X-RAY IMAGING SERVICES.—In the case of imaging services that are X rays taken using film and that are furnished during 2017 or a subsequent year, the payment amount for the technical component (including the technical component portion of a global fee) of such services that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 20 percent.

(ii) PHASED-IN LIMITATION ON PAYMENT FOR COMPUTED RADIOGRAPHY IMAGING SERVICES.—In the case of imaging services that are X rays taken using computed radiography technology (as defined in section 1848(b)(9)(C))—

(I) in the case of such services furnished during 2018, 2019, 2020, 2021, or 2022 the payment amount for the technical component (including the technical component portion of a global fee) of such services that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 7 percent; and

(II) in the case of such services furnished during 2023 or a subsequent year, the payment amount for the technical component (including the technical component portion of a global fee) of such services that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 10 percent.

(iii) APPLICATION WITHOUT REGARD TO BUDGET NEUTRALITY.—The reductions made under this paragraph—

(I) shall not be considered an adjustment under paragraph (2)(E); and

(II) shall not be implemented in a budget neutral manner.

(17) QUALITY REPORTING.—

(A) REDUCTION IN UPDATE FOR FAILURE TO REPORT.—

(i) IN GENERAL.—For purposes of paragraph (3)(C)(iv) for 2009 and each subsequent year, in the case of a subsection (d) hospital (as defined in section 1886(d)(1)(B)) that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to such a year, the OPD fee schedule increase factor under paragraph (3)(C)(iv) for such year shall be reduced by 2.0 percentage points.

(ii) NON-CUMULATIVE APPLICATION.—A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take into account such reduction in computing the OPD fee schedule increase factor for a subsequent year.

(B) FORM AND MANNER OF SUBMISSION.—Each subsection (d) hospital shall submit data on measures selected under this paragraph to the Secretary in a form and manner, and at a time, specified by the Secretary for purposes of this paragraph.

(C) DEVELOPMENT OF OUTPATIENT MEASURES.—

(i) IN GENERAL.—The Secretary shall develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

(ii) CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing the Secretary from selecting measures that are the same as (or a subset of) the measures for which data are required to be submitted under section 1886(b)(3)(B)(viii).

(D) REPLACEMENT OF MEASURES.—For purposes of this paragraph, the Secretary may replace any measures or indicators in appropriate cases, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown not to represent the best clinical practice.

(E) AVAILABILITY OF DATA.—The Secretary shall establish procedures for making data submitted under this paragraph available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in outpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(18) AUTHORIZATION OF ADJUSTMENT FOR CANCER HOSPITALS.—

(A) STUDY.—The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals described in section 1886(d)(1)(B)(v) with respect to ambulatory payment classification groups exceed those costs incurred by other hospitals furnishing services under this subsection (as determined appropriate by the Secretary). In conducting the study under this subparagraph, the Secretary shall take into consideration the cost of drugs and biologicals incurred by such hospitals.

(B) AUTHORIZATION OF ADJUSTMENT.—Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals described in section 1886(d)(1)(B)(v) ex-

ceed those costs incurred by other hospitals furnishing services under this subsection, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs effective for services furnished on or after January 1, 2011.

(19) FLOOR ON AREA WAGE ADJUSTMENT FACTOR FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES IN FRONTIER STATES.—

(A) IN GENERAL.—Subject to subparagraph (B), with respect to covered OPD services furnished on or after January 1, 2011, the area wage adjustment factor applicable under the payment system established under this subsection to any hospital outpatient department which is located in a frontier State (as defined in section 1886(d)(3)(E)(iii)(II)) may not be less than 1.00. The preceding sentence shall not be applied in a budget neutral manner.

(B) LIMITATION.—This paragraph shall not apply to any hospital outpatient department located in a State that receives a non-labor related share adjustment under section 1886(d)(5)(H).

(20) NOT BUDGET NEUTRAL APPLICATION OF REDUCED EXPENDITURES RESULTING FROM QUALITY INCENTIVES FOR COMPUTED TOMOGRAPHY.—The Secretary shall not take into account the reduced expenditures that result from the application of section 1834(p) in making any budget neutrality adjustments this subsection.

(u) INCENTIVE PAYMENTS FOR PHYSICIAN SCARCITY AREAS.—

(1) IN GENERAL.—In the case of physicians' services furnished on or after January 1, 2005, and before July 1, 2008—

(A) by a primary care physician in a primary care scarcity county (identified under paragraph (4)); or

(B) by a physician who is not a primary care physician in a specialist care scarcity county (as so identified),

in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid an amount equal to 5 percent of the payment amount for the service under this part.

(2) DETERMINATION OF RATIOS OF PHYSICIANS TO MEDICARE BENEFICIARIES IN AREA.—Based upon available data, the Secretary shall establish for each county or equivalent area in the United States, the following:

(A) NUMBER OF PHYSICIANS PRACTICING IN THE AREA.—The number of physicians who furnish physicians' services in the active practice of medicine or osteopathy in that county or area, other than physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services. Of such number, the number of such physicians who are—

(i) primary care physicians; or

(ii) physicians who are not primary care physicians.

(B) NUMBER OF MEDICARE BENEFICIARIES RESIDING IN THE AREA.—The number of individuals who are residing in the county and are entitled to benefits under part A or en-

rolled under this part, or both (in this subsection referred to as "individuals").

(C) DETERMINATION OF RATIOS.—

(i) PRIMARY CARE RATIO.—The ratio (in this paragraph referred to as the "primary care ratio") of the number of primary care physicians (determined under subparagraph (A)(i)), to the number of individuals determined under subparagraph (B).

(ii) SPECIALIST CARE RATIO.—The ratio (in this paragraph referred to as the "specialist care ratio") of the number of other physicians (determined under subparagraph (A)(ii)), to the number of individuals determined under subparagraph (B).

(3) RANKING OF COUNTIES.—The Secretary shall rank each such county or area based separately on its primary care ratio and its specialist care ratio.

(4) IDENTIFICATION OF COUNTIES.—

(A) IN GENERAL.—The Secretary shall identify—

(i) those counties and areas (in this paragraph referred to as "primary care scarcity counties") with the lowest primary care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph; and

(ii) those counties and areas (in this subsection referred to as "specialist care scarcity counties") with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph.

(B) PERIODIC REVISIONS.—The Secretary shall periodically revise the counties or areas identified in subparagraph (A) (but not less often than once every three years) unless the Secretary determines that there is no new data available on the number of physicians practicing in the county or area or the number of individuals residing in the county or area, as identified in paragraph (2).

(C) IDENTIFICATION OF COUNTIES WHERE SERVICE IS FURNISHED.—For purposes of paying the additional amount specified in paragraph (1), if the Secretary uses the 5-digit postal ZIP Code where the service is furnished, the dominant county of the postal ZIP Code (as determined by the United States Postal Service, or otherwise) shall be used to determine whether the postal ZIP Code is in a scarcity county identified in subparagraph (A) or revised in subparagraph (B).

(D) SPECIAL RULE.—With respect to physicians' services furnished on or after January 1, 2008, and before July 1, 2008, for purposes of this subsection, the Secretary shall use the primary care scarcity counties and the specialty care scarcity counties (as identified under the preceding provisions of this paragraph) that the Secretary was using

under this subsection with respect to physicians' services furnished on December 31, 2007.

(E) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting—

116.(i) the identification of a county or area;

(ii) the assignment of a specialty of any physician under this paragraph;

(iii) the assignment of a physician to a county under paragraph (2); or

(iv) the assignment of a postal ZIP Code to a county or other area under this subsection.

(5) RURAL CENSUS TRACTS.—To the extent feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)), as an equivalent area for purposes of qualifying as a primary care scarcity county or specialist care scarcity county under this subsection.

(6) PHYSICIAN DEFINED.—For purposes of this paragraph, the term "physician" means a physician described in section 1861(r)(1) and the term "primary care physician" means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

(7) PUBLICATION OF LIST OF COUNTIES; POSTING ON WEBSITE.—With respect to a year for which a county or area is identified or revised under paragraph (4), the Secretary shall identify such counties or areas as part of the proposed and final rule to implement the physician fee schedule under section 1848 for the applicable year. The Secretary shall post the list of counties identified or revised under paragraph (4) on the Internet website of the Centers for Medicare & Medicaid Services.

(v) INCREASE OF FQHC PAYMENT LIMITS.—In the case of services furnished by Federally qualified health centers (as defined in section 1861(aa)(4)), the Secretary shall establish payment limits with respect to such services under this part for services furnished—

(1) in 2010, at the limits otherwise established under this part for such year increased by $5; and

(2) in a subsequent year, at the limits established under this subsection for the previous year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year.

(w) METHODS OF PAYMENT.—The Secretary may develop alternative methods of payment for items and services provided under clinical trials and comparative effectiveness studies sponsored or supported by an agency of the Department of Health and Human Services, as determined by the Secretary, to those that would otherwise apply under this section, to the extent such alternative methods are necessary to preserve the scientific validity of such trials or studies, such as in the case where masking the identity of interventions from patients and investigators is necessary to comply with the particular trial or study design.

(x) INCENTIVE PAYMENTS FOR PRIMARY CARE SERVICES.—

(1) IN GENERAL.—In the case of primary care services furnished on or after January 1, 2011, and before January 1, 2016, by a primary care practitioner, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

(2) DEFINITIONS.—In this subsection:

(A) PRIMARY CARE PRACTITIONER.—The term "primary care practitioner" means an individual—

(i) who—

(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or

(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5)); and

(ii) for whom primary care services accounted for at least 60 percent of the allowed charges under this part for such physician or practitioner in a prior period as determined appropriate by the Secretary.

(B) PRIMARY CARE SERVICES.—The term "primary care services" means services identified, as of January 1, 2009, by the following HCPCS codes (and as subsequently modified by the Secretary):

(i) 99201 through 99215.

(ii) 99304 through 99340.

(iii) 99341 through 99350.

(3) COORDINATION WITH OTHER PAYMENTS.—The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively. The amount of the additional payment for a service under this subsection and subsection (z) shall be determined without regard to any additional payment for the service under subsection (z) and this subsection, respectively.

(4) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting the identification of primary care practitioners under this subsection.

(y) INCENTIVE PAYMENTS FOR MAJOR SURGICAL PROCEDURES FURNISHED IN HEALTH PROFESSIONAL SHORTAGE AREAS.—

(1) IN GENERAL.—In the case of major surgical procedures furnished on or after January 1, 2011, and before January 1, 2016, by a general surgeon in an area that is designated (under section 332(a)(1)(A) of the Public Health Service Act) as a health professional shortage area as identified by the Secretary prior to the beginning of the year involved, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

(2) DEFINITIONS.—In this subsection:

(A) GENERAL SURGEON.—In this subsection, the term "general surgeon" means a physician (as described in section 1861(r)(1)) who has designated CMS specialty code 02–General Surgery as their primary specialty code in the physician's enrollment under section 1866(j).

(B) MAJOR SURGICAL PROCEDURES.—The term "major surgical procedures" means physicians' services which are surgical procedures for which a 10-day or 90-day global period is used for payment under the fee schedule under section 1848(b).

(3) COORDINATION WITH OTHER PAYMENTS.—The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively. The amount of the additional payment for a service under this subsection and subsection (z) shall be determined without regard to any additional payment for the service under subsection (z) and this subsection, respectively.

(4) APPLICATION.—The provisions of paragraph (2) and (4) of subsection (m) shall apply to the determination of additional payments under this subsection in the same manner as such provisions apply to the determination of additional payments under subsection (m).

(z) INCENTIVE PAYMENTS FOR PARTICIPATION IN ELIGIBLE ALTERNATIVE PAYMENT MODELS.—

(1) PAYMENT INCENTIVE.—

(A) IN GENERAL.—In the case of covered professional services furnished by an eligible professional during a year that is in the period beginning with 2019 and ending with 2024 and for which the professional is a qualifying APM participant with respect to such year, in addition to the amount of payment that would otherwise be made for such covered professional services under this part for such year, there also shall be paid to such professional an amount equal to 5 percent of the estimated aggregate payment amounts for such covered professional services under this part for the preceding year. For purposes of the previous sentence, the payment amount for the preceding year may be an estimation for the full preceding year based on a period of such preceding year that is less than the full year. The Secretary shall establish policies to implement this subparagraph in cases in which payment for covered professional services furnished by a qualifying APM participant in an alternative payment model—

(i) is made to an eligible alternative payment entity rather than directly to the qualifying APM participant; or

(ii) is made on a basis other than a fee-for-service basis (such as payment on a capitated basis).

(B) FORM OF PAYMENT.—Payments under this subsection shall be made in a lump sum, on an annual basis, as soon as practicable.

(C) TREATMENT OF PAYMENT INCENTIVE.—Payments under this subsection shall not be taken into account for purposes of determining actual expenditures under an al-

ternative payment model and for purposes of determining or rebasing any benchmarks used under the alternative payment model.

(D) COORDINATION.—The amount of the additional payment under this subsection or subsection (m) shall be determined without regard to any additional payment under subsection (m) and this subsection, respectively. The amount of the additional payment under this subsection or subsection (x) shall be determined without regard to any additional payment under subsection (x) and this subsection, respectively. The amount of the additional payment under this subsection or subsection (y) shall be determined without regard to any additional payment under subsection (y) and this subsection, respectively.

(2) QUALIFYING APM PARTICIPANT.—For purposes of this subsection, the term "qualifying APM participant" means the following:

(A) 2019 AND 2020.—With respect to 2019 and 2020, an eligible professional for whom the Secretary determines that at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(B) 2021 AND 2022.—With respect to 2021 and 2022, an eligible professional described in either of the following clauses:

(i) MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional for whom the Secretary determines that at least 50 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(ii) COMBINATION ALL-PAYER AND MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional—

(I) for whom the Secretary determines, with respect to items and services furnished by such professional during the most recent period for which data are available (which may be less than a year), that at least 50 percent of the sum of—

(aa) payments described in clause (i); and

(bb) all other payments, regardless of payer (other than payments made by the Secretary of Defense or the Secretary of Veterans Affairs and other than payments made under title XIX in a State in which no medical home or alternative payment model is available under the State program under that title),

meet the requirement described in clause (iii)(I) with respect to payments described in item (aa) and meet the requirement described in clause

(iii)(II) with respect to payments described in item (bb);

(II) for whom the Secretary determines at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity; and

(III) who provides to the Secretary such information as is necessary for the Secretary to make a determination under subclause (I), with respect to such professional.

(iii) REQUIREMENT.—For purposes of clause (ii)(I)—

(I) the requirement described in this subclause, with respect to payments described in item (aa) of such clause, is that such payments are made to an eligible alternative payment entity; and

(II) the requirement described in this subclause, with respect to payments described in item (bb) of such clause, is that such payments are made under arrangements in which—

(aa) quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i) apply;

(bb) certified EHR technology is used; and

(cc) the eligible professional participates in an entity that—

(AA) bears more than nominal financial risk if actual aggregate expenditures exceeds expected aggregate expenditures; or

(BB) with respect to beneficiaries under title XIX, is a medical home that meets criteria comparable to medical homes expanded under section 1115A(c).

(C) BEGINNING IN 2023.—With respect to 2023 and each subsequent year, an eligible professional described in either of the following clauses:

(i) MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional for whom the Secretary determines that at least 75 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(ii) COMBINATION ALL-PAYER AND MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional—

(I) for whom the Secretary determines, with respect to items and services furnished by such professional during the most recent period for which data are available (which may be less than a year), that at least 75 percent of the sum of—

(aa) payments described in clause (i); and

(bb) all other payments, regardless of payer (other than payments made by the Secretary of Defense or the Secretary of Veterans Affairs and other than payments made under title XIX in a State in which no medical home or alternative payment model is available under the State program under that title),

meet the requirement described in clause (iii)(I) with respect to payments described in item (aa) and meet the requirement described in clause (iii)(II) with respect to payments described in item (bb);

(II) for whom the Secretary determines at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity; and

(III) who provides to the Secretary such information as is necessary for the Secretary to make a determination under subclause (I), with respect to such professional.

(iii) REQUIREMENT.—For purposes of clause (ii)(I)—

(I) the requirement described in this subclause, with respect to payments described in item (aa) of such clause, is that such payments are made to an eligible alternative payment entity; and

(II) the requirement described in this subclause, with respect to payments described in item (bb) of such clause, is that such payments are made under arrangements in which—

(aa) quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i) apply;

(bb) certified EHR technology is used; and

(cc) the eligible professional participates in an entity that—

(AA) bears more than nominal financial risk if actual aggregate expenditures exceeds expected aggregate expenditures; or

(BB) with respect to beneficiaries under title XIX, is a medical home that meets criteria comparable to medical homes expanded under section 1115A(c).

(D) USE OF PATIENT APPROACH.—The Secretary may base the determination of whether an eligible professional is a qualifying APM participant under this subsection and the determination of whether an eligible professional is a partial qualifying APM participant under section 1848(q)(1)(C)(iii) by using counts of patients in lieu of using payments and using the same or similar percentage criteria (as specified in this subsection and such section, respectively), as the Secretary determines appropriate.

(3) ADDITIONAL DEFINITIONS.—In this subsection:

(A) COVERED PROFESSIONAL SERVICES.—The term "covered professional services" has the meaning given that term in section 1848(k)(3)(A).

(B) ELIGIBLE PROFESSIONAL.—The term "eligible professional" has the meaning given that term in section 1848(k)(3)(B) and includes a group that includes such professionals.

(C) ALTERNATIVE PAYMENT MODEL (APM).—The term "alternative payment model" means, other than for purposes of subparagraphs (B)(ii)(I)(bb) and (C)(ii)(I)(bb) of paragraph (2), any of the following:

(i) A model under section 1115A (other than a health care innovation award).

(ii) The shared savings program under section 1899.

(iii) A demonstration under section 1866C.

(iv) A demonstration required by Federal law.

(D) ELIGIBLE ALTERNATIVE PAYMENT ENTITY.—The term "eligible alternative payment entity" means, with respect to a year, an entity that—

(i) participates in an alternative payment model that—

(I) requires participants in such model to use certified EHR technology (as defined in subsection (o)(4)); and

(II) provides for payment for covered professional services based on quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i); and

(ii)(I) bears financial risk for monetary losses under such alternative payment model that are in excess of a nominal amount; or

(II) is a medical home expanded under section 1115A(c).

(4) LIMITATION.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, of the following:

(A) The determination that an eligible professional is a qualifying APM participant under paragraph (2) and the determination that an entity is an eligible alternative payment entity under paragraph (3)(D).

(B) The determination of the amount of the 5 percent payment incentive under paragraph (1)(A), including any estimation as part of such determination.

(z) MEDICAL REVIEW OF SPINAL SUBLUXATION SERVICES.—

(1) IN GENERAL.—The Secretary shall implement a process for the medical review (as described in paragraph (2)) of treatment by a chiropractor described in section 1861(r)(5) by means of manual manipulation of the spine to correct a subluxation (as described in such section) of an individual who is enrolled under this part and apply such process to such services furnished on or after January 1, 2017, focusing on services such as—

(A) services furnished by a such a chiropractor whose pattern of billing is aberrant compared to peers; and

(B) services furnished by such a chiropractor who, in a prior period, has a services denial percentage in the 85th percentile or greater, taking into consideration the extent that service denials are overturned on appeal.

(2) MEDICAL REVIEW.—

(A) PRIOR AUTHORIZATION MEDICAL REVIEW.—

(i) IN GENERAL.—Subject to clause (ii), the Secretary shall use prior authorization medical review for services described in paragraph (1) that are furnished to an individual by a chiropractor described in section 1861(r)(5) that are part of an episode of treatment that includes more than 12 services. For purposes of the preceding sentence, an episode of treatment shall be determined by the underlying cause that justifies the need for services, such as a diagnosis code.

(ii) ENDING APPLICATION OF PRIOR AUTHORIZATION MEDICAL REVIEW.—The Secretary shall end the application of prior authorization medical review under clause (i) to services described in paragraph (1) by such a chiropractor if the Secretary determines that the chiropractor has a low denial rate under such prior authorization medical review. The Secretary may subsequently reapply prior authorization medical review to such chiropractor if the Secretary determines it to be appropriate and the chiropractor has, in the time period subsequent to the determination by the Secretary of a low denial rate with respect to the chiropractor, furnished such services described in paragraph (1).

(iii) EARLY REQUEST FOR PRIOR AUTHORIZATION REVIEW PERMITTED.—Nothing in this subsection shall be construed to prevent such a chiropractor from requesting prior authorization for services described in paragraph (1) that are to be furnished to an individual before the chiropractor furnishes the twelfth such service to such individual for an episode of treatment.

(B) TYPE OF REVIEW.—The Secretary may use pre-payment review or post-payment review of services described in section 1861(r)(5) that are not subject to prior authorization medical review under subparagraph (A).

(C) RELATIONSHIP TO LAW ENFORCEMENT ACTIVITIES.—The Secretary may determine that medical review under this subsection does not apply in the case where potential fraud may be involved.

(3) NO PAYMENT WITHOUT PRIOR AUTHORIZATION.—With respect to a service described in paragraph (1) for which prior authorization medical review under this subsection applies, the following shall apply:

(A) PRIOR AUTHORIZATION DETERMINATION.—The Secretary shall make a determination, prior to the service being furnished, of whether the service would or would not meet the applicable requirements of section 1862(a)(1)(A).

(B) DENIAL OF PAYMENT.—Subject to paragraph (5), no payment may be made under this part for the service unless the Secretary determines pursuant to subparagraph

(A) that the service would meet the applicable requirements of such section 1862(a)(1)(A).

(4) SUBMISSION OF INFORMATION.—A chiropractor described in section 1861(r)(5) may submit the information necessary for medical review by fax, by mail, or by electronic means. The Secretary shall make available the electronic means described in the preceding sentence as soon as practicable.

(5) TIMELINESS.—If the Secretary does not make a prior authorization determination under paragraph (3)(A) within 14 business days of the date of the receipt of medical documentation needed to make such determination, paragraph (3)(B) shall not apply.

(6) APPLICATION OF LIMITATION ON BENEFICIARY LIABILITY.—Where payment may not be made as a result of the application of paragraph (2)(B), section 1879 shall apply in the same manner as such section applies to a denial that is made by reason of section 1862(a)(1).

(7) REVIEW BY CONTRACTORS.—The medical review described in paragraph (2) may be conducted by medicare administrative contractors pursuant to section 1874A(a)(4)(G) or by any other contractor determined appropriate by the Secretary that is not a recovery audit contractor.

(8) MULTIPLE SERVICES.—The Secretary shall, where practicable, apply the medical review under this subsection in a manner so as to allow an individual described in paragraph (1) to obtain, at a single time rather than on a service-by-service basis, an authorization in accordance with paragraph (3)(A) for multiple services.

(9) CONSTRUCTION.—With respect to a service described in paragraph (1) that has been affirmed by medical review under this subsection, nothing in this subsection shall be construed to preclude the subsequent denial of a claim for such service that does not meet other applicable requirements under this Act.

(10) IMPLEMENTATION.—

(A) AUTHORITY.—The Secretary may implement the provisions of this subsection by interim final rule with comment period.

(B) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to medical review under this subsection.

SPECIAL PAYMENT RULES FOR PARTICULAR ITEMS AND SERVICES

SEC. 1834. (a) PAYMENT FOR DURABLE MEDICAL EQUIPMENT.—

(1) GENERAL RULE FOR PAYMENT.—

(A) IN GENERAL.—With respect to a covered item (as defined in paragraph (13)) for which payment is determined under this subsection, payment shall be made in the frequency specified in paragraphs (2) through (7) and in an amount equal to 80 percent of the payment basis described in subparagraph (B).

(B) PAYMENT BASIS.—Subject to subparagraph (F)(i), the payment basis described in this subparagraph is the lesser of—

(i) the actual charge for the item, or

(ii) the payment amount recognized under paragraphs (2) through (7) of this subsection for the item;

except that clause (i) shall not apply if the covered item is furnished by a public home health agency (or by another home health agency which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low income) free of charge or at nominal charges to the public.

(C) EXCLUSIVE PAYMENT RULE.—Subject to subparagraph (F)(ii), this subsection shall constitute the exclusive provision of this title for payment for covered items under this part or under part A to a home health agency.

(D) REDUCTION IN FEE SCHEDULES FOR CERTAIN ITEMS.—With respect to a seat-lift chair or transcutaneous electrical nerve stimulator furnished on or after April 1, 1990, the Secretary shall reduce the payment amount applied under subparagraph (B)(ii) for such an item by 15 percent, and, in the case of a transcutaneous electrical nerve stimulator furnished on or after January 1, 1991, the Secretary shall further reduce such payment amount (as previously reduced) by 45 percent.

(E) CLINICAL CONDITIONS FOR COVERAGE.—

(i) IN GENERAL.—The Secretary shall establish standards for clinical conditions for payment for covered items under this subsection.

(ii) REQUIREMENTS.—The standards established under clause (i) shall include the specification of types or classes of covered items that require, as a condition of payment under this subsection, a face-to-face examination of the individual by a physician (as defined in section 1861(r)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) and a prescription for the item.

(iii) PRIORITY OF ESTABLISHMENT OF STANDARDS.—In establishing the standards under this subparagraph, the Secretary shall first establish standards for those covered items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation to provide for payment of such covered items under this part.

(iv) STANDARDS FOR POWER WHEELCHAIRS.—Effective on the date of the enactment of this subparagraph, in the case of a covered item consisting of a motorized or power wheelchair for an individual, payment may not be made for such covered item unless a physician (as defined in section 1861(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) has conducted a face-to-face examination of the individual and written a prescription for the item.

(v) LIMITATION ON PAYMENT FOR COVERED ITEMS.—Payment may not be made for a covered item under

this subsection unless the item meets any standards established under this subparagraph for clinical condition of coverage.

(F) APPLICATION OF COMPETITIVE ACQUISITION; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of covered items furnished on or after January 1, 2011, subject to subparagraphs (G) and (H), that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)—

(i) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program;

(ii) the Secretary may (and, in the case of covered items furnished on or after January 1, 2016, subject to clause (iii), shall) use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847 and in the case of such adjustment, paragraph (10)(B) shall not be applied; and

(iii) in the case of covered items furnished on or after January 1, 2016, the Secretary shall continue to make such adjustments described in clause (ii) as, under such competitive acquisition programs, additional covered items are phased in or information is updated as contracts under section 1847 are recompeted in accordance with section 1847(b)(3)(B).

(G) USE OF INFORMATION ON COMPETITIVE BID RATES.—The Secretary shall specify by regulation the methodology to be used in applying the provisions of subparagraph (F)(ii) and subsection (h)(1)(H)(ii). In promulgating such regulation, the Secretary shall consider the costs of items and services in areas in which such provisions would be applied compared to the payment rates for such items and services in competitive acquisition areas.

(H) DIABETIC SUPPLIES.—

(i) IN GENERAL.—On or after the date described in clause (ii), the payment amount under this part for diabetic supplies, including testing strips, that are nonmail order items (as defined by the Secretary) shall be equal to the single payment amounts established under the national mail order competition for diabetic supplies under section 1847.

(ii) DATE DESCRIBED.—The date described in this clause is the date of the implementation of the single payment amounts under the national mail order competition for diabetic supplies under section 1847.

(I) TREATMENT OF VACUUM ERECTION SYSTEMS.—Effective for items and services furnished on and after July 1, 2015, vacuum erection systems described as prosthetic devices described in section 1861(s)(8) shall be treated in the same manner as erectile dysfunction drugs are treated for purposes of section 1860D-2(e)(2)(A).

(2) PAYMENT FOR INEXPENSIVE AND OTHER ROUTINELY PURCHASED DURABLE MEDICAL EQUIPMENT.—

(A) IN GENERAL.—Payment for an item of durable medical equipment (as defined in paragraph (13))—

(i) the purchase price of which does not exceed $150,

(ii) which the Secretary determines is acquired at least 75 percent of the time by purchase, or

(iii) which is an accessory used in conjunction with a nebulizer, aspirator, or a ventilator excluded under paragraph (3)(A),

shall be made on a rental basis or in a lump-sum amount for the purchase of the item. The payment amount recognized for purchase or rental of such equipment is the amount specified in subparagraph (B) for purchase or rental, except that the total amount of payments with respect to an item may not exceed the payment amount specified in subparagraph (B) with respect to the purchase of the item.

(B) PAYMENT AMOUNT.—For purposes of subparagraph (A), the amount specified in this subparagraph, with respect to the purchase or rental of an item furnished in a carrier service area—

(i) in 1989 and in 1990 is the average reasonable charge in the area for the purchase or rental, respectively, of the item for the 12-month period ending on June 30, 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987;

(ii) in 1991 is the sum of (I) 67 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(I) for 1991, and (II) 33 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1991;

(iii) in 1992 is the sum of (I) 33 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(II) for 1992, and (II) 67 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1992; and

(iv) in 1993 and each subsequent year is the national limited payment amount for the item or device computed under subparagraph (C)(ii) for that year (reduced by 10 percent, in the case of a blood glucose testing strip furnished after 1997 for an individual with diabetes).

(C) COMPUTATION OF LOCAL PAYMENT AMOUNT AND NATIONAL LIMITED PAYMENT AMOUNT.—For purposes of subparagraph (B)—

(i) the local payment amount for an item or device for a year is equal to—

(I) for 1991, the amount specified in subparagraph (B)(i) for 1990 increased by the covered item update for 1991, and

(II) for 1992, 1993, and 1994 the amount determined under this clause for the preceding year increased by the covered item update for the year; and

(ii) the national limited payment amount for an item or device for a year is equal to—

(I) for 1991, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the weighted average of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the weighted average of all local payment amounts determined under such clause for such item,

(II) for 1992 and 1993, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year,

(III) for 1994, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the median of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the median of all local payment amounts determined under such clause for such item or device for that year, and

(IV) for each subsequent year, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year.

(3) PAYMENT FOR ITEMS REQUIRING FREQUENT AND SUBSTANTIAL SERVICING.—

(A) IN GENERAL.—Payment for a covered item (such as IPPB machines and ventilators, excluding ventilators that are either continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices) for which there must be frequent and substantial servicing in order to avoid risk to the patient's health shall be made on a monthly basis for the rental of the item and the amount recognized is the amount specified in subparagraph (B).

(B) PAYMENT AMOUNT.—For purposes of subparagraph (A), the amount specified in this subparagraph, with respect to an item or device furnished in a carrier service area—

(i) in 1989 and in 1990 is the average reasonable charge in the area for the rental of the item or device for the 12-month period ending with June 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987;

(ii) in 1991 is the sum of (I) 67 percent of the local payment amount for the item or device computed

under subparagraph (C)(i)(I) for 1991, and (II) 33 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1991;

(iii) in 1992 is the sum of (I) 33 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(II) for 1992, and (II) 67 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1992; and

(iv) in 1993 and each subsequent year is the national limited payment amount for the item or device computed under subparagraph (C)(ii) for that year.

(C) COMPUTATION OF LOCAL PAYMENT AMOUNT AND NATIONAL LIMITED PAYMENT AMOUNT.—For purposes of subparagraph (B)—

(i) the local payment amount for an item or device for a year is equal to—

(I) for 1991, the amount specified in subparagraph (B)(i) for 1990 increased by the covered item update for 1991, and

(II) for 1992, 1993, and 1994 the amount determined under this clause for the preceding year increased by the covered item update for the year; and

(ii) the national limited payment amount for an item or device for a year is equal to—

(I) for 1991, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the weighted average of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the weighted average of all local payment amounts determined under such clause for such item,

(II) for 1992 and 1993, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year,

(III) for 1994, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the median of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the median of all local payment amounts determined under such clause for such item or device for that year, and

(IV) for each subsequent year, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year.

(4) PAYMENT FOR CERTAIN CUSTOMIZED ITEMS.—Payment with respect to a covered item that is uniquely constructed or

substantially modified to meet the specific needs of an individual patient, and for that reason cannot be grouped with similar items for purposes of payment under this title, shall be made in a lump-sum amount (A) for the purchase of the item in a payment amount based upon the carrier's individual consideration for that item, and (B) for the reasonable and necessary maintenance and servicing for parts and labor not covered by the supplier's or manufacturer's warranty, when necessary during the period of medical need, and the amount recognized for such maintenance and servicing shall be paid on a lump-sum, as needed basis based upon the carrier's individual consideration for that item. In the case of a wheelchair furnished on or after January 1, 1992, the wheelchair shall be treated as a customized item for purposes of this paragraph if the wheelchair has been measured, fitted, or adapted in consideration of the patient's body size, disability, period of need, or intended use, and has been assembled by a supplier or ordered from a manufacturer who makes available customized features, modifications, or components for wheelchairs that are intended for an individual patient's use in accordance with instructions from the patient's physician.

(5) PAYMENT FOR OXYGEN AND OXYGEN EQUIPMENT.—

(A) IN GENERAL.—Payment for oxygen and oxygen equipment shall be made on a monthly basis in the monthly payment amount recognized under paragraph (9) for oxygen and oxygen equipment (other than portable oxygen equipment), subject to subparagraphs (B), (C), (E), and (F).

(B) ADD-ON FOR PORTABLE OXYGEN EQUIPMENT.—When portable oxygen equipment is used, but subject to subparagraph (D), the payment amount recognized under subparagraph (A) shall be increased by the monthly payment amount recognized under paragraph (9) for portable oxygen equipment.

(C) VOLUME ADJUSTMENT.—When the attending physician prescribes an oxygen flow rate—

(i) exceeding 4 liters per minute, the payment amount recognized under subparagraph (A), subject to subparagraph (D), shall be increased by 50 percent, or

(ii) of less than 1 liter per minute, the payment amount recognized under subparagraph (A) shall be decreased by 50 percent.

(D) LIMIT ON ADJUSTMENT.—When portable oxygen equipment is used and the attending physician prescribes an oxygen flow rate exceeding 4 liters per minute, there shall only be an increase under either subparagraph (B) or (C), whichever increase is larger, and not under both such subparagraphs.

(E) RECERTIFICATION FOR PATIENTS RECEIVING HOME OXYGEN THERAPY.—In the case of a patient receiving home oxygen therapy services who, at the time such services are initiated, has an initial arterial blood gas value at or above a partial pressure of 56 or an arterial oxygen saturation at or above 89 percent (or such other values, pressures, or criteria as the Secretary may specify) no payment may be made under this part for such services after the expiration

of the 90-day period that begins on the date the patient first receives such services unless the patient's attending physician certifies that, on the basis of a follow-up test of the patient's arterial blood gas value or arterial oxygen saturation conducted during the final 30 days of such 90-day period, there is a medical need for the patient to continue to receive such services.

(F) RENTAL CAP.—

(i) IN GENERAL.—Payment for oxygen equipment (including portable oxygen equipment) under this paragraph may not extend over a period of continuous use (as determined by the Secretary) of longer than 36 months.

(ii) PAYMENTS AND RULES AFTER RENTAL CAP.—After the 36th continuous month during which payment is made for the equipment under this paragraph—

(I) the supplier furnishing such equipment under this subsection shall continue to furnish the equipment during any period of medical need for the remainder of the reasonable useful lifetime of the equipment, as determined by the Secretary;

(II) payments for oxygen shall continue to be made in the amount recognized for oxygen under paragraph (9) for the period of medical need; and

(III) maintenance and servicing payments shall, if the Secretary determines such payments are reasonable and necessary, be made (for parts and labor not covered by the supplier's or manufacturer's warranty, as determined by the Secretary to be appropriate for the equipment), and such payments shall be in an amount determined to be appropriate by the Secretary.

(6) PAYMENT FOR OTHER COVERED ITEMS (OTHER THAN DURABLE MEDICAL EQUIPMENT).—Payment for other covered items (other than durable medical equipment and other covered items described in paragraph (3), (4), or (5)) shall be made in a lump-sum amount for the purchase of the item in the amount of the purchase price recognized under paragraph (8).

(7) PAYMENT FOR OTHER ITEMS OF DURABLE MEDICAL EQUIPMENT.—

(A) PAYMENT.—In the case of an item of durable medical equipment not described in paragraphs (2) through (6), the following rules shall apply:

(i) RENTAL.—

(I) IN GENERAL.—Except as provided in clause (iii), payment for the item shall be made on a monthly basis for the rental of the item during the period of medical need (but payments under this clause may not extend over a period of continuous use (as determined by the Secretary) of longer than 13 months).

(II) PAYMENT AMOUNT.—Subject to subclause (III) and subparagraph (B), the amount recognized for the item, for each of the first 3 months of such period, is 10 percent of the purchase price recog-

nized under paragraph (8) with respect to the item, and, for each of the remaining months of such period, is 7.5 percent of such purchase price.

(III) SPECIAL RULE FOR POWER-DRIVEN WHEELCHAIRS.—For purposes of payment for power-driven wheelchairs, subclause (II) shall be applied by substituting "15 percent" and "6 percent" for "10 percent" and "7.5 percent", respectively.

(ii) OWNERSHIP AFTER RENTAL.—On the first day that begins after the 13th continuous month during which payment is made for the rental of an item under clause (i), the supplier of the item shall transfer title to the item to the individual.

(iii) PURCHASE AGREEMENT OPTION FOR COMPLEX, REHABILITATIVE POWER-DRIVEN WHEELCHAIRS.—In the case of a complex, rehabilitative power-driven wheelchair, at the time the supplier furnishes the item, the supplier shall offer the individual the option to purchase the item, and payment for such item shall be made on a lump-sum basis if the individual exercises such option.

(iv) MAINTENANCE AND SERVICING.—After the supplier transfers title to the item under clause (ii) or in the case of a power-driven wheelchair for which a purchase agreement has been entered into under clause (iii), maintenance and servicing payments shall, if the Secretary determines such payments are reasonable and necessary, be made (for parts and labor not covered by the supplier's or manufacturer's warranty, as determined by the Secretary to be appropriate for the particular type of durable medical equipment), and such payments shall be in an amount determined to be appropriate by the Secretary.

(B) RANGE FOR RENTAL AMOUNTS.—

(i) FOR 1989.—For items furnished during 1989, the payment amount recognized under subparagraph (A)(i) shall not be more than 115 percent, and shall not be less than 85 percent, of the prevailing charge established for rental of the item in January 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987.

(ii) FOR 1990.—For items furnished during 1990, clause (i) shall apply in the same manner as it applies to items furnished during 1989.

(C) REPLACEMENT OF ITEMS.—

(i) ESTABLISHMENT OF REASONABLE USEFUL LIFETIME.—In accordance with clause (iii), the Secretary shall determine and establish a reasonable useful lifetime for items of durable medical equipment for which payment may be made under this paragraph.

(ii) PAYMENT FOR REPLACEMENT ITEMS.—If the reasonable lifetime of such an item, as so established, has been reached during a continuous period of medical need, or the carrier determines that the item is lost or

irreparably damaged, the patient may elect to have payment for an item serving as a replacement for such item made—

(I) on a monthly basis for the rental of the replacement item in accordance with subparagraph (A); or

(II) in the case of an item for which a purchase agreement has been entered into under subparagraph (A)(iii), in a lump-sum amount for the purchase of the item.

(iii) LENGTH OF REASONABLE USEFUL LIFETIME.—The reasonable useful lifetime of an item of durable medical equipment under this subparagraph shall be equal to 5 years, except that, if the Secretary determines that, on the basis of prior experience in making payments for such an item under this title, a reasonable useful lifetime of 5 years is not appropriate with respect to a particular item, the Secretary shall establish an alternative reasonable lifetime for such item.

(8) PURCHASE PRICE RECOGNIZED FOR MISCELLANEOUS DEVICES AND ITEMS.—For purposes of paragraphs (6) and (7), the amount that is recognized under this paragraph as the purchase price for a covered item is the amount described in subparagraph (C) of this paragraph, determined as follows:

(A) COMPUTATION OF LOCAL PURCHASE PRICE.—Each carrier under section 1842 shall compute a base local purchase price for the item as follows:

(i) The carrier shall compute a base local purchase price, for each item described—

(I) in paragraph (6) equal to the average reasonable charge in the locality for the purchase of the item for the 12-month period ending with June 1987, or

(II) in paragraph (7) equal to the average of the purchase prices on the claims submitted on an assignment-related basis for the unused item supplied during the 6-month period ending with December 1986.

(ii) The carrier shall compute a local purchase price, with respect to the furnishing of each particular item—

(I) in 1989 and 1990, equal to the base local purchase price computed under clause (i) increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987,

(II) in 1991, equal to the local purchase price computed under this clause for the previous year, increased by the covered item update for 1991, and decreased by the percentage by which the average of the reasonable charges for claims paid for all items described in paragraph (7) is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988; or

(III) in 1992, 1993, and 1994 equal to the local purchase price computed under this clause for the previous year increased by the covered item update for the year.

(B) COMPUTATION OF NATIONAL LIMITED PURCHASE PRICE.—With respect to the furnishing of a particular item in a year, the Secretary shall compute a national limited purchase price—

(i) for 1991, equal to the local purchase price computed under subparagraph (A)(ii) for the item for the year, except that such national limited purchase price may not exceed 100 percent of the weighted average of all local purchase prices for the item computed under such subparagraph for the year, and may not be less than 85 percent of the weighted average of all local purchase prices for the item computed under such subparagraph for the year;

(ii) for 1992 and 1993, the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(iii) for 1994, the local purchase price computed under subparagraph (A)(ii) for the item for the year, except that such national limited purchase price may not exceed 100 percent of the median of all local purchase prices computed for the item under such subparagraph for the year and may not be less than 85 percent of the median of all local purchase prices computed under such subparagraph for the item for the year; and

(iv) for each subsequent year, equal to the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year.

(C) PURCHASE PRICE RECOGNIZED.—For purposes of paragraphs (6) and (7), the amount that is recognized under this paragraph as the purchase price for each item furnished—

(i) in 1989 or 1990, is 100 percent of the local purchase price computed under subparagraph (A)(ii)(I);

(ii) in 1991, is the sum of (I) 67 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1991, and (II) 33 percent of the national limited purchase price computed under subparagraph (B) for 1991;

(iii) in 1992, is the sum of (I) 33 percent of the local purchase price computed under subparagraph (A)(ii)(III) for 1992, and (II) 67 percent of the national limited purchase price computed under subparagraph (B) for 1992; and

(iv) in 1993 or a subsequent year, is the national limited purchase price computed under subparagraph (B) for that year.

(9) MONTHLY PAYMENT AMOUNT RECOGNIZED WITH RESPECT TO OXYGEN AND OXYGEN EQUIPMENT.—For purposes of paragraph (5), the amount that is recognized under this paragraph

for payment for oxygen and oxygen equipment is the monthly payment amount described in subparagraph (C) of this paragraph. Such amount shall be computed separately (i) for all items of oxygen and oxygen equipment (other than portable oxygen equipment) and (ii) for portable oxygen equipment (each such group referred to in this paragraph as an "item").

(A) COMPUTATION OF LOCAL MONTHLY PAYMENT RATE.—Each carrier under this section shall compute a base local payment rate for each item as follows:

(i) The carrier shall compute a base local average monthly payment rate per beneficiary as an amount equal to (I) the total reasonable charges for the item during the 12-month period ending with December 1986, divided by (II) the total number of months for all beneficiaries receiving the item in the area during the 12-month period for which the carrier made payment for the item under this title.

(ii) The carrier shall compute a local average monthly payment rate for the item applicable—

(I) to 1989 and 1990, equal to 95 percent of the base local average monthly payment rate computed under clause (i) for the item increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987, or

(II) to 1991, 1992, 1993, and 1994 equal to the local average monthly payment rate computed under this clause for the item for the previous year increased by the covered item increase for the year.

(B) COMPUTATION OF NATIONAL LIMITED MONTHLY PAYMENT RATE.—With respect to the furnishing of an item in a year, the Secretary shall compute a national limited monthly payment rate equal to—

(i) for 1991, the local monthly payment rate computed under subparagraph (A)(ii)(II) for the item for the year, except that such national limited monthly payment rate may not exceed 100 percent of the weighted average of all local monthly payment rates computed for the item under such subparagraph for the year, and may not be less than 85 percent of the weighted average of all local monthly payment rates computed for the item under such subparagraph for the year;

(ii) for 1992 and 1993, the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(iii) for 1994, the local monthly payment rate computed under subparagraph (A)(ii) for the item for the year, except that such national limited monthly payment rate may not exceed 100 percent of the median of all local monthly payment rates computed for the item under such subparagraph for the year and may not be less than 85 percent of the median of all local

monthly payment rates computed for the item under such subparagraph for the year;

(iv) for 1995, 1996, and 1997, equal to the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(v) for 1998, 75 percent of the amount determined under this subparagraph for 1997; and

(vi) for 1999 and each subsequent year, 70 percent of the amount determined under this subparagraph for 1997.

(C) MONTHLY PAYMENT AMOUNT RECOGNIZED.—For purposes of paragraph (5), the amount that is recognized under this paragraph as the base monthly payment amount for each item furnished—

(i) in 1989 and in 1990, is 100 percent of the local average monthly payment rate computed under subparagraph (A)(ii) for the item;

(ii) in 1991, is the sum of (I) 67 percent of the local average monthly payment rate computed under subparagraph (A)(ii)(II) for the item for 1991, and (II) 33 percent of the national limited monthly payment rate computed under subparagraph (B)(i) for the item for 1991;

(iii) in 1992, is the sum of (I) 33 percent of the local average monthly payment rate computed under subparagraph (A)(ii)(II) for the item for 1992, and (II) 67 percent of the national limited monthly payment rate computed under subparagraph (B)(ii) for the item for 1992; and

(iv) in a subsequent year, is the national limited monthly payment rate computed under subparagraph (B) for the item for that year.

(10) EXCEPTIONS AND ADJUSTMENTS.—

(A) AREAS OUTSIDE CONTINENTAL UNITED STATES.—Exceptions to the amounts recognized under the previous provisions of this subsection shall be made to take into account the unique circumstances of covered items furnished in Alaska, Hawaii, or Puerto Rico.

(B) ADJUSTMENT FOR INHERENT REASONABLENESS.—The Secretary is authorized to apply the provisions of paragraphs (8) and (9) of section 1842(b) to covered items and suppliers of such items and payments under this subsection in an area and with respect to covered items and services for which the Secretary does not make a payment amount adjustment under paragraph (1)(F).

(C) TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR (TENS).—In order to permit an attending physician time to determine whether the purchase of a transcutaneous electrical nerve stimulator is medically appropriate for a particular patient, the Secretary may determine an appropriate payment amount for the initial rental of such item for a period of not more than 2 months. If such item is subsequently purchased, the payment amount with respect

to such purchase is the payment amount determined under paragraph (2).

(11) IMPROPER BILLING AND REQUIREMENT OF PHYSICIAN ORDER.—

(A) IMPROPER BILLING FOR CERTAIN RENTAL ITEMS.—Notwithstanding any other provision of this title, a supplier of a covered item for which payment is made under this subsection and which is furnished on a rental basis shall continue to supply the item without charge (other than a charge provided under this subsection for the maintenance and servicing of the item) after rental payments may no longer be made under this subsection. If a supplier knowingly and willfully violates the previous sentence, the Secretary may apply sanctions against the supplier under section 1842(j)(2) in the same manner such sanctions may apply with respect to a physician.

(B) REQUIREMENT OF PHYSICIAN ORDER.—

(i) IN GENERAL.—The Secretary is authorized to require, for specified covered items, that payment may be made under this subsection with respect to the item only if a physician enrolled under section 1866(j) or an eligible professional under section 1848(k)(3)(B) that is enrolled under section 1866(j) has communicated to the supplier, before delivery of the item, a written order for the item.

(ii) REQUIREMENT FOR FACE TO FACE ENCOUNTER.—The Secretary shall require that such an order be written pursuant to a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) documenting such physician, physician assistant, practitioner, or specialist has had a face-to-face encounter (including through use of telehealth under subsection (m) and other than with respect to encounters that are incident to services involved) with the individual involved during the 6-month period preceding such written order, or other reasonable timeframe as determined by the Secretary.

(12) REGIONAL CARRIERS.—The Secretary may designate, by regulation under section 1842, one carrier for one or more entire regions to process all claims within the region for covered items under this section.

(13) COVERED ITEM.—In this subsection, the term "covered item" means durable medical equipment (as defined in section 1861(n)), including such equipment described in section 1861(m)(5), but not including implantable items for which payment may be made under section 1833(t).

(14) COVERED ITEM UPDATE.—In this subsection, the term "covered item update" means, with respect to a year—

(A) for 1991 and 1992, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced by 1 percentage point;

(B) for 1993, 1994, 1995, 1996, and 1997, the percentage increase in the consumer price index for all urban con-

sumers (U.S. city average) for the 12-month period ending with June of the previous year;

(C) for each of the years 1998 through 2000, 0 percentage points;

(D) for 2001, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 2000;

(E) for 2002, 0 percentage points;

(F) for 2003, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of 2002;

(G) for 2004 through 2006—

(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage increase described in subparagraph (B) for the year involved; and

(ii) in the case of covered items not described in clause (i), 0 percentage points;

(H) for 2007—

(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage change determined by the Secretary to be appropriate taking into account recommendations contained in the report of the Comptroller General of the United States under section 302(c)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and

(ii) in the case of covered items not described in clause (i), 0 percentage points;

(I) for 2008—

(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage increase described in subparagraph (B) (as applied to the payment amount for 2007 determined after the application of the percentage change under subparagraph (H)(i)); and

(ii) in the case of covered items not described in clause (i), 0 percentage points;

(J) for 2009—

(i) in the case of items and services furnished in any geographic area, if such items or services were selected for competitive acquisition in any area under the competitive acquisition program under section 1847(a)(1)(B)(i)(I) before July 1, 2008, including related accessories but only if furnished with such items and services selected for such competition and diabetic supplies but only if furnished through mail order, - 9.5 percent; or

(ii) in the case of other items and services, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2008;

(K) for 2010, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year; and

(L) for 2011 and each subsequent year—

(i) the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, reduced by—

(ii) the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).

The application of subparagraph (L)(ii) may result in the covered item update under this paragraph being less than 0.0 for a year, and may result in payment rates under this subsection for a year being less than such payment rates for the preceding year.

(15) ADVANCE DETERMINATIONS OF COVERAGE FOR CERTAIN ITEMS.—

(A) DEVELOPMENT OF LISTS OF ITEMS BY SECRETARY.—The Secretary may develop and periodically update a list of items for which payment may be made under this subsection that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization throughout a carrier's entire service area or a portion of such area.

(B) DEVELOPMENT OF LISTS OF SUPPLIERS BY SECRETARY.—The Secretary may develop and periodically update a list of suppliers of items for which payment may be made under this subsection with respect to whom—

(i) the Secretary has found that a substantial number of claims for payment under this part for items furnished by the supplier have been denied on the basis of the application of section 1862(a)(1); or

(ii) the Secretary has identified a pattern of overutilization resulting from the business practice of the supplier.

(C) DETERMINATIONS OF COVERAGE IN ADVANCE.—A carrier shall determine in advance of delivery of an item whether payment for the item may not be made because the item is not covered or because of the application of section 1862(a)(1) if—

(i) the item is included on the list developed by the Secretary under subparagraph (A);

(ii) the item is furnished by a supplier included on the list developed by the Secretary under subparagraph (B); or

(iii) the item is a customized item (other than inexpensive items specified by the Secretary) and the patient to whom the item is to be furnished or the supplier requests that such advance determination be made.

(16) DISCLOSURE OF INFORMATION AND SURETY BOND.—The Secretary shall not provide for the issuance (or renewal) of a provider number for a supplier of durable medical equipment, for purposes of payment under this part for durable medical

equipment furnished by the supplier, unless the supplier provides the Secretary on a continuing basis—

(A) with—

(i) full and complete information as to the identity of each person with an ownership or control interest (as defined in section 1124(a)(3)) in the supplier or in any subcontractor (as defined by the Secretary in regulations) in which the supplier directly or indirectly has a 5 percent or more ownership interest; and

(ii) to the extent determined to be feasible under regulations of the Secretary, the name of any disclosing entity (as defined in section 1124(a)(2)) with respect to which a person with such an ownership or control interest in the supplier is a person with such an ownership or control interest in the disclosing entity; and

(B) with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000 that the Secretary determines is commensurate with the volume of the billing of the supplier.

The Secretary may waive the requirement of a bond under subparagraph (B) in the case of a supplier that provides a comparable surety bond under State law. The Secretary, at the Secretary's discretion, may impose the requirements of the first sentence with respect to some or all providers of items or services under part A or some or all suppliers or other persons (other than physicians or other practitioners, as defined in section 1842(b)(18)(C)) who furnish items or services under this part.

(17) PROHIBITION AGAINST UNSOLICITED TELEPHONE CONTACTS BY SUPPLIERS.—

(A) IN GENERAL.—A supplier of a covered item under this subsection may not contact an individual enrolled under this part by telephone regarding the furnishing of a covered item to the individual unless 1 of the following applies:

(i) The individual has given written permission to the supplier to make contact by telephone regarding the furnishing of a covered item.

(ii) The supplier has furnished a covered item to the individual and the supplier is contacting the individual only regarding the furnishing of such covered item.

(iii) If the contact is regarding the furnishing of a covered item other than a covered item already furnished to the individual, the supplier has furnished at least 1 covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

(B) PROHIBITING PAYMENT FOR ITEMS FURNISHED SUBSEQUENT TO UNSOLICITED CONTACTS.—If a supplier knowingly contacts an individual in violation of subparagraph (A), no payment may be made under this part for any item subsequently furnished to the individual by the supplier.

(C) EXCLUSION FROM PROGRAM FOR SUPPLIERS ENGAGING IN PATTERN OF UNSOLICITED CONTACTS.—If a supplier knowingly contacts individuals in violation of subparagraph (A) to such an extent that the supplier's conduct establishes a pattern of contacts in violation of such subparagraph, the Secretary shall exclude the supplier from participation in the programs under this Act, in accordance with the procedures set forth in subsections (c), (f), and (g) of section 1128.

(18) REFUND OF AMOUNTS COLLECTED FOR CERTAIN DISALLOWED ITEMS.—

(A) IN GENERAL.—If a nonparticipating supplier furnishes to an individual enrolled under this part a covered item for which no payment may be made under this part by reason of paragraph (17)(B), the supplier shall refund on a timely basis to the patient (and shall be liable to the patient for) any amounts collected from the patient for the item, unless—

(i) the supplier establishes that the supplier did not know and could not reasonably have been expected to know that payment may not be made for the item by reason of paragraph (17)(B), or

(ii) before the item was furnished, the patient was informed that payment under this part may not be made for that item and the patient has agreed to pay for that item.

(B) SANCTIONS.—If a supplier knowingly and willfully fails to make refunds in violation of subparagraph (A), the Secretary may apply sanctions against the supplier in accordance with section 1842(j)(2).

(C) NOTICE.—Each carrier with a contract in effect under this part with respect to suppliers of covered items shall send any notice of denial of payment for covered items by reason of paragraph (17)(B) and for which payment is not requested on an assignment-related basis to the supplier and the patient involved.

(D) TIMELY BASIS DEFINED.—A refund under subparagraph (A) is considered to be on a timely basis only if—

(i) in the case of a supplier who does not request reconsideration or seek appeal on a timely basis, the refund is made within 30 days after the date the supplier receives a denial notice under subparagraph (C), or

(ii) in the case in which such a reconsideration or appeal is taken, the refund is made within 15 days after the date the supplier receives notice of an adverse determination on reconsideration or appeal.

(19) CERTAIN UPGRADED ITEMS.—

(A) INDIVIDUAL'S RIGHT TO CHOOSE UPGRADED ITEM.—Notwithstanding any other provision of this title, the Secretary may issue regulations under which an individual may purchase or rent from a supplier an item of upgraded durable medical equipment for which payment would be made under this subsection if the item were a standard item.

(B) PAYMENTS TO SUPPLIER.—In the case of the purchase or rental of an upgraded item under subparagraph (A)—

(i) the supplier shall receive payment under this subsection with respect to such item as if such item were a standard item; and

(ii) the individual purchasing or renting the item shall pay the supplier an amount equal to the difference between the supplier's charge and the amount under clause (i).

In no event may the supplier's charge for an upgraded item exceed the applicable fee schedule amount (if any) for such item.

(C) CONSUMER PROTECTION SAFEGUARDS.—Any regulations under subparagraph (A) shall provide for consumer protection standards with respect to the furnishing of upgraded equipment under subparagraph (A). Such regulations shall provide for—

(i) determination of fair market prices with respect to an upgraded item;

(ii) full disclosure of the availability and price of standard items and proof of receipt of such disclosure information by the beneficiary before the furnishing of the upgraded item;

(iii) conditions of participation for suppliers in the billing arrangement;

(iv) sanctions of suppliers who are determined to engage in coercive or abusive practices, including exclusion; and

(v) such other safeguards as the Secretary determines are necessary.

(20) IDENTIFICATION OF QUALITY STANDARDS.—

(A) IN GENERAL.—Subject to subparagraph (C), the Secretary shall establish and implement quality standards for suppliers of items and services described in subparagraph (D) to be applied by recognized independent accreditation organizations (as designated under subparagraph (B)) and with which such suppliers shall be required to comply in order to—

(i) furnish any such item or service for which payment is made under this part; and

(ii) receive or retain a provider or supplier number used to submit claims for reimbursement for any such item or service for which payment may be made under this title.

(B) DESIGNATION OF INDEPENDENT ACCREDITATION ORGANIZATIONS.—Not later than the date that is 1 year after the date on which the Secretary implements the quality standards under subparagraph (A), notwithstanding section 1865(a), the Secretary shall designate and approve one or more independent accreditation organizations for purposes of such subparagraph.

(C) QUALITY STANDARDS.—The quality standards described in subparagraph (A) may not be less stringent than the quality standards that would otherwise apply if this

paragraph did not apply and shall include consumer services standards.

(D) ITEMS AND SERVICES DESCRIBED.—The items and services described in this subparagraph are the following items and services, as the Secretary determines appropriate:

(i) Covered items (as defined in paragraph (13)) for which payment may otherwise be made under this subsection.

(ii) Prosthetic devices and orthotics and prosthetics described in section 1834(h)(4).

(iii) Items and services described in section 1842(s)(2).

(E) IMPLEMENTATION.—The Secretary may establish by program instruction or otherwise the quality standards under this paragraph, including subparagraph (F), after consultation with representatives of relevant parties. Such standards shall be applied prospectively and shall be published on the Internet website of the Centers for Medicare & Medicaid Services.

(F) APPLICATION OF ACCREDITATION REQUIREMENT.—In implementing quality standards under this paragraph—

(i) subject to clause (ii) and subparagraph (G), the Secretary shall require suppliers furnishing items and services described in subparagraph (D) on or after October 1, 2009, directly or as a subcontractor for another entity, to have submitted to the Secretary evidence of accreditation by an accreditation organization designated under subparagraph (B) as meeting applicable quality standards, except that the Secretary shall not require under this clause pharmacies to obtain such accreditation before January 1, 2010, except that the Secretary shall not require a pharmacy to have submitted to the Secretary such evidence of accreditation prior to January 1, 2011; and

(ii) in applying such standards and the accreditation requirement of clause (i) with respect to eligible professionals (as defined in section 1848(k)(3)(B)), and including such other persons, such as orthotists and prosthetists, as specified by the Secretary, furnishing such items and services—

(I) such standards and accreditation requirement shall not apply to such professionals and persons unless the Secretary determines that the standards being applied are designed specifically to be applied to such professionals and persons; and

(II) the Secretary may exempt such professionals and persons from such standards and requirement if the Secretary determines that licensing, accreditation, or other mandatory quality requirements apply to such professionals and persons with respect to the furnishing of such items and services.

(G) APPLICATION OF ACCREDITATION REQUIREMENT TO CERTAIN PHARMACIES.—

(i) IN GENERAL.—With respect to items and services furnished on or after January 1, 2011, in implementing quality standards under this paragraph—

(I) subject to subclause (II), in applying such standards and the accreditation requirement of subparagraph (F)(i) with respect to pharmacies described in clause (ii) furnishing such items and services, such standards and accreditation requirement shall not apply to such pharmacies; and

(II) the Secretary may apply to such pharmacies an alternative accreditation requirement established by the Secretary if the Secretary determines such alternative accreditation requirement is more appropriate for such pharmacies.

(ii) PHARMACIES DESCRIBED.—A pharmacy described in this clause is a pharmacy that meets each of the following criteria:

(I) The total billings by the pharmacy for such items and services under this title are less than 5 percent of total pharmacy sales, as determined based on the average total pharmacy sales for the previous 3 calendar years, 3 fiscal years, or other yearly period specified by the Secretary.

(II) The pharmacy has been enrolled under section 1866(j) as a supplier of durable medical equipment, prosthetics, orthotics, and supplies, has been issued (which may include the renewal of) a provider number for at least 5 years, and for which a final adverse action (as defined in section 424.57(a) of title 42, Code of Federal Regulations) has not been imposed in the past 5 years.

(III) The pharmacy submits to the Secretary an attestation, in a form and manner, and at a time, specified by the Secretary, that the pharmacy meets the criteria described in subclauses (I) and (II). Such attestation shall be subject to section 1001 of title 18, United States Code.

(IV) The pharmacy agrees to submit materials as requested by the Secretary, or during the course of an audit conducted on a random sample of pharmacies selected annually, to verify that the pharmacy meets the criteria described in subclauses (I) and (II). Materials submitted under the preceding sentence shall include a certification by an accountant on behalf of the pharmacy or the submission of tax returns filed by the pharmacy during the relevant periods, as requested by the Secretary.

(21) SPECIAL PAYMENT RULE FOR SPECIFIED ITEMS AND SUPPLIES.—

(A) IN GENERAL.—Notwithstanding the preceding provisions of this subsection, for specified items and supplies

(described in subparagraph (B)) furnished during 2005, the payment amount otherwise determined under this subsection for such specified items and supplies shall be reduced by the percentage difference between—

(i) the amount of payment otherwise determined for the specified item or supply under this subsection for 2002, and

(ii) the amount of payment for the specified item or supply under chapter 89 of title 5, United States Code, as identified in the column entitled "Median FEHP Price" in the table entitled "SUMMARY OF MEDICARE PRICES COMPARED TO VA, MEDICAID, RETAIL, AND FEHP PRICES FOR 16 ITEMS" included in the Testimony of the Inspector General before the Senate Committee on Appropriations, June 12, 2002, or any subsequent report by the Inspector General.

(B) SPECIFIED ITEM OR SUPPLY DESCRIBED.—For purposes of subparagraph (A), a specified item or supply means oxygen and oxygen equipment, standard wheelchairs (including standard power wheelchairs), nebulizers, diabetic supplies consisting of lancets and testing strips, hospital beds, and air mattresses, but only if the HCPCS code for the item or supply is identified in a table referred to in subparagraph (A)(ii).

(C) APPLICATION OF UPDATE TO SPECIAL PAYMENT AMOUNT.—The covered item update under paragraph (14) for specified items and supplies for 2006 and each subsequent year shall be applied to the payment amount under subparagraph (A) unless payment is made for such items and supplies under section 1847.

(22) SPECIAL PAYMENT RULE FOR DIABETIC SUPPLIES.—Notwithstanding the preceding provisions of this subsection, for purposes of determining the payment amount under this subsection for diabetic supplies furnished on or after the first day of the calendar quarter during 2013 that is at least 30 days after the date of the enactment of this paragraph and before the date described in paragraph (1)(H)(ii), the Secretary shall recalculate and apply the covered item update under paragraph (14) as if subparagraph (J)(i) of such paragraph was amended by striking "but only if furnished through mail order".

(b) FEE SCHEDULES FOR RADIOLOGIST SERVICES.—

(1) DEVELOPMENT.—The Secretary shall develop—

(A) a relative value scale to serve as the basis for the payment for radiologist services under this part, and

(B) using such scale and appropriate conversion factors and subject to subsection (c)(1)(A), fee schedules (on a regional, statewide, locality, or carrier service area basis) for payment for radiologist services under this part, to be implemented for such services furnished during 1989.

(2) CONSULTATION.—In carrying out paragraph (1), the Secretary shall regularly consult closely with the Physician Payment Review Commission, the American College of Radiology, and other organizations representing physicians or suppliers who furnish radiologist services and shall share with them the

data and data analysis being used to make the determinations under paragraph (1), including data on variations in current medicare payments by geographic area, and by service and physician specialty.

(3) CONSIDERATIONS.—In developing the relative value scale and fee schedules under paragraph (1), the Secretary—

(A) shall take into consideration variations in the cost of furnishing such services among geographic areas and among different sites where services are furnished, and

(B) may also take into consideration such other factors respecting the manner in which physicians in different specialties furnish such services as may be appropriate to assure that payment amounts are equitable and designed to promote effective and efficient provision of radiologist services by physicians in the different specialties.

(4) SAVINGS.—

(A) BUDGET NEUTRAL FEE SCHEDULES.—The Secretary shall develop preliminary fee schedules for 1989, which are designed to result in the same amount of aggregate payments (net of any coinsurance and deductibles under sections 1833(a)(1)(J) and 1833(b)) for radiologist services furnished in 1989 as would have been made if this subsection had not been enacted.

(B) INITIAL SAVINGS.—The fee schedules established for payment purposes under this subsection for services furnished in 1989 shall be 97 percent of the amounts permitted under these preliminary fee schedules developed under subparagraph (A).

(C) 1990 FEE SCHEDULES.—For radiologist services (other than portable X-ray services) furnished under this part during 1990, after March 31 of such year, the conversion factors used under this subsection shall be 96 percent of the conversion factors that applied under this subsection as of December 31, 1989.

(D) 1991 FEE SCHEDULES.—For radiologist services (other than portable X-ray services) furnished under this part during 1991, the conversion factors used in a locality under this subsection shall, subject to clause (vii), be reduced to the adjusted conversion factor for the locality determined as follows:

(i) NATIONAL WEIGHTED AVERAGE CONVERSION FACTOR.—The Secretary shall estimate the national weighted average of the conversion factors used under this subsection for services furnished during 1990 beginning on April 1, using the best available data.

(ii) REDUCED NATIONAL WEIGHTED AVERAGE.—The national weighted average estimated under clause (i) shall be reduced by 13 percent.

(iii) COMPUTATION OF 1990 LOCALITY INDEX RELATIVE TO NATIONAL AVERAGE.—The Secretary shall establish an index which reflects, for each locality, the ratio of the conversion factor used in the locality under this subsection to the national weighted average estimated under clause (i).

(iv) ADJUSTED CONVERSION FACTOR.—The adjusted conversion factor for the professional or technical component of a service in a locality is the sum of ½ of the locally-adjusted amount determined under clause (v) and ½ of the GPCI-adjusted amount determined under clause (vi).

(v) LOCALLY-ADJUSTED AMOUNT.—For purposes of clause (iv), the locally adjusted amount determined under this clause is the product of (I) the national weighted average conversion factor computed under clause (ii), and (II) the index value established under clause (iii) for the locality.

(vi) GPCI-ADJUSTED AMOUNT.—For purposes of clause (iv), the GPCI-adjusted amount determined under this clause is the sum of—

(I) the product of (a) the portion of the reduced national weighted average conversion factor computed under clause (ii) which is attributable to physician work and (b) the geographic work index value for the locality (specified in Addendum C to the Model Fee Schedule for Physician Services (published on September 4, 1990, 55 Federal Register pp. 36238–36243)); and

(II) the product of (a) the remaining portion of the reduced national weighted average conversion factor computed under clause (ii), and (b) the geographic practice cost index value specified in section 1842(b)(14)(C)(iv) for the locality.

In applying this clause with respect to the professional component of a service, 80 percent of the conversion factor shall be considered to be attributable to physician work and with respect to the technical component of the service, 0 percent shall be considered to be attributable to physician work.

(vii) LIMITS ON CONVERSION FACTOR.—The conversion factor to be applied to a locality to the professional or technical component of a service shall not be reduced under this subparagraph by more than 9.5 percent below the conversion factor applied in the locality under subparagraph (C) to such component, but in no case shall the conversion factor be less than 60 percent of the national weighted average of the conversion factors (computed under clause (i)).

(E) RULE FOR CERTAIN SCANNING SERVICES.—In the case of the technical components of magnetic resonance imaging (MRI) services and computer assisted tomography (CAT) services furnished after December 31, 1990, the amount otherwise payable shall be reduced by 10 percent.

(F) SUBSEQUENT UPDATING.—For radiologist services furnished in subsequent years, the fee schedules shall be the schedules for the previous year updated by the percentage increase in the MEI (as defined in section 1842(i)(3)) for the year.

(G) NONPARTICIPATING PHYSICIANS AND SUPPLIERS.—Each fee schedule so established shall provide that the

payment rate recognized for nonparticipating physicians and suppliers is equal to the appropriate percent (as defined in section 1842(b)(4)(A)(iv)) of the payment rate recognized for participating physicians and suppliers.

(5) LIMITING CHARGES OF NONPARTICIPATING PHYSICIANS AND SUPPLIERS.—

(A) IN GENERAL.—In the case of radiologist services furnished after January 1, 1989, for which payment is made under a fee schedule under this subsection, if a nonparticipating physician or supplier furnishes the service to an individual entitled to benefits under this part, the physician or supplier may not charge the individual more than the limiting charge (as defined in subparagraph (B)).

(B) LIMITING CHARGE DEFINED.—In subparagraph (A), the term "limiting charge" means, with respect to a service furnished—

(i) in 1989, 125 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1),

(ii) in 1990, 120 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1), and

(iii) after 1990, 115 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1).

(C) ENFORCEMENT.—If a physician or supplier knowingly and willfully bills in violation of subparagraph (A), the Secretary may apply sanctions against such physician or supplier in accordance with section 1842(j)(2) in the same manner as such sanctions may apply to a physician.

(6) RADIOLOGIST SERVICES DEFINED.—For the purposes of this subsection and section 1833(a)(1)(J), the term "radiologist services" only includes radiology services performed by, or under the direction or supervision of, a physician—

(A) who is certified, or eligible to be certified, by the American Board of Radiology, or

(B) for whom radiology services account for at least 50 percent of the total amount of charges made under this part.

(c) PAYMENT AND STANDARDS FOR SCREENING MAMMOGRAPHY.—

(1) IN GENERAL.—With respect to expenses incurred for screening mammography (as defined in section 1861(jj)), payment may be made only—

(A) for screening mammography conducted consistent with the frequency permitted under paragraph (2); and

(B) if the screening mammography is conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act.

(2) FREQUENCY COVERED.—

(A) IN GENERAL.—Subject to revision by the Secretary under subparagraph (B)—

(i) no payment may be made under this part for screening mammography performed on a woman under 35 years of age;

(ii) payment may be made under this part for only one screening mammography performed on a woman over 34 years of age, but under 40 years of age; and

(iii) in the case of a woman over 39 years of age, payment may not be made under this part for screening mammography performed within 11 months following the month in which a previous screening mammography was performed.

(B) REVISION OF FREQUENCY.—

(i) REVIEW.—The Secretary, in consultation with the Director of the National Cancer Institute, shall review periodically the appropriate frequency for performing screening mammography, based on age and such other factors as the Secretary believes to be pertinent.

(ii) REVISION OF FREQUENCY.—The Secretary, taking into consideration the review made under clause (i), may revise from time to time the frequency with which screening mammography may be paid for under this subsection.

(d) FREQUENCY LIMITS AND PAYMENT FOR COLORECTAL CANCER SCREENING TESTS.—

(1) SCREENING FECAL-OCCULT BLOOD TESTS.—

(A) PAYMENT AMOUNT.—The payment amount for colorectal cancer screening tests consisting of screening fecal-occult blood tests is equal to the payment amount established for diagnostic fecal-occult blood tests under section 1833(h).

(B) FREQUENCY LIMIT.—No payment may be made under this part for a colorectal cancer screening test consisting of a screening fecal-occult blood test—

(i) if the individual is under 50 years of age; or

(ii) if the test is performed within the 11 months after a previous screening fecal-occult blood test.

(2) SCREENING FLEXIBLE SIGMOIDOSCOPIES.—

(A) FEE SCHEDULE.—With respect to colorectal cancer screening tests consisting of screening flexible sigmoidoscopies, payment under section 1848 shall be consistent with payment under such section for similar or related services.

(B) PAYMENT LIMIT.—In the case of screening flexible sigmoidoscopy services, payment under this part shall not exceed such amount as the Secretary specifies, based upon the rates recognized for diagnostic flexible sigmoidoscopy services.

(C) FACILITY PAYMENT LIMIT.—

(i) IN GENERAL.—Notwithstanding subsections (i)(2)(A) and (t) of section 1833, in the case of screening flexible sigmoidoscopy services furnished on or after January 1, 1999, that—

(I) in accordance with regulations, may be performed in an ambulatory surgical center and for which the Secretary permits ambulatory surgical center payments under this part, and

(II) are performed in an ambulatory surgical center or hospital outpatient department,

payment under this part shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area.

(ii) LIMITATION ON COINSURANCE.—Notwithstanding any other provision of this title, in the case of a beneficiary who receives the services described in clause (i)—

(I) in computing the amount of any applicable copayment, the computation of such coinsurance shall be based upon the fee schedule under which payment is made for the services, and

(II) the amount of such coinsurance is equal to 25 percent of the payment amount under the fee schedule described in subclause (I).

(D) SPECIAL RULE FOR DETECTED LESIONS.—If during the course of such screening flexible sigmoidoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part shall not be made for the screening flexible sigmoidoscopy but shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal.

(E) FREQUENCY LIMIT.—No payment may be made under this part for a colorectal cancer screening test consisting of a screening flexible sigmoidoscopy—

(i) if the individual is under 50 years of age; or

(ii) if the procedure is performed within the 47 months after a previous screening flexible sigmoidoscopy or, in the case of an individual who is not at high risk for colorectal cancer, if the procedure is performed within the 119 months after a previous screening colonoscopy.

(3) SCREENING COLONOSCOPY.—

(A) FEE SCHEDULE.—With respect to colorectal cancer screening test consisting of a screening colonoscopy, payment under section 1848 shall be consistent with payment amounts under such section for similar or related services.

(B) PAYMENT LIMIT.—In the case of screening colonoscopy services, payment under this part shall not exceed such amount as the Secretary specifies, based upon the rates recognized for diagnostic colonoscopy services.

(C) FACILITY PAYMENT LIMIT.—

(i) IN GENERAL.—Notwithstanding subsections (i)(2)(A) and (t) of section 1833, in the case of screening colonoscopy services furnished on or after January 1, 1999, that are performed in an ambulatory surgical center or a hospital outpatient department, payment under this part shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if

they were performed in an ambulatory surgical center in the same area.

(ii) LIMITATION ON COINSURANCE.—Notwithstanding any other provision of this title, in the case of a beneficiary who receives the services described in clause (i)—

(I) in computing the amount of any applicable coinsurance, the computation of such coinsurance shall be based upon the fee schedule under which payment is made for the services, and

(II) the amount of such coinsurance is equal to 25 percent of the payment amount under the fee schedule described in subclause (I).

(D) SPECIAL RULE FOR DETECTED LESIONS.—If during the course of such screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal.

(E) FREQUENCY LIMIT.—No payment may be made under this part for a colorectal cancer screening test consisting of a screening colonoscopy for individuals at high risk for colorectal cancer if the procedure is performed within the 23 months after a previous screening colonoscopy or for other individuals if the procedure is performed within the 119 months after a previous screening colonoscopy or within 47 months after a previous screening flexible sigmoidoscopy.

(e) ACCREDITATION REQUIREMENT FOR ADVANCED DIAGNOSTIC IMAGING SERVICES.—

(1) IN GENERAL.—

(A) IN GENERAL.—Beginning with January 1, 2012, with respect to the technical component of advanced diagnostic imaging services for which payment is made under the fee schedule established under section 1848(b) and that are furnished by a supplier, payment may only be made if such supplier is accredited by an accreditation organization designated by the Secretary under paragraph (2)(B)(i).

(B) ADVANCED DIAGNOSTIC IMAGING SERVICES DEFINED.—In this subsection, the term "advanced diagnostic imaging services" includes—

(i) diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and

(ii) such other diagnostic imaging services, including services described in section 1848(b)(4)(B) (excluding X-ray, ultrasound, and fluoroscopy), as specified by the Secretary in consultation with physician specialty organizations and other stakeholders.

(C) SUPPLIER DEFINED.—In this subsection, the term "supplier" has the meaning given such term in section 1861(d).

(2) ACCREDITATION ORGANIZATIONS.—

(A) FACTORS FOR DESIGNATION OF ACCREDITATION ORGANIZATIONS.—The Secretary shall consider the following factors in designating accreditation organizations under subparagraph (B)(i) and in reviewing and modifying the list of accreditation organizations designated pursuant to subparagraph (C):

(i) The ability of the organization to conduct timely reviews of accreditation applications.

(ii) Whether the organization has established a process for the timely integration of new advanced diagnostic imaging services into the organization's accreditation program.

(iii) Whether the organization uses random site visits, site audits, or other strategies for ensuring accredited suppliers maintain adherence to the criteria described in paragraph (3).

(iv) The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D)).

(v) Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

(vi) Such other factors as the Secretary determines appropriate.

(B) DESIGNATION.—Not later than January 1, 2010, the Secretary shall designate organizations to accredit suppliers furnishing the technical component of advanced diagnostic imaging services. The list of accreditation organizations so designated may be modified pursuant to subparagraph (C).

(C) REVIEW AND MODIFICATION OF LIST OF ACCREDITATION ORGANIZATIONS.—

(i) IN GENERAL.—The Secretary shall review the list of accreditation organizations designated under subparagraph (B) taking into account the factors under subparagraph (A). Taking into account the results of such review, the Secretary may, by regulation, modify the list of accreditation organizations designated under subparagraph (B).

(ii) SPECIAL RULE FOR ACCREDITATIONS DONE PRIOR TO REMOVAL FROM LIST OF DESIGNATED ACCREDITATION ORGANIZATIONS.—In the case where the Secretary removes an organization from the list of accreditation organizations designated under subparagraph (B), any supplier that is accredited by the organization during the period beginning on the date on which the organization is designated as an accreditation organization under subparagraph (B) and ending on the date on which the organization is removed from such list shall be considered to have been accredited by an organization designated by the Secretary under subparagraph (B) for the remaining period such accreditation is in effect.

(3) CRITERIA FOR ACCREDITATION.—The Secretary shall establish procedures to ensure that the criteria used by an accredi-

tation organization designated under paragraph (2)(B) to evaluate a supplier that furnishes the technical component of advanced diagnostic imaging services for the purpose of accreditation of such supplier is specific to each imaging modality. Such criteria shall include—

(A) standards for qualifications of medical personnel who are not physicians and who furnish the technical component of advanced diagnostic imaging services;

(B) standards for qualifications and responsibilities of medical directors and supervising physicians, including standards that recognize the considerations described in paragraph (4);

(C) procedures to ensure that equipment used in furnishing the technical component of advanced diagnostic imaging services meets performance specifications;

(D) standards that require the supplier have procedures in place to ensure the safety of persons who furnish the technical component of advanced diagnostic imaging services and individuals to whom such services are furnished;

(E) standards that require the establishment and maintenance of a quality assurance and quality control program by the supplier that is adequate and appropriate to ensure the reliability, clarity, and accuracy of the technical quality of diagnostic images produced by such supplier; and

(F) any other standards or procedures the Secretary determines appropriate.

(4) RECOGNITION IN STANDARDS FOR THE EVALUATION OF MEDICAL DIRECTORS AND SUPERVISING PHYSICIANS.—The standards described in paragraph (3)(B) shall recognize whether a medical director or supervising physician—

(A) in a particular specialty receives training in advanced diagnostic imaging services in a residency program;

(B) has attained, through experience, the necessary expertise to be a medical director or a supervising physician;

(C) has completed any continuing medical education courses relating to such services; or

(D) has met such other standards as the Secretary determines appropriate.

(5) RULE FOR ACCREDITATIONS MADE PRIOR TO DESIGNATION.—In the case of a supplier that is accredited before January 1, 2010, by an accreditation organization designated by the Secretary under paragraph (2)(B) as of January 1, 2010, such supplier shall be considered to have been accredited by an organization designated by the Secretary under such paragraph as of January 1, 2012, for the remaining period such accreditation is in effect.

(f) REDUCTION IN PAYMENTS FOR PHYSICIAN PATHOLOGY SERVICES DURING 1991.—

(1) IN GENERAL.—For physician pathology services furnished under this part during 1991, the prevailing charges used in a locality under this part shall be 7 percent below the prevailing charges used in the locality under this part in 1990 after March 31.

(2) LIMITATION.—The prevailing charge for the technical and professional components of an physician pathology service fur-

nished by a physician through an independent laboratory shall not be reduced pursuant to paragraph (1) to the extent that such reduction would reduce such prevailing charge below 115 percent of the prevailing charge for the professional component of such service when furnished by a hospital-based physician in the same locality. For purposes of the preceding sentence, an independent laboratory is a laboratory that is independent of a hospital and separate from the attending or consulting physicians' office.

(g) PAYMENT FOR OUTPATIENT CRITICAL ACCESS HOSPITAL SERVICES.—

(1) IN GENERAL.—The amount of payment for outpatient critical access hospital services of a critical access hospital is equal to 101 percent of the reasonable costs of the hospital in providing such services, unless the hospital makes the election under paragraph (2).

(2) ELECTION OF COST-BASED HOSPITAL OUTPATIENT SERVICE PAYMENT PLUS FEE SCHEDULE FOR PROFESSIONAL SERVICES.—A critical access hospital may elect to be paid for outpatient critical access hospital services amounts equal to the sum of the following, less the amount that such hospital may charge as described in section 1866(a)(2)(A):

(A) FACILITY FEE.—With respect to facility services, not including any services for which payment may be made under subparagraph (B), 101 percent of the reasonable costs of the critical access hospital in providing such services.

(B) FEE SCHEDULE FOR PROFESSIONAL SERVICES.—With respect to professional services otherwise included within outpatient critical access hospital services, 115 percent of such amounts as would otherwise be paid under this part if such services were not included in outpatient critical access hospital services. Subsections (x) and (y) of section 1833 shall not be taken into account in determining the amounts that would otherwise be paid pursuant to the preceding sentence.

The Secretary may not require, as a condition for applying subparagraph (B) with respect to a critical access hospital, that each physician or other practitioner providing professional services in the hospital must assign billing rights with respect to such services, except that such subparagraph shall not apply to those physicians and practitioners who have not assigned such billing rights.

(3) DISREGARDING CHARGES.—The payment amounts under this subsection shall be determined without regard to the amount of the customary or other charge.

(4) TREATMENT OF CLINICAL DIAGNOSTIC LABORATORY SERVICES.—No coinsurance, deductible, copayment, or other cost-sharing otherwise applicable under this part shall apply with respect to clinical diagnostic laboratory services furnished as an outpatient critical access hospital service. Nothing in this title shall be construed as providing for payment for clinical diagnostic laboratory services furnished as part of outpatient critical access hospital services, other than on the basis described in this subsection. For purposes of the preceding sen-

tence and section 1861(mm)(3), clinical diagnostic laboratory services furnished by a critical access hospital shall be treated as being furnished as part of outpatient critical access services without regard to whether the individual with respect to whom such services are furnished is physically present in the critical access hospital, or in a skilled nursing facility or a clinic (including a rural health clinic) that is operated by a critical access hospital, at the time the specimen is collected.

(5) COVERAGE OF COSTS FOR CERTAIN EMERGENCY ROOM ON-CALL PROVIDERS.—In determining the reasonable costs of outpatient critical access hospital services under paragraphs (1) and (2)(A), the Secretary shall recognize as allowable costs, amounts (as defined by the Secretary) for reasonable compensation and related costs for physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on-call (as defined by the Secretary) to provide emergency services but who are not present on the premises of the critical access hospital involved, and are not otherwise furnishing services covered under this title and are not on-call at any other provider or facility.

(h) PAYMENT FOR PROSTHETIC DEVICES AND ORTHOTICS AND PROSTHETICS.—

(1) GENERAL RULE FOR PAYMENT.—

(A) IN GENERAL.—Payment under this subsection for prosthetic devices and orthotics and prosthetics shall be made in a lump-sum amount for the purchase of the item in an amount equal to 80 percent of the payment basis described in subparagraph (B).

(B) PAYMENT BASIS.—Except as provided in subparagraphs (C), (E), and (H)(i), the payment basis described in this subparagraph is the lesser of—

(i) the actual charge for the item; or

(ii) the amount recognized under paragraph (2) as the purchase price for the item.

(C) EXCEPTION FOR CERTAIN PUBLIC HOME HEALTH AGENCIES.—Subparagraph (B)(i) shall not apply to an item furnished by a public home health agency (or by another home health agency which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low income) free of charge or at nominal charges to the public.

(D) EXCLUSIVE PAYMENT RULE.—Subject to subparagraph (H)(ii), this subsection shall constitute the exclusive provision of this title for payment for prosthetic devices, orthotics, and prosthetics under this part or under part A to a home health agency.

(E) EXCEPTION FOR CERTAIN ITEMS.—Payment for ostomy supplies, tracheostomy supplies, and urologicals shall be made in accordance with subparagraphs (B) and (C) of section 1834(a)(2).

(F) SPECIAL PAYMENT RULES FOR CERTAIN PROSTHETICS AND CUSTOM-FABRICATED ORTHOTICS.—

(i) IN GENERAL.—No payment shall be made under this subsection for an item of custom-fabricated

orthotics described in clause (ii) or for an item of prosthetics unless such item is—

(I) furnished by a qualified practitioner; and

(II) fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the Secretary determines appropriate.

(ii) DESCRIPTION OF CUSTOM-FABRICATED ITEM.—

(I) IN GENERAL.—An item described in this clause is an item of custom-fabricated orthotics that requires education, training, and experience to custom-fabricate and that is included in a list established by the Secretary in subclause (II). Such an item does not include shoes and shoe inserts.

(II) LIST OF ITEMS.—The Secretary, in consultation with appropriate experts in orthotics (including national organizations representing manufacturers of orthotics), shall establish and update as appropriate a list of items to which this subparagraph applies. No item may be included in such list unless the item is individually fabricated for the patient over a positive model of the patient.

(iii) QUALIFIED PRACTITIONER DEFINED.—In this subparagraph, the term "qualified practitioner" means a physician or other individual who—

(I) is a qualified physical therapist or a qualified occupational therapist;

(II) in the case of a State that provides for the licensing of orthotics and prosthetics, is licensed in orthotics or prosthetics by the State in which the item is supplied; or

(III) in the case of a State that does not provide for the licensing of orthotics and prosthetics, is specifically trained and educated to provide or manage the provision of prosthetics and custom-designed or -fabricated orthotics, and is certified by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or is credentialed and approved by a program that the Secretary determines, in consultation with appropriate experts in orthotics and prosthetics, has training and education standards that are necessary to provide such prosthetics and orthotics.

(iv) QUALIFIED SUPPLIER DEFINED.—In this subparagraph, the term "qualified supplier" means any entity that is accredited by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or accredited and approved by a program that the Secretary determines has accreditation and approval standards that are essentially equivalent to those of such Board.

(G) REPLACEMENT OF PROSTHETIC DEVICES AND PARTS.—

(i) IN GENERAL.—Payment shall be made for the replacement of prosthetic devices which are artificial

limbs, or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if an ordering physician determines that the provision of a replacement device, or a replacement part of such a device, is necessary because of any of the following:

(I) A change in the physiological condition of the patient.

(II) An irreparable change in the condition of the device, or in a part of the device.

(III) The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.

(ii) CONFIRMATION MAY BE REQUIRED IF DEVICE OR PART BEING REPLACED IS LESS THAN 3 YEARS OLD.—If a physician determines that a replacement device, or a replacement part, is necessary pursuant to clause (i)—

(I) such determination shall be controlling; and

(II) such replacement device or part shall be deemed to be reasonable and necessary for purposes of section 1862(a)(1)(A);

except that if the device, or part, being replaced is less than 3 years old (calculated from the date on which the beneficiary began to use the device or part), the Secretary may also require confirmation of necessity of the replacement device or replacement part, as the case may be.

(H) APPLICATION OF COMPETITIVE ACQUISITION TO ORTHOTICS; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of orthotics described in paragraph (2)(C) of section 1847(a) furnished on or after January 1, 2009, subject to subsection (a)(1)(G), that are included in a competitive acquisition program in a competitive acquisition area under such section—

(i) the payment basis under this subsection for such orthotics furnished in such area shall be the payment basis determined under such competitive acquisition program; and

(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.

(2) PURCHASE PRICE RECOGNIZED.—For purposes of paragraph (1), the amount that is recognized under this paragraph as the purchase price for prosthetic devices, orthotics, and prosthetics is the amount described in subparagraph (C) of this paragraph, determined as follows:

(A) COMPUTATION OF LOCAL PURCHASE PRICE.—Each carrier under section 1842 shall compute a base local purchase price for the item as follows:

(i) The carrier shall compute a base local purchase price for each item equal to the average reasonable charge in the locality for the purchase of the item for the 12-month period ending with June 1987.

(ii) The carrier shall compute a local purchase price, with respect to the furnishing of each particular item—

(I) in 1989 and 1990, equal to the base local purchase price computed under clause (i) increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 6-month period ending with December 1987, or

(II) in 1991, 1992 or 1993, equal to the local purchase price computed under this clause for the previous year increased by the applicable percentage increase for the year.

(B) COMPUTATION OF REGIONAL PURCHASE PRICE.—With respect to the furnishing of a particular item in each region (as defined by the Secretary), the Secretary shall compute a regional purchase price—

(i) for 1992, equal to the average (weighted by relative volume of all claims among carriers) of the local purchase prices for the carriers in the region computed under subparagraph (A)(ii)(II) for the year, and

(ii) for each subsequent year, equal to the regional purchase price computed under this subparagraph for the previous year increased by the applicable percentage increase for the year.

(C) PURCHASE PRICE RECOGNIZED.—For purposes of paragraph (1) and subject to subparagraph (D), the amount that is recognized under this paragraph as the purchase price for each item furnished—

(i) in 1989, 1990, or 1991, is 100 percent of the local purchase price computed under subparagraph (A)(ii);

(ii) in 1992, is the sum of (I) 75 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1992, and (II) 25 percent of the regional purchase price computed under subparagraph (B) for 1992;

(iii) in 1993, is the sum of (I) 50 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1993, and (II) 50 percent of the regional purchase price computed under subparagraph (B) for 1993; and

(iv) in 1994 or a subsequent year, is the regional purchase price computed under subparagraph (B) for that year.

(D) RANGE ON AMOUNT RECOGNIZED.—The amount that is recognized under subparagraph (C) as the purchase price for an item furnished—

(i) in 1992, may not exceed 125 percent, and may not be lower than 85 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year; and

(ii) in a subsequent year, may not exceed 120 percent, and may not be lower than 90 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year.

(3) APPLICABILITY OF CERTAIN PROVISIONS RELATING TO DURABLE MEDICAL EQUIPMENT.—Paragraphs (12) and (17) and subparagraphs (A) and (B) of paragraph (10) and paragraph (11) of subsection (a) shall apply to prosthetic devices, orthotics, and prosthetics in the same manner as such provisions apply to covered items under such subsection.

(4) DEFINITIONS.—In this subsection—

(A) the term "applicable percentage increase" means—

(i) for 1991, 0 percent;

(ii) for 1992 and 1993, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;

(iii) for 1994 and 1995, 0 percent;

(iv) for 1996 and 1997, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;

(v) for each of the years 1998 through 2000, 1 percent;

(vi) for 2001, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 2000;

(vii) for 2002, 1 percent;

(viii) for 2003, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;

(ix) for 2004, 2005, and 2006, 0 percent;

(x) for for each of 2007 through 2010, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year; and

(xi) for 2011 and each subsequent year—

(I) the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, reduced by—

(II) the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).

(B) the term "prosthetic devices" has the meaning given such term in section 1861(s)(8), except that such term does not include parenteral and enteral nutrition nutrients, supplies, and equipment and does not include an

implantable item for which payment may be made under section 1833(t); and

(C) the term "orthotics and prosthetics" has the meaning given such term in section 1861(s)(9) (and includes shoes described in section 1861(s)(12)), but does not include intraocular lenses or medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care) furnished by a home health agency under section 1861(m)(5).

The application of subparagraph (A)(xi)(II) may result in the applicable percentage increase under subparagraph (A) being less than 0.0 for a year, and may result in payment rates under this subsection for a year being less than such payment rates for the preceding year.

(i) PAYMENT FOR SURGICAL DRESSINGS.—

(1) IN GENERAL.—Payment under this subsection for surgical dressings (described in section 1861(s)(5)) shall be made in a lump sum amount for the purchase of the item in an amount equal to 80 percent of the lesser of—

(A) the actual charge for the item; or

(B) a payment amount determined in accordance with the methodology described in subparagraphs (B) and (C) of subsection (a)(2) (except that in applying such methodology, the national limited payment amount referred to in such subparagraphs shall be initially computed based on local payment amounts using average reasonable charges for the 12-month period ending December 31, 1992, increased by the covered item updates described in such subsection for 1993 and 1994).

(2) EXCEPTIONS.—Paragraph (1) shall not apply to surgical dressings that are—

(A) furnished as an incident to a physician's professional service; or

(B) furnished by a home health agency.

(j) REQUIREMENTS FOR SUPPLIERS OF MEDICAL EQUIPMENT AND SUPPLIES.—

(1) ISSUANCE AND RENEWAL OF SUPPLIER NUMBER.—

(A) PAYMENT.—Except as provided in subparagraph (C), no payment may be made under this part after the date of the enactment of the Social Security Act Amendments of 1994 for items furnished by a supplier of medical equipment and supplies unless such supplier obtains (and renews at such intervals as the Secretary may require) a supplier number.

(B) STANDARDS FOR POSSESSING A SUPPLIER NUMBER.—A supplier may not obtain a supplier number unless—

(i) for medical equipment and supplies furnished on or after the date of the enactment of the Social Security Act Amendments of 1994 and before January 1, 1996, the supplier meets standards prescribed by the Secretary in regulations issued on June 18, 1992; and

(ii) for medical equipment and supplies furnished on or after January 1, 1996, the supplier meets revised standards prescribed by the Secretary (in consultation with representatives of suppliers of medical equipment

and supplies, carriers, and consumers) that shall include requirements that the supplier—

(I) comply with all applicable State and Federal licensure and regulatory requirements;

(II) maintain a physical facility on an appropriate site;

(III) have proof of appropriate liability insurance; and

(IV) meet such other requirements as the Secretary may specify.

(C) EXCEPTION FOR ITEMS FURNISHED AS INCIDENT TO A PHYSICIAN'S SERVICE.—Subparagraph (A) shall not apply with respect to medical equipment and supplies furnished incident to a physician's service.

(D) PROHIBITION AGAINST MULTIPLE SUPPLIER NUMBERS.—The Secretary may not issue more than one supplier number to any supplier of medical equipment and supplies unless the issuance of more than one number is appropriate to identify subsidiary or regional entities under the supplier's ownership or control.

(E) PROHIBITION AGAINST DELEGATION OF SUPPLIER DETERMINATIONS.—The Secretary may not delegate (other than by contract under section 1842) the responsibility to determine whether suppliers meet the standards necessary to obtain a supplier number.

(2) CERTIFICATES OF MEDICAL NECESSITY.—

(A) LIMITATION ON INFORMATION PROVIDED BY SUPPLIERS ON CERTIFICATES OF MEDICAL NECESSITY.—

(i) IN GENERAL.—Effective 60 days after the date of the enactment of the Social Security Act Amendments of 1994, a supplier of medical equipment and supplies may distribute to physicians, or to individuals entitled to benefits under this part, a certificate of medical necessity for commercial purposes which contains no more than the following information completed by the supplier:

(I) An identification of the supplier and the beneficiary to whom such medical equipment and supplies are furnished.

(II) A description of such medical equipment and supplies.

(III) Any product code identifying such medical equipment and supplies.

(IV) Any other administrative information (other than information relating to the beneficiary's medical condition) identified by the Secretary.

(ii) INFORMATION ON PAYMENT AMOUNT AND CHARGES.—If a supplier distributes a certificate of medical necessity containing any of the information permitted to be supplied under clause (i), the supplier shall also list on the certificate of medical necessity the fee schedule amount and the supplier's charge for the medical equipment or supplies being furnished

prior to distribution of such certificate to the physician.

(iii) PENALTY.—Any supplier of medical equipment and supplies who knowingly and willfully distributes a certificate of medical necessity in violation of clause (i) or fails to provide the information required under clause (ii) is subject to a civil money penalty in an amount not to exceed $1,000 for each such certificate of medical necessity so distributed. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under section 1128A(a).

(B) DEFINITION.—For purposes of this paragraph, the term "certificate of medical necessity" means a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

(3) COVERAGE AND REVIEW CRITERIA.—The Secretary shall annually review the coverage and utilization of items of medical equipment and supplies to determine whether such items should be made subject to coverage and utilization review criteria, and if appropriate, shall develop and apply such criteria to such items.

(4) LIMITATION ON PATIENT LIABILITY.—If a supplier of medical equipment and supplies (as defined in paragraph (5))—

(A) furnishes an item or service to a beneficiary for which no payment may be made by reason of paragraph (1);

(B) furnishes an item or service to a beneficiary for which payment is denied in advance under subsection (a)(15); or

(C) furnishes an item or service to a beneficiary for which payment is denied under section 1862(a)(1);

any expenses incurred for items and services furnished to an individual by such a supplier not on an assigned basis shall be the responsibility of such supplier. The individual shall have no financial responsibility for such expenses and the supplier shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected from the individual for such items or services. The provisions of subsection (a)(18) shall apply to refunds required under the previous sentence in the same manner as such provisions apply to refunds under such subsection.

(5) DEFINITION.—The term "medical equipment and supplies" means—

(A) durable medical equipment (as defined in section 1861(n));

(B) prosthetic devices (as described in section 1861(s)(8));

(C) orthotics and prosthetics (as described in section 1861(s)(9));

(D) surgical dressings (as described in section 1861(s)(5));

(E) such other items as the Secretary may determine; and

(F) for purposes of paragraphs (1) and (3)—

(i) home dialysis supplies and equipment (as described in section 1861(s)(2)(F)),

(ii) immunosuppressive drugs (as described in section 1861(s)(2)(J)),

(iii) therapeutic shoes for diabetics (as described in section 1861(s)(12)),

(iv) oral drugs prescribed for use as an anticancer therapeutic agent (as described in section 1861(s)(2)(Q)), and

(v) self-administered erythropoetin (as described in section 1861(s)(2)(P)).

(k) PAYMENT FOR OUTPATIENT THERAPY SERVICES AND COMPREHENSIVE OUTPATIENT REHABILITATION SERVICES.—

(1) IN GENERAL.—With respect to services described in section 1833(a)(8) or 1833(a)(9) for which payment is determined under this subsection, the payment basis shall be—

(A) for services furnished during 1998, the amount determined under paragraph (2); or

(B) for services furnished during a subsequent year, 80 percent of the lesser of—

(i) the actual charge for the services, or

(ii) the applicable fee schedule amount (as defined in paragraph (3)) for the services.

(2) PAYMENT IN 1998 BASED UPON ADJUSTED REASONABLE COSTS.—The amount under this paragraph for services is the lesser of—

(A) the charges imposed for the services, or

(B) the adjusted reasonable costs (as defined in paragraph (4)) for the services,

less 20 percent of the amount of the charges imposed for such services.

(3) APPLICABLE FEE SCHEDULE AMOUNT.—In this subsection, the term "applicable fee schedule amount" means, with respect to services furnished in a year, the amount determined under the fee schedule established under section 1848 for such services furnished during the year or, if there is no such fee schedule established for such services, the amount determined under the fee schedule established for such comparable services as the Secretary specifies.

(4) ADJUSTED REASONABLE COSTS.—In paragraph (2), the term "adjusted reasonable costs" means, with respect to any services, reasonable costs determined for such services, reduced by 10 percent. The 10-percent reduction shall not apply to services described in section 1833(a)(8)(B) (relating to services provided by hospitals).

(5) UNIFORM CODING.—For claims for services submitted on or after April 1, 1998, for which the amount of payment is determined under this subsection, the claim shall include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(6) RESTRAINT ON BILLING.—The provisions of subparagraphs (A) and (B) of section 1842(b)(18) shall apply to therapy serv-

ices for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1842(b)(18)(C).

(7) ADJUSTMENT IN DISCOUNT FOR CERTAIN MULTIPLE THERAPY SERVICES.—In the case of therapy services furnished on or after April 1, 2013, and for which payment is made under this subsection pursuant to the applicable fee schedule amount (as defined in paragraph (3)), instead of the 25 percent multiple procedure payment reduction specified in the final rule published by the Secretary in the Federal Register on November 29, 2010, the reduction percentage shall be 50 percent.

(l) ESTABLISHMENT OF FEE SCHEDULE FOR AMBULANCE SERVICES.—

(1) IN GENERAL.—The Secretary shall establish a fee schedule for payment for ambulance services whether provided directly by a supplier or provider or under arrangement with a provider under this part through a negotiated rulemaking process described in title 5, United States Code, and in accordance with the requirements of this subsection.

(2) CONSIDERATIONS.—In establishing such fee schedule, the Secretary shall—

(A) establish mechanisms to control increases in expenditures for ambulance services under this part;

(B) establish definitions for ambulance services which link payments to the type of services provided;

(C) consider appropriate regional and operational differences;

(D) consider adjustments to payment rates to account for inflation and other relevant factors; and

(E) phase in the application of the payment rates under the fee schedule in an efficient and fair manner consistent with paragraph (11), except that such phase-in shall provide for full payment of any national mileage rate for ambulance services provided by suppliers that are paid by carriers in any of the 50 States where payment by a carrier for such services for all such suppliers in such State did not, prior to the implementation of the fee schedule, include a separate amount for all mileage within the county from which the beneficiary is transported.

(3) SAVINGS.—In establishing such fee schedule, the Secretary shall—

(A) ensure that the aggregate amount of payments made for ambulance services under this part during 2000 does not exceed the aggregate amount of payments which would have been made for such services under this part during such year if the amendments made by section 4531(a) of the Balanced Budget Act of 1997 continued in effect, except that in making such determination the Secretary shall assume an update in such payments for 2002 equal to percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2002 by 1.0 percentage points;

(B) set the payment amounts provided under the fee schedule for services furnished in 2001 and each subse-

quent year at amounts equal to the payment amounts under the fee schedule for services furnished during the previous year, increased, subject to subparagraph (C) and the succeeding sentence of this paragraph, by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2002 by 1.0 percentage points; and

(C) for 2011 and each subsequent year, after determining the percentage increase under subparagraph (B) for the year, reduce such percentage increase by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).

The application of subparagraph (C) may result in the percentage increase under subparagraph (B) being less than 0.0 for a year, and may result in payment rates under the fee schedule under this subsection for a year being less than such payment rates for the preceding year.

(4) CONSULTATION.—In establishing the fee schedule for ambulance services under this subsection, the Secretary shall consult with various national organizations representing individuals and entities who furnish and regulate ambulance services and share with such organizations relevant data in establishing such schedule.

(5) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869 or otherwise of the amounts established under the fee schedule for ambulance services under this subsection, including matters described in paragraph (2).

(6) RESTRAINT ON BILLING.—The provisions of subparagraphs (A) and (B) of section 1842(b)(18) shall apply to ambulance services for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1842(b)(18)(C).

(7) CODING SYSTEM.—The Secretary may require the claim for any services for which the amount of payment is determined under this subsection to include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(8) SERVICES FURNISHED BY CRITICAL ACCESS HOSPITALS.—Notwithstanding any other provision of this subsection, the Secretary shall pay 101 percent of the reasonable costs incurred in furnishing ambulance services if such services are furnished—

(A) by a critical access hospital (as defined in section 1861(mm)(1)), or

(B) by an entity that is owned and operated by a critical access hospital,

but only if the critical access hospital or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of such critical access hospital.

(9) TRANSITIONAL ASSISTANCE FOR RURAL PROVIDERS.—In the case of ground ambulance services furnished on or after July 1, 2001, and before January 1, 2004, for which the transportation originates in a rural area (as defined in section

1886(d)(2)(D)) or in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)), the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 17 miles, and up to 50 miles, the rate otherwise established shall be increased by not less than ½ of the additional payment per mile established for the first 17 miles of such a trip originating in a rural area.

(10) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—In carrying out the phase-in under paragraph (2)(E) for each level of ground service furnished in a year, the portion of the payment amount that is based on the fee schedule shall be the greater of the amount determined under such fee schedule (without regard to this paragraph) or the following blended rate of the fee schedule under paragraph (1) and of a regional fee schedule for the region involved:

(A) For 2004 (for services furnished on or after July 1, 2004), the blended rate shall be based 20 percent on the fee schedule under paragraph (1) and 80 percent on the regional fee schedule.

(B) For 2005, the blended rate shall be based 40 percent on the fee schedule under paragraph (1) and 60 percent on the regional fee schedule.

(C) For 2006, the blended rate shall be based 60 percent on the fee schedule under paragraph (1) and 40 percent on the regional fee schedule.

(D) For 2007, 2008, and 2009, the blended rate shall be based 80 percent on the fee schedule under paragraph (1) and 20 percent on the regional fee schedule.

(E) For 2010 and each succeeding year, the blended rate shall be based 100 percent on the fee schedule under paragraph (1).

For purposes of this paragraph, the Secretary shall establish a regional fee schedule for each of the nine census divisions (referred to in section 1886(d)(2)) using the methodology (used in establishing the fee schedule under paragraph (1)) to calculate a regional conversion factor and a regional mileage payment rate and using the same payment adjustments and the same relative value units as used in the fee schedule under such paragraph.

(11) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG TRIPS.—In the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2009, regardless of where the transportation originates, the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 50 miles the per mile rate otherwise established shall be increased by ¼ of the payment per mile otherwise applicable to miles in excess of 50 miles in such trip.

(12) ASSISTANCE FOR RURAL PROVIDERS FURNISHING SERVICES IN LOW POPULATION DENSITY AREAS.—

(A) IN GENERAL.—In the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2018, for which the transportation originates in a qualified rural area (identified under subparagraph (B)(iii)), the Secretary shall provide for a percent increase in the base rate of the fee schedule for a trip established under this subsection. In establishing such percent increase, the Secretary shall estimate the average cost per trip for such services (not taking into account mileage) in the lowest quartile as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of all rural county populations.

(B) IDENTIFICATION OF QUALIFIED RURAL AREAS.—

(i) DETERMINATION OF POPULATION DENSITY IN AREA.—Based upon data from the United States decennial census for the year 2000, the Secretary shall determine, for each rural area, the population density for that area.

(ii) RANKING OF AREAS.—The Secretary shall rank each such area based on such population density.

(iii) IDENTIFICATION OF QUALIFIED RURAL AREAS.—The Secretary shall identify those areas (in subparagraph (A) referred to as "qualified rural areas") with the lowest population densities that represent, if each such area were weighted by the population of such area (as used in computing such population densities), an aggregate total of 25 percent of the total of the population of all such areas.

(iv) RURAL AREA.—For purposes of this paragraph, the term "rural area" has the meaning given such term in section 1886(d)(2)(D). If feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725) as a rural area for purposes of this paragraph.

(v) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting the identification of an area under this subparagraph.

(13) TEMPORARY INCREASE FOR GROUND AMBULANCE SERVICES.—

(A) IN GENERAL.—After computing the rates with respect to ground ambulance services under the other applicable provisions of this subsection, in the case of such services furnished on or after July 1, 2004, and before January 1, 2007, and for such services furnished on or after July 1, 2008, and before January 1, 2018, for which the transportation originates in—

(i) a rural area described in paragraph (9) or in a rural census tract described in such paragraph, the fee schedule established under this section shall provide that the rate for the service otherwise established, after the application of any increase under paragraphs

(11) and (12), shall be increased by 2 percent (or 3 percent if such service is furnished on or after July 1, 2008, and before January 1, 2018); and

(ii) an area not described in clause (i), the fee schedule established under this subsection shall provide that the rate for the service otherwise established, after the application of any increase under paragraph (11), shall be increased by 1 percent (or 2 percent if such service is furnished on or after July 1, 2008, and before January 1, 2018).

(B) APPLICATION OF INCREASED PAYMENTS AFTER APPLICABLE PERIOD.—The increased payments under subparagraph (A) shall not be taken into account in calculating payments for services furnished after the applicable period specified in such subparagraph.

(14) PROVIDING APPROPRIATE COVERAGE OF RURAL AIR AMBULANCE SERVICES.—

(A) IN GENERAL.—The regulations described in section 1861(s)(7) shall provide, to the extent that any ambulance services (whether ground or air) may be covered under such section, that a rural air ambulance service (as defined in subparagraph (C)) is reimbursed under this subsection at the air ambulance rate if the air ambulance service—

(i) is reasonable and necessary based on the health condition of the individual being transported at or immediately prior to the time of the transport; and

(ii) complies with equipment and crew requirements established by the Secretary.

(B) SATISFACTION OF REQUIREMENT OF MEDICALLY NECESSARY.—The requirement of subparagraph (A)(i) is deemed to be met for a rural air ambulance service if—

(i) subject to subparagraph (D), such service is requested by a physician or other qualified medical personnel (as specified by the Secretary) who certifies or reasonably determines that the individual's condition is such that the time needed to transport the individual by land or the instability of transportation by land poses a threat to the individual's survival or seriously endangers the individual's health; or

(ii) such service is furnished pursuant to a protocol that is established by a State or regional emergency medical service (EMS) agency and recognized or approved by the Secretary under which the use of an air ambulance is recommended, if such agency does not have an ownership interest in the entity furnishing such service.

(C) RURAL AIR AMBULANCE SERVICE DEFINED.—For purposes of this paragraph, the term "rural air ambulance service" means fixed wing and rotary wing air ambulance service in which the point of pick up of the individual occurs in a rural area (as defined in section 1886(d)(2)(D)) or in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)).

(D) LIMITATION.—

(i) IN GENERAL.—Subparagraph (B)(i) shall not apply if there is a financial or employment relationship between the person requesting the rural air ambulance service and the entity furnishing the ambulance service, or an entity under common ownership with the entity furnishing the air ambulance service, or a financial relationship between an immediate family member of such requester and such an entity.

(ii) EXCEPTION.—Where a hospital and the entity furnishing rural air ambulance services are under common ownership, clause (i) shall not apply to remuneration (through employment or other relationship) by the hospital of the requester or immediate family member if the remuneration is for provider-based physician services furnished in a hospital (as described in section 1887) which are reimbursed under part A and the amount of the remuneration is unrelated directly or indirectly to the provision of rural air ambulance services.

(15) PAYMENT ADJUSTMENT FOR NON-EMERGENCY AMBULANCE TRANSPORTS FOR ESRD BENEFICIARIES.—The fee schedule amount otherwise applicable under the preceding provisions of this subsection shall be reduced by 10 percent for ambulance services furnished on or after October 1, 2013, consisting of non-emergency basic life support services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B)) furnished other than on an emergency basis by a provider of services or a renal dialysis facility.

(16) PRIOR AUTHORIZATION FOR REPETITIVE SCHEDULED NON-EMERGENT AMBULANCE TRANSPORTS.—

(A) IN GENERAL.—Beginning January 1, 2017, if the expansion to all States of the model of prior authorization described in paragraph (2) of section 515(a) of the Medicare Access and CHIP Reauthorization Act of 2015 meets the requirements described in paragraphs (1) through (3) of section 1115A(c), then the Secretary shall expand such model to all States.

(B) FUNDING.—The Secretary shall use funds made available under section 1893(h)(10) to carry out this paragraph.

(C) CLARIFICATION REGARDING BUDGET NEUTRALITY.—Nothing in this paragraph may be construed to limit or modify the application of section 1115A(b)(3)(B) to models described in such section, including with respect to the model described in subparagraph (A) and expanded beginning on January 1, 2017, under such subparagraph.

(m) PAYMENT FOR TELEHEALTH SERVICES.—

(1) IN GENERAL.—The Secretary shall pay for telehealth services that are furnished via a telecommunications system by a physician (as defined in section 1861(r)) or a practitioner (described in section 1842(b)(18)(C)) to an eligible telehealth individual enrolled under this part notwithstanding that the individual physician or practitioner providing the telehealth serv-

ice is not at the same location as the beneficiary. For purposes of the preceding sentence, in the case of any Federal telemedicine demonstration program conducted in Alaska or Hawaii, the term "telecommunications system" includes store-and-forward technologies that provide for the asynchronous transmission of health care information in single or multimedia formats.

(2) PAYMENT AMOUNT.—

(A) DISTANT SITE.—The Secretary shall pay to a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid under this title had such service been furnished without the use of a telecommunications system.

(B) FACILITY FEE FOR ORIGINATING SITE.—With respect to a telehealth service, subject to section 1833(a)(1)(U), there shall be paid to the originating site a facility fee equal to—

(i) for the period beginning on October 1, 2001, and ending on December 31, 2001, and for 2002, $20; and

(ii) for a subsequent year, the facility fee specified in clause (i) or this clause for the preceding year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year.

(C) TELEPRESENTER NOT REQUIRED.—Nothing in this subsection shall be construed as requiring an eligible telehealth individual to be presented by a physician or practitioner at the originating site for the furnishing of a service via a telecommunications system, unless it is medically necessary (as determined by the physician or practitioner at the distant site).

(3) LIMITATION ON BENEFICIARY CHARGES.—

(A) PHYSICIAN AND PRACTITIONER.—The provisions of section 1848(g) and subparagraphs (A) and (B) of section 1842(b)(18) shall apply to a physician or practitioner receiving payment under this subsection in the same manner as they apply to physicians or practitioners under such sections.

(B) ORIGINATING SITE.—The provisions of section 1842(b)(18) shall apply to originating sites receiving a facility fee in the same manner as they apply to practitioners under such section.

(4) DEFINITIONS.—For purposes of this subsection:

(A) DISTANT SITE.—The term "distant site" means the site at which the physician or practitioner is located at the time the service is provided via a telecommunications system.

(B) ELIGIBLE TELEHEALTH INDIVIDUAL.—The term "eligible telehealth individual" means an individual enrolled under this part who receives a telehealth service furnished at an originating site.

(C) ORIGINATING SITE.—

(i) IN GENERAL.—The term "originating site" means only those sites described in clause (ii) at which the eligible telehealth individual is located at the time the

service is furnished via a telecommunications system and only if such site is located—

(I) in an area that is designated as a rural health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A));

(II) in a county that is not included in a Metropolitan Statistical Area; or

(III) from an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000.

(ii) SITES DESCRIBED.—The sites referred to in clause (i) are the following sites:

(I) The office of a physician or practitioner.

(II) A critical access hospital (as defined in section 1861(mm)(1)).

(III) A rural health clinic (as defined in section 1861(aa)(2)).

(IV) A Federally qualified health center (as defined in section 1861(aa)(4)).

(V) A hospital (as defined in section 1861(e)).

(VI) A hospital-based or critical access hospital-based renal dialysis center (including satellites).

(VII) A skilled nursing facility (as defined in section 1819(a)).

(VIII) A community mental health center (as defined in section 1861(ff)(3)(B)).

(D) PHYSICIAN.—The term "physician" has the meaning given that term in section 1861(r).

(E) PRACTITIONER.—The term "practitioner" has the meaning given that term in section 1842(b)(18)(C).

(F) TELEHEALTH SERVICE.—

(i) IN GENERAL.—The term "telehealth service" means professional consultations, office visits, and office psychiatry services (identified as of July 1, 2000, by HCPCS codes 99241–99275, 99201–99215, 90804–90809, and 90862 (and as subsequently modified by the Secretary)), and any additional service specified by the Secretary.

(ii) YEARLY UPDATE.—The Secretary shall establish a process that provides, on an annual basis, for the addition or deletion of services (and HCPCS codes), as appropriate, to those specified in clause (i) for authorized payment under paragraph (1).

(n) AUTHORITY TO MODIFY OR ELIMINATE COVERAGE OF CERTAIN PREVENTIVE SERVICES.—Notwithstanding any other provision of this title, effective beginning on January 1, 2010, if the Secretary determines appropriate, the Secretary may—

(1) modify—

(A) the coverage of any preventive service described in subparagraph (A) of section 1861(ddd)(3) to the extent that such modification is consistent with the recommendations of the United States Preventive Services Task Force; and

(B) the services included in the initial preventive physical examination described in subparagraph (B) of such section; and

(2) provide that no payment shall be made under this title for a preventive service described in subparagraph (A) of such section that has not received a grade of A, B, C, or I by such Task Force.

(o) DEVELOPMENT AND IMPLEMENTATION OF PROSPECTIVE PAYMENT SYSTEM.—

(1) DEVELOPMENT.—

(A) IN GENERAL.—The Secretary shall develop a prospective payment system for payment for Federally qualified health center services furnished by Federally qualified health centers under this title. Such system shall include a process for appropriately describing the services furnished by Federally qualified health centers and shall establish payment rates for specific payment codes based on such appropriate descriptions of services. Such system shall be established to take into account the type, intensity, and duration of services furnished by Federally qualified health centers. Such system may include adjustments, including geographic adjustments, determined appropriate by the Secretary.

(B) COLLECTION OF DATA AND EVALUATION.—By not later than January 1, 2011, the Secretary shall require Federally qualified health centers to submit to the Secretary such information as the Secretary may require in order to develop and implement the prospective payment system under this subsection, including the reporting of services using HCPCS codes.

(2) IMPLEMENTATION.—

(A) IN GENERAL.—Notwithstanding section 1833(a)(3)(A), the Secretary shall provide, for cost reporting periods beginning on or after October 1, 2014, for payments of prospective payment rates for Federally qualified health center services furnished by Federally qualified health centers under this title in accordance with the prospective payment system developed by the Secretary under paragraph (1).

(B) PAYMENTS.—

(i) INITIAL PAYMENTS.—The Secretary shall implement such prospective payment system so that the estimated aggregate amount of prospective payment rates (determined prior to the application of section 1833(a)(1)(Z)) under this title for Federally qualified health center services in the first year that such system is implemented is equal to 100 percent of the estimated amount of reasonable costs (determined without the application of a per visit payment limit or productivity screen and prior to the application of section 1866(a)(2)(A)(ii)) that would have occurred for such services under this title in such year if the system had not been implemented.

(ii) PAYMENTS IN SUBSEQUENT YEARS.—Payment rates in years after the year of implementation of such

system shall be the payment rates in the previous year increased—

(I) in the first year after implementation of such system, by the percentage increase in the MEI (as defined in section 1842(i)(3)) for the year involved; and

(II) in subsequent years, by the percentage increase in a market basket of Federally qualified health center goods and services as promulgated through regulations, or if such an index is not available, by the percentage increase in the MEI (as defined in section 1842(i)(3)) for the year involved.

(C) PREPARATION FOR PPS IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may establish and implement by program instruction or otherwise the payment codes to be used under the prospective payment system under this section.

(p) QUALITY INCENTIVES TO PROMOTE PATIENT SAFETY AND PUBLIC HEALTH IN COMPUTED TOMOGRAPHY.—

(1) QUALITY INCENTIVES.—In the case of an applicable computed tomography service (as defined in paragraph (2)) for which payment is made under an applicable payment system (as defined in paragraph (3)) and that is furnished on or after January 1, 2016, using equipment that is not consistent with the CT equipment standard (described in paragraph (4)), the payment amount for such service shall be reduced by the applicable percentage (as defined in paragraph (5)).

(2) APPLICABLE COMPUTED TOMOGRAPHY SERVICES DEFINED.—In this subsection, the term "applicable computed tomography service" means a service billed using diagnostic radiological imaging codes for computed tomography (identified as of January 1, 2014, by HCPCS codes 70450–70498, 71250–71275, 72125–72133, 72191–72194, 73200–73206, 73700–73706, 74150–74178, 74261–74263, and 75571–75574 (and any succeeding codes).

(3) APPLICABLE PAYMENT SYSTEM DEFINED.—In this subsection, the term "applicable payment system" means the following:

(A) The technical component and the technical component of the global fee under the fee schedule established under section 1848(b).

(B) The prospective payment system for hospital outpatient department services under section 1833(t).

(4) CONSISTENCY WITH CT EQUIPMENT STANDARD.—In this subsection, the term "not consistent with the CT equipment standard" means, with respect to an applicable computed tomography service, that the service was furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR–29–2013, entitled "Standard Attributes on CT Equipment Related to Dose Optimization and Management". Through rulemaking, the Secretary may apply successor standards.

(5) APPLICABLE PERCENTAGE DEFINED.—In this subsection, the term "applicable percentage" means—

(A) for 2016, 5 percent; and

(B) for 2017 and subsequent years, 15 percent.

(6) IMPLEMENTATION.—

(A) INFORMATION.—The Secretary shall require that information be provided and attested to by a supplier and a hospital outpatient department that indicates whether an applicable computed tomography service was furnished that was not consistent with the CT equipment standard (described in paragraph (4)). Such information may be included on a claim and may be a modifier. Such information shall be verified, as appropriate, as part of the periodic accreditation of suppliers under section 1834(e) and hospitals under section 1865(a).

(B) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to information described in subparagraph (A).

(q) RECOGNIZING APPROPRIATE USE CRITERIA FOR CERTAIN IMAGING SERVICES.—

(1) PROGRAM ESTABLISHED.—

(A) IN GENERAL.—The Secretary shall establish a program to promote the use of appropriate use criteria (as defined in subparagraph (B)) for applicable imaging services (as defined in subparagraph (C)) furnished in an applicable setting (as defined in subparagraph (D)) by ordering professionals and furnishing professionals (as defined in subparagraphs (E) and (F), respectively).

(B) APPROPRIATE USE CRITERIA DEFINED.—In this subsection, the term "appropriate use criteria" means criteria, only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria shall be evidence-based.

(C) APPLICABLE IMAGING SERVICE DEFINED.—In this subsection, the term "applicable imaging service" means an advanced diagnostic imaging service (as defined in subsection (e)(1)(B)) for which the Secretary determines—

(i) one or more applicable appropriate use criteria specified under paragraph (2) apply;

(ii) there are one or more qualified clinical decision support mechanisms listed under paragraph (3)(C); and

(iii) one or more of such mechanisms is available free of charge.

(D) APPLICABLE SETTING DEFINED.—In this subsection, the term "applicable setting" means a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary.

(E) ORDERING PROFESSIONAL DEFINED.—In this subsection, the term "ordering professional" means a physician (as defined in section 1861(r)) or a practitioner de-

scribed in section 1842(b)(18)(C) who orders an applicable imaging service.

(F) FURNISHING PROFESSIONAL DEFINED.—In this subsection, the term "furnishing professional" means a physician (as defined in section 1861(r)) or a practitioner described in section 1842(b)(18)(C) who furnishes an applicable imaging service.

(2) ESTABLISHMENT OF APPLICABLE APPROPRIATE USE CRITERIA.—

(A) IN GENERAL.—Not later than November 15, 2015, the Secretary shall through rulemaking, and in consultation with physicians, practitioners, and other stakeholders, specify applicable appropriate use criteria for applicable imaging services only from among appropriate use criteria developed or endorsed by national professional medical specialty societies or other provider-led entities.

(B) CONSIDERATIONS.—In specifying applicable appropriate use criteria under subparagraph (A), the Secretary shall take into account whether the criteria—

(i) have stakeholder consensus;

(ii) are scientifically valid and evidence based; and

(iii) are based on studies that are published and reviewable by stakeholders.

(C) REVISIONS.—The Secretary shall review, on an annual basis, the specified applicable appropriate use criteria to determine if there is a need to update or revise (as appropriate) such specification of applicable appropriate use criteria and make such updates or revisions through rulemaking.

(D) TREATMENT OF MULTIPLE APPLICABLE APPROPRIATE USE CRITERIA.—In the case where the Secretary determines that more than one appropriate use criterion applies with respect to an applicable imaging service, the Secretary shall apply one or more applicable appropriate use criteria under this paragraph for the service.

(3) MECHANISMS FOR CONSULTATION WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(A) IDENTIFICATION OF MECHANISMS TO CONSULT WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(i) IN GENERAL.—The Secretary shall specify qualified clinical decision support mechanisms that could be used by ordering professionals to consult with applicable appropriate use criteria for applicable imaging services.

(ii) CONSULTATION.—The Secretary shall consult with physicians, practitioners, health care technology experts, and other stakeholders in specifying mechanisms under this paragraph.

(iii) INCLUSION OF CERTAIN MECHANISMS.—Mechanisms specified under this paragraph may include any or all of the following that meet the requirements described in subparagraph (B)(ii):

(I) Use of clinical decision support modules in certified EHR technology (as defined in section 1848(o)(4)).

(II) Use of private sector clinical decision support mechanisms that are independent from certified EHR technology, which may include use of clinical decision support mechanisms available from medical specialty organizations.

(III) Use of a clinical decision support mechanism established by the Secretary.

(B) QUALIFIED CLINICAL DECISION SUPPORT MECHANISMS.—

(i) IN GENERAL.—For purposes of this subsection, a qualified clinical decision support mechanism is a mechanism that the Secretary determines meets the requirements described in clause (ii).

(ii) REQUIREMENTS.—The requirements described in this clause are the following:

(I) The mechanism makes available to the ordering professional applicable appropriate use criteria specified under paragraph (2) and the supporting documentation for the applicable imaging service ordered.

(II) In the case where there is more than one applicable appropriate use criterion specified under such paragraph for an applicable imaging service, the mechanism indicates the criteria that it uses for the service.

(III) The mechanism determines the extent to which an applicable imaging service ordered is consistent with the applicable appropriate use criteria so specified.

(IV) The mechanism generates and provides to the ordering professional a certification or documentation that documents that the qualified clinical decision support mechanism was consulted by the ordering professional.

(V) The mechanism is updated on a timely basis to reflect revisions to the specification of applicable appropriate use criteria under such paragraph.

(VI) The mechanism meets privacy and security standards under applicable provisions of law.

(VII) The mechanism performs such other functions as specified by the Secretary, which may include a requirement to provide aggregate feedback to the ordering professional.

(C) LIST OF MECHANISMS FOR CONSULTATION WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(i) INITIAL LIST.—Not later than April 1, 2016, the Secretary shall publish a list of mechanisms specified under this paragraph.

(ii) PERIODIC UPDATING OF LIST.—The Secretary shall identify on an annual basis the list of qualified clinical decision support mechanisms specified under this paragraph.

(4) CONSULTATION WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(A) CONSULTATION BY ORDERING PROFESSIONAL.—Beginning with January 1, 2017, subject to subparagraph (C), with respect to an applicable imaging service ordered by an ordering professional that would be furnished in an applicable setting and paid for under an applicable payment system (as defined in subparagraph (D)), an ordering professional shall—

(i) consult with a qualified decision support mechanism listed under paragraph (3)(C); and

(ii) provide to the furnishing professional the information described in clauses (i) through (iii) of subparagraph (B).

(B) REPORTING BY FURNISHING PROFESSIONAL.—Beginning with January 1, 2017, subject to subparagraph (C), with respect to an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system (as defined in subparagraph (D)), payment for such service may only be made if the claim for the service includes the following:

(i) Information about which qualified clinical decision support mechanism was consulted by the ordering professional for the service.

(ii) Information regarding—

(I) whether the service ordered would adhere to the applicable appropriate use criteria specified under paragraph (2);

(II) whether the service ordered would not adhere to such criteria; or

(III) whether such criteria was not applicable to the service ordered.

(iii) The national provider identifier of the ordering professional (if different from the furnishing professional).

(C) EXCEPTIONS.—The provisions of subparagraphs (A) and (B) and paragraph (6)(A) shall not apply to the following:

(i) EMERGENCY SERVICES.—An applicable imaging service ordered for an individual with an emergency medical condition (as defined in section 1867(e)(1)).

(ii) INPATIENT SERVICES.—An applicable imaging service ordered for an inpatient and for which payment is made under part A.

(iii) SIGNIFICANT HARDSHIP.—An applicable imaging service ordered by an ordering professional who the Secretary may, on a case-by-case basis, exempt from the application of such provisions if the Secretary determines, subject to annual renewal, that consultation with applicable appropriate use criteria would result in a significant hardship, such as in the case of a professional who practices in a rural area without sufficient Internet access.

(D) APPLICABLE PAYMENT SYSTEM DEFINED.—In this subsection, the term "applicable payment system" means the following:

(i) The physician fee schedule established under section 1848(b).

(ii) The prospective payment system for hospital outpatient department services under section 1833(t).

(iii) The ambulatory surgical center payment systems under section 1833(i).

(5) IDENTIFICATION OF OUTLIER ORDERING PROFESSIONALS.—

(A) IN GENERAL.—With respect to applicable imaging services furnished beginning with 2017, the Secretary shall determine, on an annual basis, no more than five percent of the total number of ordering professionals who are outlier ordering professionals.

(B) OUTLIER ORDERING PROFESSIONALS.—The determination of an outlier ordering professional shall—

(i) be based on low adherence to applicable appropriate use criteria specified under paragraph (2), which may be based on comparison to other ordering professionals; and

(ii) include data for ordering professionals for whom prior authorization under paragraph (6)(A) applies.

(C) USE OF TWO YEARS OF DATA.—The Secretary shall use two years of data to identify outlier ordering professionals under this paragraph.

(D) PROCESS.—The Secretary shall establish a process for determining when an outlier ordering professional is no longer an outlier ordering professional.

(E) CONSULTATION WITH STAKEHOLDERS.—The Secretary shall consult with physicians, practitioners and other stakeholders in developing methods to identify outlier ordering professionals under this paragraph.

(6) PRIOR AUTHORIZATION FOR ORDERING PROFESSIONALS WHO ARE OUTLIERS.—

(A) IN GENERAL.—Beginning January 1, 2020, subject to paragraph (4)(C), with respect to services furnished during a year, the Secretary shall, for a period determined appropriate by the Secretary, apply prior authorization for applicable imaging services that are ordered by an outlier ordering professional identified under paragraph (5).

(B) APPROPRIATE USE CRITERIA IN PRIOR AUTHORIZATION.—In applying prior authorization under subparagraph (A), the Secretary shall utilize only the applicable appropriate use criteria specified under this subsection.

(C) FUNDING.—For purposes of carrying out this paragraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of $5,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for each of fiscal years 2019 through 2021. Amounts transferred under the preceding sentence shall remain available until expended.

(7) CONSTRUCTION.—Nothing in this subsection shall be construed as granting the Secretary the authority to develop or initiate the development of clinical practice guidelines or appropriate use criteria.

(r) PAYMENT FOR CERTAIN DISPOSABLE DEVICES.—

(1) IN GENERAL.—The Secretary shall make separate payment in the amount established under paragraph (3) to a home health agency for a device described in paragraph (2) when furnished to an individual who receives home health services for which payment is made under section 1895(b).

(2) DEVICE DESCRIBED.—For purposes of paragraph (1), a device described in this paragraph is a disposable device for which, as of January 1, 2015, there is—

(A) a Level I Healthcare Common Procedure Coding System (HCPCS) code for which the description for a professional service includes the furnishing of such device; and

(B) a separate Level I HCPCS code for a professional service that uses durable medical equipment instead of such device.

(3) PAYMENT AMOUNT.—The Secretary shall establish the separate payment amount for such a device such that such amount does not exceed the payment that would be made for the HCPCS code described in paragraph (2)(A) under section 1833(t) (relating to payment for covered OPD services).

(s) SITE-OF-SERVICE PRICE TRANSPARENCY.—

(1) IN GENERAL.—In order to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or to an ambulatory surgical center under this title, the Secretary shall, for 2017 and each year thereafter, make available to the public via a searchable website, with respect to an appropriate number of such items and services—

(A) the estimated payment amount for the item or service under the outpatient department fee schedule under subsection (t) of section 1833 and the ambulatory surgical center payment system under subsection (i) of such section; and

(B) the estimated amount of beneficiary liability applicable to the item or service.

(2) CALCULATION OF ESTIMATED BENEFICIARY LIABILITY.—For purposes of paragraph (1)(B), the estimated amount of beneficiary liability, with respect to an item or service, is the amount for such item or service for which an individual who does not have coverage under a medicare supplemental policy certified under section 1882 or any other supplemental insurance coverage is responsible.

(3) IMPLEMENTATION.—In carrying out this subsection, the Secretary—

(A) shall include in the notice described in section 1804(a) a notification of the availability of the estimated amounts made available under paragraph (1); and

(B) may utilize mechanisms in existence on the date of the enactment of this subsection, such as the portion of the website of the Centers for Medicare & Medicaid Services on which information comparing physician performance is posted (commonly referred to as the Physician Compare website), to make available such estimated amounts under such paragraph.

(4) FUNDING.—For purposes of implementing this subsection, the Secretary shall provide for the transfer, from the Supple-

mental Medical Insurance Trust Fund under section 1841 to the Centers for Medicare & Medicaid Services Program Management Account, of $6,000,000 for fiscal year 2015, to remain available until expended.

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PAYMENT FOR PHYSICIANS' SERVICES

SEC. 1848. (a) PAYMENT BASED ON FEE SCHEDULE.—

(1) IN GENERAL.—Effective for all physicians' services (as defined in subsection (j)(3)) furnished under this part during a year (beginning with 1992) for which payment is otherwise made on the basis of a reasonable charge or on the basis of a fee schedule under section 1834(b), payment under this part shall instead be based on the lesser of—

(A) the actual charge for the service, or

(B) subject to the succeeding provisions of this subsection, the amount determined under the fee schedule established under subsection (b) for services furnished during that year (in this subsection referred to as the "fee schedule amount").

(2) TRANSITION TO FULL FEE SCHEDULE.—

(A) LIMITING REDUCTIONS AND INCREASES TO 15 PERCENT IN 1992.—

(i) LIMIT ON INCREASE.—In the case of a service in a fee schedule area (as defined in subsection (j)(2)) for which the adjusted historical payment basis (as defined in subparagraph (D)) is less than 85 percent of the fee schedule amount for services furnished in 1992, there shall be substituted for the fee schedule amount an amount equal to the adjusted historical payment basis plus 15 percent of the fee schedule amount otherwise established (without regard to this paragraph).

(ii) LIMIT IN REDUCTION.—In the case of a service in a fee schedule area for which the adjusted historical payment basis exceeds 115 percent of the fee schedule amount for services furnished in 1992, there shall be substituted for the fee schedule amount an amount equal to the adjusted historical payment basis minus 15 percent of the fee schedule amount otherwise established (without regard to this paragraph).

(B) SPECIAL RULE FOR 1993, 1994, AND 1995.—If a physicians' service in a fee schedule area is subject to the provisions of subparagraph (A) in 1992, for physicians' services furnished in the area—

(i) during 1993, there shall be substituted for the fee schedule amount an amount equal to the sum of—

(I) 75 percent of the fee schedule amount determined under subparagraph (A), adjusted by the update established under subsection (d)(3) for 1993, and

(II) 25 percent of the fee schedule amount determined under paragraph (1) for 1993 without regard to this paragraph;

(ii) during 1994, there shall be substituted for the fee schedule amount an amount equal to the sum of—

(I) 67 percent of the fee schedule amount determined under clause (i), adjusted by the update established under subsection (d)(3) for 1994 and as adjusted under subsection (c)(2)(F)(ii) and under section 13515(b) of the Omnibus Budget Reconciliation Act of 1993, and

(II) 33 percent of the fee schedule amount determined under paragraph (1) for 1994 without regard to this paragraph; and

(iii) during 1995, there shall be substituted for the fee schedule amount an amount equal to the sum of—

(I) 50 percent of the fee schedule amount determined under clause (ii) adjusted by the update established under subsection (d)(3) for 1995, and

(II) 50 percent of the fee schedule amount determined under paragraph (1) for 1995 without regard to this paragraph.

(C) SPECIAL RULE FOR ANESTHESIA AND RADIOLOGY SERVICES.—With respect to physicians' services which are anesthesia services, the Secretary shall provide for a transition in the same manner as a transition is provided for other services under subparagraph (B). With respect to radiology services, "109 percent" and "9 percent" shall be substituted for "115 percent" and "15 percent", respectively, in subparagraph (A)(ii).

(D) ADJUSTED HISTORICAL PAYMENT BASIS DEFINED.—

(i) IN GENERAL.—In this paragraph, the term "adjusted historical payment basis" means, with respect to a physicians' service furnished in a fee schedule area, the weighted average prevailing charge applied in the area for the service in 1991 (as determined by the Secretary without regard to physician specialty and as adjusted to reflect payments for services with customary charges below the prevailing charge or other payment limitations imposed by law or regulation) adjusted by the update established under subsection (d)(3) for 1992.

(ii) APPLICATION TO RADIOLOGY SERVICES.—In applying clause (i) in the case of physicians' services which are radiology services (including radiologist services, as defined in section 1834(b)(6)), but excluding nuclear medicine services that are subject to section 6105(b) of the Omnibus Budget Reconciliation Act of 1989, there shall be substituted for the weighted average prevailing charge the amount provided under the fee schedule established for the service for the fee schedule area under section 1834(b).

(iii) NUCLEAR MEDICINE SERVICES.—In applying clause (i) in the case of physicians' services which are nuclear medicine services, there shall be substituted for the weighted average prevailing charge the amount provided under section 6105(b) of the Omnibus Budget Reconciliation Act of 1989.

(3) INCENTIVES FOR PARTICIPATING PHYSICIANS AND SUPPLIERS.—In applying paragraph (1)(B) in the case of a nonparticipating physician or a nonparticipating supplier or other person, the fee schedule amount shall be 95 percent of such amount otherwise applied under this subsection (without regard to this paragraph). In the case of physicians' services (including services which the Secretary excludes pursuant to subsection (j)(3)) of a nonparticipating physician, supplier, or other person for which payment is made under this part on a basis other than the fee schedule amount, the payment shall be based on 95 percent of the payment basis for such services furnished by a participating physician, supplier, or other person.

(4) SPECIAL RULE FOR MEDICAL DIRECTION.—

(A) IN GENERAL.—With respect to physicians' services furnished on or after January 1, 1994, and consisting of medical direction of two, three, or four concurrent anesthesia cases, except as provided in paragraph (5), the fee schedule amount to be applied shall be equal to one-half of the amount described in subparagraph (B).

(B) AMOUNT.—The amount described in this subparagraph, for a physician's medical direction of the performance of anesthesia services, is the following percentage of the fee schedule amount otherwise applicable under this section if the anesthesia services were personally performed by the physician alone:

(i) For services furnished during 1994, 120 percent.

(ii) For services furnished during 1995, 115 percent.

(iii) For services furnished during 1996, 110 percent.

(iv) For services furnished during 1997, 105 percent.

(v) For services furnished after 1997, 100 percent.

(5) INCENTIVES FOR ELECTRONIC PRESCRIBING.—

(A) ADJUSTMENT.—

(i) IN GENERAL.—Subject to subparagraph (B) and subsection (m)(2)(B), with respect to covered professional services furnished by an eligible professional during 2012, 2013 or 2014, if the eligible professional is not a successful electronic prescriber for the reporting period for the year (as determined under subsection (m)(3)(B)), the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes of determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services under this subsection (determined after application of paragraph (3) but without regard to this paragraph).

(ii) APPLICABLE PERCENT.—For purposes of clause (i), the term "applicable percent" means—

(I) for 2012, 99 percent;

(II) for 2013, 98.5 percent; and

(III) for 2014, 98 percent.

(B) SIGNIFICANT HARDSHIP EXCEPTION.—The Secretary may, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment

under subparagraph (A) if the Secretary determines, subject to annual renewal, that compliance with the requirement for being a successful electronic prescriber would result in a significant hardship, such as in the case of an eligible professional who practices in a rural area without sufficient Internet access.

(C) APPLICATION.—

(i) PHYSICIAN REPORTING SYSTEM RULES.—Paragraphs (5), (6), and (8) of subsection (k) shall apply for purposes of this paragraph in the same manner as they apply for purposes of such subsection.

(ii) INCENTIVE PAYMENT VALIDATION RULES.—Clauses (ii) and (iii) of subsection (m)(5)(D) shall apply for purposes of this paragraph in a similar manner as they apply for purposes of such subsection.

(D) DEFINITIONS.—For purposes of this paragraph:

(i) ELIGIBLE PROFESSIONAL; COVERED PROFESSIONAL SERVICES.—The terms "eligible professional" and "covered professional services" have the meanings given such terms in subsection (k)(3).

(ii) PHYSICIAN REPORTING SYSTEM.—The term "physician reporting system" means the system established under subsection (k).

(iii) REPORTING PERIOD.—The term "reporting period" means, with respect to a year, a period specified by the Secretary.

(6) SPECIAL RULE FOR TEACHING ANESTHESIOLOGISTS.—With respect to physicians' services furnished on or after January 1, 2010, in the case of teaching anesthesiologists involved in the training of physician residents in a single anesthesia case or two concurrent anesthesia cases, the fee schedule amount to be applied shall be 100 percent of the fee schedule amount otherwise applicable under this section if the anesthesia services were personally performed by the teaching anesthesiologist alone and paragraph (4) shall not apply if—

(A) the teaching anesthesiologist is present during all critical or key portions of the anesthesia service or procedure involved; and

(B) the teaching anesthesiologist (or another anesthesiologist with whom the teaching anesthesiologist has entered into an arrangement) is immediately available to furnish anesthesia services during the entire procedure.

(7) INCENTIVES FOR MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY.—

(A) ADJUSTMENT.—

(i) IN GENERAL.—Subject to subparagraphs (B) and (D), with respect to covered professional services furnished by an eligible professional during each of 2015 through 2018, if the eligible professional is not a meaningful EHR user (as determined under subsection (o)(2)) for an EHR reporting period for the year, the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes of determining a payment based on such amount) shall be equal to the ap-

plicable percent of the fee schedule amount that would otherwise apply to such services under this subsection (determined after application of paragraph (3) but without regard to this paragraph).

(ii) APPLICABLE PERCENT.—Subject to clause (iii), for purposes of clause (i), the term "applicable percent" means—

(I) for 2015, 99 percent (or, in the case of an eligible professional who was subject to the application of the payment adjustment under section 1848(a)(5) for 2014, 98 percent);

(II) for 2016, 98 percent; and

(III) for 2017 and 2018, 97 percent.

(iii) AUTHORITY TO DECREASE APPLICABLE PERCENTAGE FOR 2018.—For 2018, if the Secretary finds that the proportion of eligible professionals who are meaningful EHR users (as determined under subsection (o)(2)) is less than 75 percent, the applicable percent shall be decreased by 1 percentage point from the applicable percent in the preceding year.

[(B) SIGNIFICANT HARDSHIP EXCEPTION.—The Secretary may, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment under subparagraph (A) if the Secretary determines, subject to annual renewal, that compliance with the requirement for being a meaningful EHR user would result in a significant hardship, such as in the case of an eligible professional who practices in a rural area without sufficient Internet access. In no case may an eligible professional be granted an exemption under this subparagraph for more than 5 years.]

(B) SIGNIFICANT HARDSHIP EXCEPTION.—

(i) IN GENERAL.—The Secretary may, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment under subparagraph (A) if the Secretary determines, subject to annual renewal, that compliance with the requirement for being a meaningful EHR user would result in a significant hardship, such as in the case of an eligible professional who practices in a rural area without sufficient Internet access.

(ii) DECERTIFICATION.—

(I) IN GENERAL.—The Secretary may, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment under subparagraph (A) if the Secretary determines that such professional was determined to not be a meaningful EHR user because the qualified electronic health record used by such professional was decertified under section 3001(c)(5)(C) of the Public Health Service Act. An exemption under the previous sentence may be applied to an eligible professional only, subject to subclause (II), during the first payment year with respect to the first EHR re-

porting period to which such decertification applies.

(II) DURATION.—

(aa) IN GENERAL.—In no case shall an exemption by reason of this clause be for a period of less than 12 months.

(bb) EXTENSION.—An exemption under this clause may be extended for a period of an additional 12 months subject to the limitation described in clause (ii).

(iii) LIMITATION.—Subject to clause (ii)(II)(aa), in no case may an eligible professional be granted an exemption under this subparagraph for more than 5 years.

(C) APPLICATION OF PHYSICIAN REPORTING SYSTEM RULES.—Paragraphs (5), (6), and (8) of subsection (k) shall apply for purposes of this paragraph in the same manner as they apply for purposes of such subsection.

(D) NON-APPLICATION TO HOSPITAL-BASED ELIGIBLE PROFESSIONALS.—No payment adjustment may be made under subparagraph (A) in the case of hospital-based eligible professionals (as defined in subsection (o)(1)(C)(ii)).

(E) DEFINITIONS.—For purposes of this paragraph:

(i) COVERED PROFESSIONAL SERVICES.—The term "covered professional services" has the meaning given such term in subsection (k)(3).

(ii) EHR REPORTING PERIOD.—The term "EHR reporting period" means, with respect to a year, a period (or periods) specified by the Secretary.

(iii) ELIGIBLE PROFESSIONAL.—The term "eligible professional" means a physician, as defined in section 1861(r).

(8) INCENTIVES FOR QUALITY REPORTING.—

(A) ADJUSTMENT.—

(i) IN GENERAL.—With respect to covered professional services furnished by an eligible professional during each of 2015 through 2018, if the eligible professional does not satisfactorily submit data on quality measures for covered professional services for the quality reporting period for the year (as determined under subsection (m)(3)(A)), the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes of determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services under this subsection (determined after application of paragraphs (3), (5), and (7), but without regard to this paragraph).

(ii) APPLICABLE PERCENT.—For purposes of clause (i), the term "applicable percent" means—

(I) for 2015, 98.5 percent; and

(II) for 2016, 2017, and 2018, 98 percent.

(B) APPLICATION.—

(i) PHYSICIAN REPORTING SYSTEM RULES.—Paragraphs (5), (6), and (8) of subsection (k) shall apply for

purposes of this paragraph in the same manner as they apply for purposes of such subsection.

(ii) INCENTIVE PAYMENT VALIDATION RULES.—Clauses (ii) and (iii) of subsection (m)(5)(D) shall apply for purposes of this paragraph in a similar manner as they apply for purposes of such subsection.

(C) DEFINITIONS.—For purposes of this paragraph:

(i) ELIGIBLE PROFESSIONAL; COVERED PROFESSIONAL SERVICES.—The terms "eligible professional" and "covered professional services" have the meanings given such terms in subsection (k)(3).

(ii) PHYSICIAN REPORTING SYSTEM.—The term "physician reporting system" means the system established under subsection (k).

(iii) QUALITY REPORTING PERIOD.—The term "quality reporting period" means, with respect to a year, a period specified by the Secretary.

(9) INFORMATION REPORTING ON SERVICES INCLUDED IN GLOBAL SURGICAL PACKAGES.—With respect to services for which a physician is required to report information in accordance with subsection (c)(8)(B)(i), the Secretary may through rulemaking delay payment of 5 percent of the amount that would otherwise be payable under the physician fee schedule under this section for such services until the information so required is reported.

(b) ESTABLISHMENT OF FEE SCHEDULES.—

(1) IN GENERAL.—Before November 1 of the preceding year, for each year beginning with 1998, subject to subsection (p), the Secretary shall establish, by regulation, fee schedules that establish payment amounts for all physicians' services furnished in all fee schedule areas (as defined in subsection (j)(2)) for the year. Except as provided in paragraph (2), each such payment amount for a service shall be equal to the product of—

(A) the relative value for the service (as determined in subsection (c)(2)),

(B) the conversion factor (established under subsection (d)) for the year, and

(C) the geographic adjustment factor (established under subsection (e)(2)) for the service for the fee schedule area.

(2) TREATMENT OF RADIOLOGY SERVICES AND ANESTHESIA SERVICES.—

(A) RADIOLOGY SERVICES.—With respect to radiology services (including radiologist services, as defined in section 1834(b)(6)), the Secretary shall base the relative values on the relative value scale developed under section 1834(b)(1)(A), with appropriate modifications of the relative values to assure that the relative values established for radiology services which are similar or related to other physicians' services are consistent with the relative values established for those similar or related services.

(B) ANESTHESIA SERVICES.—In establishing the fee schedule for anesthesia services for which a relative value guide has been established under section 4048(b) of the Omnibus Budget Reconciliation Act of 1987, the Secretary shall use, to the extent practicable, such relative value

guide, with appropriate adjustment of the conversion factor, in a manner to assure that the fee schedule amounts for anesthesia services are consistent with the fee schedule amounts for other services determined by the Secretary to be of comparable value. In applying the previous sentence, the Secretary shall adjust the conversion factor by geographic adjustment factors in the same manner as such adjustment is made under paragraph (1)(C).

(C) CONSULTATION.—The Secretary shall consult with the Physician Payment Review Commission and organizations representing physicians or suppliers who furnish radiology services and anesthesia services in applying subparagraphs (A) and (B).

(3) TREATMENT OF INTERPRETATION OF ELECTROCARDIOGRAMS.—The Secretary—

(A) shall make separate payment under this section for the interpretation of electrocardiograms performed or ordered to be performed as part of or in conjunction with a visit to or a consultation with a physician, and

(B) shall adjust the relative values established for visits and consultations under subsection (c) so as not to include relative value units for interpretations of electrocardiograms in the relative value for visits and consultations.

(4) SPECIAL RULE FOR IMAGING SERVICES.—

(A) IN GENERAL.—In the case of imaging services described in subparagraph (B) furnished on or after January 1, 2007, if—

(i) the technical component (including the technical component portion of a global fee) of the service established for a year under the fee schedule described in paragraph (1) without application of the geographic adjustment factor described in paragraph (1)(C), exceeds

(ii) the Medicare OPD fee schedule amount established under the prospective payment system for hospital outpatient department services under paragraph (3)(D) of section 1833(t) for such service for such year, determined without regard to geographic adjustment under paragraph (2)(D) of such section,

the Secretary shall substitute the amount described in clause (ii), adjusted by the geographic adjustment factor described in paragraph (1)(C), for the fee schedule amount for such technical component for such year.

(B) IMAGING SERVICES DESCRIBED.—For purposes of this paragraph, imaging services described in this subparagraph are imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography, and for 2010, 2011, and the first 2 months of 2012, dual-energy x-ray absorptiometry services (as described in paragraph (6)).

(C) ADJUSTMENT IN IMAGING UTILIZATION RATE.—With respect to fee schedules established for 2011, 2012, and

2013, in the methodology for determining practice expense relative value units for expensive diagnostic imaging equipment under the final rule published by the Secretary in the Federal Register on November 25, 2009 (42 CFR 410 et al.), the Secretary shall use a 75 percent assumption instead of the utilization rates otherwise established in such final rule. With respect to fee schedules established for 2014 and subsequent years, in such methodology, the Secretary shall use a 90 percent utilization rate.

(D) ADJUSTMENT IN TECHNICAL COMPONENT DISCOUNT ON SINGLE-SESSION IMAGING INVOLVING CONSECUTIVE BODY PARTS.—For services furnished on or after July 1, 2010, the Secretary shall increase the reduction in payments attributable to the multiple procedure payment reduction applicable to the technical component for imaging under the final rule published by the Secretary in the Federal Register on November 21, 2005 (part 405 of title 42, Code of Federal Regulations) from 25 percent to 50 percent.

(E) ELIMINATION OF APPLICATION OF MULTIPLE PROCEDURE PAYMENT REDUCTION.—

(i) IN GENERAL.—Not later than January 1, 2016, the Secretary shall not apply a multiple procedure payment reduction policy to the professional component of imaging services furnished in any subsequent year that is prior to a year in which the Secretary conducts and publishes, as part of the Medicare Physician Fee Schedule Proposed Rule for a year, the empirical analysis described in clause (ii).

(ii) EMPIRICAL ANALYSIS DESCRIBED.—The empirical analysis described in this clause is an analysis of the Resource-Based Relative Value Scale (commonly known as the "RBRVS") Data Manager information that is used to determine what, if any, efficiencies exist within the professional component of imaging services when two or more studies are performed on the same patient on the same day. Such empirical analysis shall include—

(I) work sheets and other information detailing which physician work activities performed given the typical vignettes were assigned reduction percentages of 0, 25, 50, 75 and 100 percent;

(II) a discussion of the clinical aspects that informed the assignment of the reduction percentages described in subclause (I);

(III) an explanation of how the percentage reductions for pre-, intra-, and post-service work were determined and calculated; and

(IV) a demonstration that the Centers for Medicare & Medicaid Services has consulted with practicing radiologists to gain knowledge of how radiologists interpret studies of multiple body parts on the same individual on the same day.

(5) TREATMENT OF INTENSIVE CARDIAC REHABILITATION PROGRAM.—

(A) IN GENERAL.—In the case of an intensive cardiac rehabilitation program described in section 1861(eee)(4), the Secretary shall substitute the Medicare OPD fee schedule amount established under the prospective payment system for hospital outpatient department service under paragraph (3)(D) of section 1833(t) for cardiac rehabilitation (under HCPCS codes 93797 and 93798 for calendar year 2007, or any succeeding HCPCS codes for cardiac rehabilitation).

(B) DEFINITION OF SESSION.—Each of the services described in subparagraphs (A) through (E) of section 1861(eee)(3), when furnished for one hour, is a separate session of intensive cardiac rehabilitation.

(C) MULTIPLE SESSIONS PER DAY.—Payment may be made for up to 6 sessions per day of the series of 72 one-hour sessions of intensive cardiac rehabilitation services described in section 1861(eee)(4)(B).

(6) TREATMENT OF BONE MASS SCANS.—For dual-energy x-ray absorptiometry services (identified in 2006 by HCPCS codes 76075 and 76077 (and any succeeding codes)) furnished during 2010, 2011, and the first 2 months of 2012, instead of the payment amount that would otherwise be determined under this section for such years, the payment amount shall be equal to 70 percent of the product of—

(A) the relative value for the service (as determined in subsection (c)(2)) for 2006;

(B) the conversion factor (established under subsection (d)) for 2006; and

(C) the geographic adjustment factor (established under subsection (e)(2)) for the service for the fee schedule area for 2010, 2011, and the first 2 months of 2012, respectively.

(7) ADJUSTMENT IN DISCOUNT FOR CERTAIN MULTIPLE THERAPY SERVICES.—In the case of therapy services furnished on or after January 1, 2011, and before April 1, 2013, and for which payment is made under fee schedules established under this section, instead of the 25 percent multiple procedure payment reduction specified in the final rule published by the Secretary in the Federal Register on November 29, 2010, the reduction percentage shall be 20 percent. In the case of such services furnished on or after April 1, 2013, and for which payment is made under such fee schedules, instead of the 25 percent multiple procedure payment reduction specified in such final rule, the reduction percentage shall be 50 percent.

(8) ENCOURAGING CARE MANAGEMENT FOR INDIVIDUALS WITH CHRONIC CARE NEEDS.—

(A) IN GENERAL.—In order to encourage the management of care for individuals with chronic care needs the Secretary shall, subject to subparagraph (B), make payment (as the Secretary determines to be appropriate) under this section for chronic care management services furnished on or after January 1, 2015, by a physician (as defined in section 1861(r)(1)), physician assistant or nurse practitioner (as defined in section 1861(aa)(5)(A)), clinical nurse spe-

cialist (as defined in section 1861(aa)(5)(B)), or certified nurse midwife (as defined in section 1861(gg)(2)).

(B) POLICIES RELATING TO PAYMENT.—In carrying out this paragraph, with respect to chronic care management services, the Secretary shall—

(i) make payment to only one applicable provider for such services furnished to an individual during a period;

(ii) not make payment under subparagraph (A) if such payment would be duplicative of payment that is otherwise made under this title for such services; and

(iii) not require that an annual wellness visit (as defined in section 1861(hhh)) or an initial preventive physical examination (as defined in section 1861(ww)) be furnished as a condition of payment for such management services.

(9) SPECIAL RULE TO INCENTIVIZE TRANSITION FROM TRADITIONAL X-RAY IMAGING TO DIGITAL RADIOGRAPHY.—

(A) LIMITATION ON PAYMENT FOR FILM X-RAY IMAGING SERVICES.—In the case of imaging services that are X rays taken using film and that are furnished during 2017 or a subsequent year, the payment amount for the technical component (including the technical component portion of a global fee) of such services that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this section) for such year shall be reduced by 20 percent.

(B) PHASED-IN LIMITATION ON PAYMENT FOR COMPUTED RADIOGRAPHY IMAGING SERVICES.—In the case of imaging services that are X rays taken using computed radiography technology—

(i) in the case of such services furnished during 2018, 2019, 2020, 2021, or 2022 the payment amount for the technical component (including the technical component portion of a global fee) of such services that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this section) for such year shall be reduced by 7 percent; and

(ii) in the case of such services furnished during 2023 or a subsequent year, the payment amount for the technical component (including the technical component portion of a global fee) of such services that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this section) for such year shall be reduced by 10 percent.

(C) COMPUTED RADIOGRAPHY TECHNOLOGY DEFINED.—For purposes of this paragraph, the term "computed radiography technology" means cassette-based imaging which utilizes an imaging plate to create the image involved.

(D) IMPLEMENTATION.—In order to implement this paragraph, the Secretary shall adopt appropriate mechanisms which may include use of modifiers.

(c) DETERMINATION OF RELATIVE VALUES FOR PHYSICIANS' SERVICES.—

(1) DIVISION OF PHYSICIANS' SERVICES INTO COMPONENTS.—In this section, with respect to a physicians' service:

(A) WORK COMPONENT DEFINED.—The term "work component" means the portion of the resources used in furnishing the service that reflects physician time and intensity in furnishing the service. Such portion shall—

(i) include activities before and after direct patient contact, and

(ii) be defined, with respect to surgical procedures, to reflect a global definition including pre-operative and post-operative physicians' services.

(B) PRACTICE EXPENSE COMPONENT DEFINED.—The term "practice expense component" means the portion of the resources used in furnishing the service that reflects the general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising practice expenses.

(C) MALPRACTICE COMPONENT DEFINED.—The term "malpractice component" means the portion of the resources used in furnishing the service that reflects malpractice expenses in furnishing the service.

(2) DETERMINATION OF RELATIVE VALUES.—

(A) IN GENERAL.—

(i) COMBINATION OF UNITS FOR COMPONENTS.—The Secretary shall develop a methodology for combining the work, practice expense, and malpractice relative value units, determined under subparagraph (C), for each service in a manner to produce a single relative value for that service. Such relative values are subject to adjustment under subparagraph (F)(i) and section 13515(b) of the Omnibus Budget Reconciliation Act of 1993.

(ii) EXTRAPOLATION.—The Secretary may use extrapolation and other techniques to determine the number of relative value units for physicians' services for which specific data are not available and shall take into account recommendations of the Physician Payment Review Commission and the results of consultations with organizations representing physicians who provide such services.

(B) PERIODIC REVIEW AND ADJUSTMENTS IN RELATIVE VALUES.—

(i) PERIODIC REVIEW.—The Secretary, not less often than every 5 years, shall review the relative values established under this paragraph for all physicians' services.

(ii) ADJUSTMENTS.—

(I) IN GENERAL.—The Secretary shall, to the extent the Secretary determines to be necessary and subject to subclause (II) and paragraph (7), adjust the number of such units to take into account changes in medical practice, coding changes, new data on relative value components, or the addition

of new procedures. The Secretary shall publish an explanation of the basis for such adjustments.

(II) LIMITATION ON ANNUAL ADJUSTMENTS.—Subject to clauses (iv) and (v), the adjustments under subclause (I) for a year may not cause the amount of expenditures under this part for the year to differ by more than $20,000,000 from the amount of expenditures under this part that would have been made if such adjustments had not been made.

(iii) CONSULTATION.—The Secretary, in making adjustments under clause (ii), shall consult with the Medicare Payment Advisory Commission and organizations representing physicians.

(iv) EXEMPTION OF CERTAIN ADDITIONAL EXPENDITURES FROM BUDGET NEUTRALITY.—The additional expenditures attributable to—

(I) subparagraph (H) shall not be taken into account in applying clause (ii)(II) for 2004;

(II) subparagraph (I) insofar as it relates to a physician fee schedule for 2005 or 2006 shall not be taken into account in applying clause (ii)(II) for drug administration services under the fee schedule for such year for a specialty described in subparagraph (I)(ii)(II);

(III) subparagraph (J) insofar as it relates to a physician fee schedule for 2005 or 2006 shall not be taken into account in applying clause (ii)(II) for drug administration services under the fee schedule for such year; and

(IV) subsection (b)(6) shall not be taken into account in applying clause (ii)(II) for 2010, 2011, or the first 2 months of 2012.

(v) EXEMPTION OF CERTAIN REDUCED EXPENDITURES FROM BUDGET-NEUTRALITY CALCULATION.—The following reduced expenditures, as estimated by the Secretary, shall not be taken into account in applying clause (ii)(II):

(I) REDUCED PAYMENT FOR MULTIPLE IMAGING PROCEDURES.—Effective for fee schedules established beginning with 2007, reduced expenditures attributable to the multiple procedure payment reduction for imaging under the final rule published by the Secretary in the Federal Register on November 21, 2005 (42 CFR 405, et al.) insofar as it relates to the physician fee schedules for 2006 and 2007.

(II) OPD PAYMENT CAP FOR IMAGING SERVICES.—Effective for fee schedules established beginning with 2007, reduced expenditures attributable to subsection (b)(4).

(III) CHANGE IN UTILIZATION RATE FOR CERTAIN IMAGING SERVICES.—Effective for fee schedules established beginning with 2011, reduced expenditures attributable to the changes in the utilization

rate applicable to 2011 and 2014, as described in the first and second sentence, respectively, of subsection (b)(4)(C).

(VI) ADDITIONAL REDUCED PAYMENT FOR MULTIPLE IMAGING PROCEDURES.—Effective for fee schedules established beginning with 2010 (but not applied for services furnished prior to July 1, 2010), reduced expenditures attributable to the increase in the multiple procedure payment reduction from 25 to 50 percent (as described in subsection (b)(4)(D)).

(VII) REDUCED EXPENDITURES FOR MULTIPLE THERAPY SERVICES.—Effective for fee schedules established beginning with 2011, reduced expenditures attributable to the multiple procedure payment reduction for therapy services (as described in subsection (b)(7)).

(VIII) REDUCED EXPENDITURES ATTRIBUTABLE TO APPLICATION OF QUALITY INCENTIVES FOR COMPUTED TOMOGRAPHY.—Effective for fee schedules established beginning with 2016, reduced expenditures attributable to the application of the quality incentives for computed tomography under section 1834(p)

(IX) REDUCTIONS FOR MISVALUED SERVICES IF TARGET NOT MET.—Effective for fee schedules beginning with 2016, reduced expenditures attributable to the application of the target recapture amount described in subparagraph (O)(iii).

(X) REDUCED EXPENDITURES ATTRIBUTABLE TO INCENTIVES TO TRANSITION TO DIGITAL RADIOGRAPHY.—Effective for fee schedules established beginning with 2017, reduced expenditures attributable to subparagraph (A) of subsection (b)(9) and effective for fee schedules established beginning with 2018, reduced expenditures attributable to subparagraph (B) of such subsection.

(vi) ALTERNATIVE APPLICATION OF BUDGET-NEUTRALITY ADJUSTMENT.—Notwithstanding subsection (d)(9)(A), effective for fee schedules established beginning with 2009, with respect to the 5-year review of work relative value units used in fee schedules for 2007 and 2008, in lieu of continuing to apply budget-neutrality adjustments required under clause (ii) for 2007 and 2008 to work relative value units, the Secretary shall apply such budget-neutrality adjustments to the conversion factor otherwise determined for years beginning with 2009.

(C) COMPUTATION OF RELATIVE VALUE UNITS FOR COMPONENTS.—For purposes of this section for each physicians' service—

(i) WORK RELATIVE VALUE UNITS.—The Secretary shall determine a number of work relative value units for the service or group of services based on the relative resources incorporating physician time and in-

tensity required in furnishing the service or group of services.

(ii) PRACTICE EXPENSE RELATIVE VALUE UNITS.—The Secretary shall determine a number of practice expense relative value units for the service for years before 1999 equal to the product of—

(I) the base allowed charges (as defined in subparagraph (D)) for the service, and

(II) the practice expense percentage for the service (as determined under paragraph (3)(C)(ii)),

and for years beginning with 1999 based on the relative practice expense resources involved in furnishing the service or group of services. For 1999, such number of units shall be determined based 75 percent on such product and based 25 percent on the relative practice expense resources involved in furnishing the service. For 2000, such number of units shall be determined based 50 percent on such product and based 50 percent on such relative practice expense resources. For 2001, such number of units shall be determined based 25 percent on such product and based 75 percent on such relative practice expense resources. For a subsequent year, such number of units shall be determined based entirely on such relative practice expense resources.

(iii) MALPRACTICE RELATIVE VALUE UNITS.—The Secretary shall determine a number of malpractice relative value units for the service or group of services for years before 2000 equal to the product of—

(I) the base allowed charges (as defined in subparagraph (D)) for the service or group of services, and

(II) the malpractice percentage for the service or group of services (as determined under paragraph (3)(C)(iii)),

and for years beginning with 2000 based on the malpractice expense resources involved in furnishing the service or group of services.

(D) BASE ALLOWED CHARGES DEFINED.—In this paragraph, the term "base allowed charges" means, with respect to a physician's service, the national average allowed charges for the service under this part for services furnished during 1991, as estimated by the Secretary using the most recent data available.

(E) REDUCTION IN PRACTICE EXPENSE RELATIVE VALUE UNITS FOR CERTAIN SERVICES.—

(i) IN GENERAL.—Subject to clause (ii), the Secretary shall reduce the practice expense relative value units applied to services described in clause (iii) furnished in—

(I) 1994, by 25 percent of the number by which the number of practice expense relative value units (determined for 1994 without regard to this subparagraph) exceeds the number of work relative value units determined for 1994,

(II) 1995, by an additional 25 percent of such excess, and

(III) 1996, by an additional 25 percent of such excess.

(ii) FLOOR ON REDUCTIONS.—The practice expense relative value units for a physician's service shall not be reduced under this subparagraph to a number less than 128 percent of the number of work relative value units.

(iii) Services covered.—For purposes of clause (i), the services described in this clause are physicians' services that are not described in clause (iv) and for which—

(I) there are work relative value units, and

(II) the number of practice expense relative value units (determined for 1994) exceeds 128 percent of the number of work relative value units (determined for such year).

(iv) EXCLUDED SERVICES.—For purposes of clause (iii), the services described in this clause are services which the Secretary determines at least 75 percent of which are provided under this title in an office setting.

(F) BUDGET NEUTRALITY ADJUSTMENTS.—The Secretary—

(i) shall reduce the relative values for all services (other than anesthesia services) established under this paragraph (and in the case of anesthesia services, the conversion factor established by the Secretary for such services) by such percentage as the Secretary determines to be necessary so that, beginning in 1996, the amendment made by section 13514(a) of the Omnibus Budget Reconciliation Act of 1993 would not result in expenditures under this section that exceed the amount of such expenditures that would have been made if such amendment had not been made, and

(ii) shall reduce the amounts determined under subsection (a)(2)(B)(ii)(I) by such percentage as the Secretary determines to be required to assure that, taking into account the reductions made under clause (i), the amendment made by section 13514(a) of the Omnibus Budget Reconciliation Act of 1993 would not result in expenditures under this section in 1994 that exceed the amount of such expenditures that would have been made if such amendment had not been made.

(G) ADJUSTMENTS IN RELATIVE VALUE UNITS FOR 1998.—

(i) IN GENERAL.—The Secretary shall—

(I) subject to clauses (iv) and (v), reduce the practice expense relative value units applied to any services described in clause (ii) furnished in 1998 to a number equal to 110 percent of the number of work relative value units, and

(II) increase the practice expense relative value units for office visit procedure codes during 1998 by a uniform percentage which the Secretary estimates will result in an aggregate increase in pay-

ments for such services equal to the aggregate decrease in payments by reason of subclause (I).

(ii) SERVICES COVERED.—For purposes of clause (i), the services described in this clause are physicians' services that are not described in clause (iii) and for which—

(I) there are work relative value units, and

(II) the number of practice expense relative value units (determined for 1998) exceeds 110 percent of the number of work relative value units (determined for such year).

(iii) EXCLUDED SERVICES.—For purposes of clause (ii), the services described in this clause are services which the Secretary determines at least 75 percent of which are provided under this title in an office setting.

(iv) LIMITATION ON AGGREGATE REALLOCATION.—If the application of clause (i)(I) would result in an aggregate amount of reductions under such clause in excess of $390,000,000, such clause shall be applied by substituting for 110 percent such greater percentage as the Secretary estimates will result in the aggregate amount of such reductions equaling $390,000,000.

(v) NO REDUCTION FOR CERTAIN SERVICES.—Practice expense relative value units for a procedure performed in an office or in a setting out of an office shall not be reduced under clause (i) if the in-office or out-of-office practice expense relative value, respectively, for the procedure would increase under the proposed rule on resource-based practice expenses issued by the Secretary on June 18, 1997 (62 Federal Register 33158 et seq.).

(H) ADJUSTMENTS IN PRACTICE EXPENSE RELATIVE VALUE UNITS FOR CERTAIN DRUG ADMINISTRATION SERVICES BEGINNING IN 2004.—

(i) USE OF SURVEY DATA.—In establishing the physician fee schedule under subsection (b) with respect to payments for services furnished on or after January 1, 2004, the Secretary shall, in determining practice expense relative value units under this subsection, utilize a survey submitted to the Secretary as of January 1, 2003, by a physician specialty organization pursuant to section 212 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 if the survey—

(I) covers practice expenses for oncology drug administration services; and

(II) meets criteria established by the Secretary for acceptance of such surveys.

(ii) PRICING OF CLINICAL ONCOLOGY NURSES IN PRACTICE EXPENSE METHODOLOGY.—If the survey described in clause (i) includes data on wages, salaries, and compensation of clinical oncology nurses, the Secretary shall utilize such data in the methodology for determining practice expense relative value units under subsection (c).

(iii) WORK RELATIVE VALUE UNITS FOR CERTAIN DRUG ADMINISTRATION SERVICES.—In establishing the relative value units under this paragraph for drug administration services described in clause (iv) furnished on or after January 1, 2004, the Secretary shall establish work relative value units equal to the work relative value units for a level 1 office medical visit for an established patient.

(iv) DRUG ADMINISTRATION SERVICES DESCRIBED.—The drug administration services described in this clause are physicians' services—

(I) which are classified as of October 1, 2003, within any of the following groups of procedures: therapeutic or diagnostic infusions (excluding chemotherapy); chemotherapy administration services; and therapeutic, prophylactic, or diagnostic injections;

(II) for which there are no work relative value units assigned under this subsection as of such date; and

(III) for which national relative value units have been assigned under this subsection as of such date.

(I) ADJUSTMENTS IN PRACTICE EXPENSE RELATIVE VALUE UNITS FOR CERTAIN DRUG ADMINISTRATION SERVICES BEGINNING WITH 2005.—

(i) IN GENERAL.—In establishing the physician fee schedule under subsection (b) with respect to payments for services furnished on or after January 1, 2005 or 2006, the Secretary shall adjust the practice expense relative value units for such year consistent with clause (ii).

(ii) USE OF SUPPLEMENTAL SURVEY DATA.—

(I) IN GENERAL.—Subject to subclause (II), if a specialty submits to the Secretary by not later than March 1, 2004, for 2005, or March 1, 2005, for 2006, data that includes expenses for the administration of drugs and biologicals for which the payment amount is determined pursuant to section 1842(o), the Secretary shall use such supplemental survey data in carrying out this subparagraph for the years involved insofar as they are collected and provided by entities and organizations consistent with the criteria established by the Secretary pursuant to section 212(a) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999.

(II) LIMITATION ON SPECIALTY.—Subclause (I) shall apply to a specialty only insofar as not less than 40 percent of payments for the specialty under this title in 2002 are attributable to the administration of drugs and biologicals, as determined by the Secretary.

(III) APPLICATION.—This clause shall not apply with respect to a survey to which subparagraph (H)(i) applies.

(J) PROVISIONS FOR APPROPRIATE REPORTING AND BILLING FOR PHYSICIANS' SERVICES ASSOCIATED WITH THE ADMINISTRATION OF COVERED OUTPATIENT DRUGS AND BIOLOGICALS.—

(i) EVALUATION OF CODES.—The Secretary shall promptly evaluate existing drug administration codes for physicians' services to ensure accurate reporting and billing for such services, taking into account levels of complexity of the administration and resource consumption.

(ii) USE OF EXISTING PROCESSES.—In carrying out clause (i), the Secretary shall use existing processes for the consideration of coding changes and, to the extent coding changes are made, shall use such processes in establishing relative values for such services.

(iii) IMPLEMENTATION.—In carrying out clause (i), the Secretary shall consult with representatives of physician specialties affected by the implementation of section 1847A or section 1847B, and shall take such steps within the Secretary's authority to expedite such considerations under clause (ii).

(iv) SUBSEQUENT, BUDGET NEUTRAL ADJUSTMENTS PERMITTED.—Nothing in subparagraph (H) or (I) or this subparagraph shall be construed as preventing the Secretary from providing for adjustments in practice expense relative value units under (and consistent with) subparagraph (B) for years after 2004, 2005, or 2006, respectively.

(K) POTENTIALLY MISVALUED CODES.—

(i) IN GENERAL.—The Secretary shall—

(I) periodically identify services as being potentially misvalued using criteria specified in clause (ii); and

(II) review and make appropriate adjustments to the relative values established under this paragraph for services identified as being potentially misvalued under subclause (I).

(ii) IDENTIFICATION OF POTENTIALLY MISVALUED CODES.—For purposes of identifying potentially misvalued codes pursuant to clause (i)(I), the Secretary shall examine codes (and families of codes as appropriate) based on any or all of the following criteria:

(I) Codes that have experienced the fastest growth.

(II) Codes that have experienced substantial changes in practice expenses.

(III) Codes that describe new technologies or services within an appropriate time period (such as 3 years) after the relative values are initially established for such codes.

(IV) Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.

(V) Codes with low relative values, particularly those that are often billed multiple times for a single treatment.

(VI) Codes that have not been subject to review since implementation of the fee schedule.

(VII) Codes that account for the majority of spending under the physician fee schedule.

(VIII) Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.

(IX) Codes for which there may be a change in the typical site of service since the code was last valued.

(X) Codes for which there is a significant difference in payment for the same service between different sites of service.

(XI) Codes for which there may be anomalies in relative values within a family of codes.

(XII) Codes for services where there may be efficiencies when a service is furnished at the same time as other services.

(XIII) Codes with high intra-service work per unit of time.

(XIV) Codes with high practice expense relative value units.

(XV) Codes with high cost supplies.

(XVI) Codes as determined appropriate by the Secretary.

(iii) REVIEW AND ADJUSTMENTS.—

(I) The Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services described in clause (i)(II).

(II) The Secretary may conduct surveys, other data collection activities, studies, or other analyses as the Secretary determines to be appropriate to facilitate the review and appropriate adjustment described in clause (i)(II).

(III) The Secretary may use analytic contractors to identify and analyze services identified under clause (i)(I), conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of services described in clause (i)(II).

(IV) The Secretary may coordinate the review and appropriate adjustment described in clause (i)(II) with the periodic review described in subparagraph (B).

(V) As part of the review and adjustment described in clause (i)(II), including with respect to codes with low relative values described in clause (ii), the Secretary may make appropriate coding

revisions (including using existing processes for consideration of coding changes) which may include consolidation of individual services into bundled codes for payment under the fee schedule under subsection (b).

(VI) The provisions of subparagraph (B)(ii)(II) and paragraph (7) shall apply to adjustments to relative value units made pursuant to this subparagraph in the same manner as such provisions apply to adjustments under subparagraph (B)(ii)(I).

(L) VALIDATING RELATIVE VALUE UNITS.—

(i) IN GENERAL.—The Secretary shall establish a process to validate relative value units under the fee schedule under subsection (b).

(ii) COMPONENTS AND ELEMENTS OF WORK.—The process described in clause (i) may include validation of work elements (such as time, mental effort and professional judgment, technical skill and physical effort, and stress due to risk) involved with furnishing a service and may include validation of the pre-, post-, and intra-service components of work.

(iii) SCOPE OF CODES.—The validation of work relative value units shall include a sampling of codes for services that is the same as the codes listed under subparagraph (K)(ii).

(iv) METHODS.—The Secretary may conduct the validation under this subparagraph using methods described in subclauses (I) through (V) of subparagraph (K)(iii) as the Secretary determines to be appropriate.

(v) ADJUSTMENTS.—The Secretary shall make appropriate adjustments to the work relative value units under the fee schedule under subsection (b). The provisions of subparagraph (B)(ii)(II) shall apply to adjustments to relative value units made pursuant to this subparagraph in the same manner as such provisions apply to adjustments under subparagraph (B)(ii)(II).

(M) AUTHORITY TO COLLECT AND USE INFORMATION ON PHYSICIANS' SERVICES IN THE DETERMINATION OF RELATIVE VALUES.—

(i) COLLECTION OF INFORMATION.—Notwithstanding any other provision of law, the Secretary may collect or obtain information on the resources directly or indirectly related to furnishing services for which payment is made under the fee schedule established under subsection (b). Such information may be collected or obtained from any eligible professional or any other source.

(ii) USE OF INFORMATION.—Notwithstanding any other provision of law, subject to clause (v), the Secretary may (as the Secretary determines appropriate) use information collected or obtained pursuant to clause (i) in the determination of relative values for services under this section.

(iii) TYPES OF INFORMATION.—The types of information described in clauses (i) and (ii) may, at the Secretary's discretion, include any or all of the following:

(I) Time involved in furnishing services.

(II) Amounts and types of practice expense inputs involved with furnishing services.

(III) Prices (net of any discounts) for practice expense inputs, which may include paid invoice prices or other documentation or records.

(IV) Overhead and accounting information for practices of physicians and other suppliers.

(V) Any other element that would improve the valuation of services under this section.

(iv) INFORMATION COLLECTION MECHANISMS.—Information may be collected or obtained pursuant to this subparagraph from any or all of the following:

(I) Surveys of physicians, other suppliers, providers of services, manufacturers, and vendors.

(II) Surgical logs, billing systems, or other practice or facility records.

(III) Electronic health records.

(IV) Any other mechanism determined appropriate by the Secretary.

(v) TRANSPARENCY OF USE OF INFORMATION.—

(I) IN GENERAL.—Subject to subclauses (II) and (III), if the Secretary uses information collected or obtained under this subparagraph in the determination of relative values under this subsection, the Secretary shall disclose the information source and discuss the use of such information in such determination of relative values through notice and comment rulemaking.

(II) THRESHOLDS FOR USE.—The Secretary may establish thresholds in order to use such information, including the exclusion of information collected or obtained from eligible professionals who use very high resources (as determined by the Secretary) in furnishing a service.

(III) DISCLOSURE OF INFORMATION.—The Secretary shall make aggregate information available under this subparagraph but shall not disclose information in a form or manner that identifies an eligible professional or a group practice, or information collected or obtained pursuant to a nondisclosure agreement.

(vi) INCENTIVE TO PARTICIPATE.—The Secretary may provide for such payments under this part to an eligible professional that submits such solicited information under this subparagraph as the Secretary determines appropriate in order to compensate such eligible professional for such submission. Such payments shall be provided in a form and manner specified by the Secretary.

(vii) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to information collected or obtained under this subparagraph.

(viii) DEFINITION OF ELIGIBLE PROFESSIONAL.—In this subparagraph, the term "eligible professional" has the meaning given such term in subsection (k)(3)(B).

(ix) FUNDING.—For purposes of carrying out this subparagraph, in addition to funds otherwise appropriated, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of $2,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for each fiscal year beginning with fiscal year 2014. Amounts transferred under the preceding sentence for a fiscal year shall be available until expended.

(N) AUTHORITY FOR ALTERNATIVE APPROACHES TO ESTABLISHING PRACTICE EXPENSE RELATIVE VALUES.—The Secretary may establish or adjust practice expense relative values under this subsection using cost, charge, or other data from suppliers or providers of services, including information collected or obtained under subparagraph (M).

(O) TARGET FOR RELATIVE VALUE ADJUSTMENTS FOR MISVALUED SERVICES.—With respect to fee schedules established for each of 2016 through 2018, the following shall apply:

(i) DETERMINATION OF NET REDUCTION IN EXPENDITURES.—For each year, the Secretary shall determine the estimated net reduction in expenditures under the fee schedule under this section with respect to the year as a result of adjustments to the relative values established under this paragraph for misvalued codes.

(ii) BUDGET NEUTRAL REDISTRIBUTION OF FUNDS IF TARGET MET AND COUNTING OVERAGES TOWARDS THE TARGET FOR THE SUCCEEDING YEAR.—If the estimated net reduction in expenditures determined under clause (i) for the year is equal to or greater than the target for the year—

(I) reduced expenditures attributable to such adjustments shall be redistributed for the year in a budget neutral manner in accordance with subparagraph (B)(ii)(II); and

(II) the amount by which such reduced expenditures exceeds the target for the year shall be treated as a reduction in expenditures described in clause (i) for the succeeding year, for purposes of determining whether the target has or has not been met under this subparagraph with respect to that year.

(iii) EXEMPTION FROM BUDGET NEUTRALITY IF TARGET NOT MET.—If the estimated net reduction in expenditures determined under clause (i) for the year is less than the target for the year, reduced expenditures in an amount equal to the target recapture amount shall not be taken into account in applying subparagraph

(B)(ii)(II) with respect to fee schedules beginning with 2016.

(iv) TARGET RECAPTURE AMOUNT.—For purposes of clause (iii), the target recapture amount is, with respect to a year, an amount equal to the difference between—

(I) the target for the year; and

(II) the estimated net reduction in expenditures determined under clause (i) for the year.

(v) TARGET.—For purposes of this subparagraph, with respect to a year, the target is calculated as 0.5 percent (or, for 2016, 1.0 percent) of the estimated amount of expenditures under the fee schedule under this section for the year.

(3) COMPONENT PERCENTAGES.—For purposes of paragraph (2), the Secretary shall determine a work percentage, a practice expense percentage, and a malpractice percentage for each physician's service as follows:

(A) DIVISION OF SERVICES BY SPECIALTY.—For each physician's service or class of physicians' services, the Secretary shall determine the average percentage of each such service or class of services that is performed, nationwide, under this part by physicians in each of the different physician specialties (as identified by the Secretary).

(B) DIVISION OF SPECIALTY BY COMPONENT.—The Secretary shall determine the average percentage division of resources, among the work component, the practice expense component, and the malpractice component, used by physicians in each of such specialties in furnishing physicians' services. Such percentages shall be based on national data that describe the elements of physician practice costs and revenues, by physician specialty. The Secretary may use extrapolation and other techniques to determine practice costs and revenues for specialties for which adequate data are not available.

(C) DETERMINATION OF COMPONENT PERCENTAGES.—

(i) WORK PERCENTAGE.—The work percentage for a service (or class of services) is equal to the sum (for all physician specialties) of—

(I) the average percentage division for the work component for each physician specialty (determined under subparagraph (B)), multiplied by

(II) the proportion (determined under subparagraph (A)) of such service (or services) performed by physicians in that specialty.

(ii) PRACTICE EXPENSE PERCENTAGE.—For years before 2002, the practice expense percentage for a service (or class of services) is equal to the sum (for all physician specialties) of—

(I) the average percentage division for the practice expense component for each physician specialty (determined under subparagraph (B)), multiplied by

(II) the proportion (determined under subparagraph (A)) of such service (or services) performed by physicians in that specialty.

(iii) MALPRACTICE PERCENTAGE.—For years before 1999, the malpractice percentage for a service (or class of services) is equal to the sum (for all physician specialties) of—

(I) the average percentage division for the malpractice component for each physician specialty (determined under subparagraph (B)), multiplied by

(II) the proportion (determined under subparagraph (A)) of such service (or services) performed by physicians in that specialty.

(D) PERIODIC RECOMPUTATION.—The Secretary may, from time to time, provide for the recomputation of work percentages, practice expense percentages, and malpractice percentages determined under this paragraph.

(4) ANCILLARY POLICIES.—The Secretary may establish ancillary policies (with respect to the use of modifiers, local codes, and other matters) as may be necessary to implement this section.

(5) CODING.—The Secretary shall establish a uniform procedure coding system for the coding of all physicians' services. The Secretary shall provide for an appropriate coding structure for visits and consultations. The Secretary may incorporate the use of time in the coding for visits and consultations. The Secretary, in establishing such coding system, shall consult with the Physician Payment Review Commission and other organizations representing physicians.

(6) NO VARIATION FOR SPECIALISTS.—The Secretary may not vary the conversion factor or the number of relative value units for a physicians' service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician.

(7) PHASE-IN OF SIGNIFICANT RELATIVE VALUE UNIT (RVU) REDUCTIONS.—Effective for fee schedules established beginning with 2016, for services that are not new or revised codes, if the total relative value units for a service for a year would otherwise be decreased by an estimated amount equal to or greater than 20 percent as compared to the total relative value units for the previous year, the applicable adjustments in work, practice expense, and malpractice relative value units shall be phased-in over a 2-year period.

(8) GLOBAL SURGICAL PACKAGES.—

(A) PROHIBITION OF IMPLEMENTATION OF RULE REGARDING GLOBAL SURGICAL PACKAGES.—

(i) IN GENERAL.—The Secretary shall not implement the policy established in the final rule published on November 13, 2014 (79 Fed. Reg. 67548 et seq.), that requires the transition of all 10-day and 90-day global surgery packages to 0-day global periods.

(ii) CONSTRUCTION.—Nothing in clause (i) shall be construed to prevent the Secretary from revaluing misvalued codes for specific surgical services or assign-

ing values to new or revised codes for surgical services.

(B) COLLECTION OF DATA ON SERVICES INCLUDED IN GLOBAL SURGICAL PACKAGES.—

(i) IN GENERAL.—Subject to clause (ii), the Secretary shall through rulemaking develop and implement a process to gather, from a representative sample of physicians, beginning not later than January 1, 2017, information needed to value surgical services. Such information shall include the number and level of medical visits furnished during the global period and other items and services related to the surgery and furnished during the global period, as appropriate. Such information shall be reported on claims at the end of the global period or in another manner specified by the Secretary. For purposes of carrying out this paragraph (other than clause (iii)), the Secretary shall transfer from the Federal Supplemental Medical Insurance Trust Fund under section 1841 $2,000,000 to the Center for Medicare & Medicaid Services Program Management Account for fiscal year 2015. Amounts transferred under the previous sentence shall remain available until expended.

(ii) REASSESSMENT AND POTENTIAL SUNSET.—Every 4 years, the Secretary shall reassess the value of the information collected pursuant to clause (i). Based on such a reassessment and by regulation, the Secretary may discontinue the requirement for collection of information under such clause if the Secretary determines that the Secretary has adequate information from other sources, such as qualified clinical data registries, surgical logs, billing systems or other practice or facility records, and electronic health records, in order to accurately value global surgical services under this section.

(iii) INSPECTOR GENERAL AUDIT.—The Inspector General of the Department of Health and Human Services shall audit a sample of the information reported under clause (i) to verify the accuracy of the information so reported.

(C) IMPROVING ACCURACY OF PRICING FOR SURGICAL SERVICES.—For years beginning with 2019, the Secretary shall use the information reported under subparagraph (B)(i) as appropriate and other available data for the purpose of improving the accuracy of valuation of surgical services under the physician fee schedule under this section.

(d) CONVERSION FACTORS.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—The conversion factor for each year shall be the conversion factor established under this subsection for the previous year (or, in the case of 1992, specified in subparagraph (B)) adjusted by the update (established under paragraph (3)) for the year involved (for years before 2001) and, for years beginning with 2001 and end-

ing with 2025, multiplied by the update (established under paragraph (4) or a subsequent paragraph) for the year involved. There shall be two separate conversion factors for each year beginning with 2026, one for items and services furnished by a qualifying APM participant (as defined in section 1833(z)(2)) (referred to in this subsection as the "qualifying APM conversion factor") and the other for other items and services (referred to in this subsection as the "nonqualifying APM conversion factor"), equal to the respective conversion factor for the previous year (or, in the case of 2026, equal to the single conversion factor for 2025) multiplied by the update established under paragraph (20) for such respective conversion factor for such year.

(B) SPECIAL PROVISION FOR 1992.—For purposes of subparagraph (A), the conversion factor specified in this subparagraph is a conversion factor (determined by the Secretary) which, if this section were to apply during 1991 using such conversion factor, would result in the same aggregate amount of payments under this part for physicians' services as the estimated aggregate amount of the payments under this part for such services in 1991.

(C) SPECIAL RULES FOR 1998.—Except as provided in subparagraph (D), the single conversion factor for 1998 under this subsection shall be the conversion factor for primary care services for 1997, increased by the Secretary's estimate of the weighted average of the three separate updates that would otherwise occur were it not for the enactment of chapter 1 of subtitle F of title IV of the Balanced Budget Act of 1997.

(D) SPECIAL RULES FOR ANESTHESIA SERVICES.—The separate conversion factor for anesthesia services for a year shall be equal to 46 percent of the single conversion factor (or, beginning with 2026, applicable conversion factor) established for other physicians' services, except as adjusted for changes in work, practice expense, or malpractice relative value units.

(E) PUBLICATION AND DISSEMINATION OF INFORMATION.—The Secretary shall—

(i) cause to have published in the Federal Register not later than November 1 of each year (beginning with 2000) the conversion factor which will apply to physicians' services for the succeeding year, the update determined under paragraph (4) for such succeeding year, and the allowed expenditures under such paragraph for such succeeding year; and

(ii) make available to the Medicare Payment Advisory Commission and the public by March 1 of each year (beginning with 2000) an estimate of the sustainable growth rate and of the conversion factor which will apply to physicians' services for the succeeding year and data used in making such estimate.

(3) UPDATE FOR 1999 AND 2000.—

(A) IN GENERAL.—Unless otherwise provided by law, subject to subparagraph (D) and the budget-neutrality factor determined by the Secretary under subsection

(c)(2)(B)(ii), the update to the single conversion factor established in paragraph (1)(C) for 1999 and 2000 is equal to the product of—

(i) 1 plus the Secretary's estimate of the percentage increase in the MEI (as defined in section 1842(i)(3)) for the year (divided by 100), and

(ii) 1 plus the Secretary's estimate of the update adjustment factor for the year (divided by 100),

minus 1 and multiplied by 100.

(B) UPDATE ADJUSTMENT FACTOR.—For purposes of subparagraph (A)(ii), the "update adjustment factor" for a year is equal (as estimated by the Secretary) to—

(i) the difference between (I) the sum of the allowed expenditures for physicians' services (as determined under subparagraph (C)) for the period beginning April 1, 1997, and ending on March 31 of the year involved, and (II) the amount of actual expenditures for physicians' services furnished during the period beginning April 1, 1997, and ending on March 31 of the preceding year; divided by

(ii) the actual expenditures for physicians' services for the 12-month period ending on March 31 of the preceding year, increased by the sustainable growth rate under subsection (f) for the fiscal year which begins during such 12-month period.

(C) DETERMINATION OF ALLOWED EXPENDITURES.—For purposes of this paragraph and paragraph (4), the allowed expenditures for physicians' services for the 12-month period ending with March 31 of—

(i) 1997 is equal to the actual expenditures for physicians' services furnished during such 12-month period, as estimated by the Secretary; or

(ii) a subsequent year is equal to the allowed expenditures for physicians' services for the previous year, increased by the sustainable growth rate under subsection (f) for the fiscal year which begins during such 12-month period.

(D) RESTRICTION ON VARIATION FROM MEDICARE ECONOMIC INDEX.—Notwithstanding the amount of the update adjustment factor determined under subparagraph (B) for a year, the update in the conversion factor under this paragraph for the year may not be—

(i) greater than 100 times the following amount: (1.03 + (MEI percentage/100)) − 1; or

(ii) less than 100 times the following amount: (0.93 + (MEI percentage/100)) − 1,

where "MEI percentage" means the Secretary's estimate of the percentage increase in the MEI (as defined in section 1842(i)(3)) for the year involved.

(4) UPDATE FOR YEARS BEGINNING WITH 2001 AND ENDING WITH 2014.—

(A) IN GENERAL.—Unless otherwise provided by law, subject to the budget-neutrality factor determined by the Secretary under subsection (c)(2)(B)(ii) and subject to adjustment under subparagraph (F), the update to the single

conversion factor established in paragraph (1)(C) for a year beginning with 2001 and ending with 2014 is equal to the product of—

(i) 1 plus the Secretary's estimate of the percentage increase in the MEI (as defined in section 1842(i)(3)) for the year (divided by 100); and

(ii) 1 plus the Secretary's estimate of the update adjustment factor under subparagraph (B) for the year.

(B) UPDATE ADJUSTMENT FACTOR.—For purposes of subparagraph (A)(ii), subject to subparagraph (D) and the succeeding paragraphs of this subsection, the "update adjustment factor" for a year is equal (as estimated by the Secretary) to the sum of the following:

(i) PRIOR YEAR ADJUSTMENT COMPONENT.—An amount determined by—

(I) computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services for the prior year (as determined under subparagraph (C)) and the amount of the actual expenditures for such services for that year;

(II) dividing that difference by the amount of the actual expenditures for such services for that year; and

(III) multiplying that quotient by 0.75.

(ii) CUMULATIVE ADJUSTMENT COMPONENT.—An amount determined by—

(I) computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services (as determined under subparagraph (C)) from April 1, 1996, through the end of the prior year and the amount of the actual expenditures for such services during that period;

(II) dividing that difference by actual expenditures for such services for the prior year as increased by the sustainable growth rate under subsection (f) for the year for which the update adjustment factor is to be determined; and

(III) multiplying that quotient by 0.33.

(C) DETERMINATION OF ALLOWED EXPENDITURES.—For purposes of this paragraph:

(i) PERIOD UP TO APRIL 1, 1999.—The allowed expenditures for physicians' services for a period before April 1, 1999, shall be the amount of the allowed expenditures for such period as determined under paragraph (3)(C).

(ii) TRANSITION TO CALENDAR YEAR ALLOWED EXPENDITURES.—Subject to subparagraph (E), the allowed expenditures for—

(I) the 9-month period beginning April 1, 1999, shall be the Secretary's estimate of the amount of the allowed expenditures that would be permitted under paragraph (3)(C) for such period; and

(II) the year of 1999, shall be the Secretary's estimate of the amount of the allowed expenditures that would be permitted under paragraph (3)(C) for such year.

(iii) YEARS BEGINNING WITH 2000.—The allowed expenditures for a year (beginning with 2000) is equal to the allowed expenditures for physicians' services for the previous year, increased by the sustainable growth rate under subsection (f) for the year involved.

(D) RESTRICTION ON UPDATE ADJUSTMENT FACTOR.—The update adjustment factor determined under subparagraph (B) for a year may not be less than −0.07 or greater than 0.03.

(E) RECALCULATION OF ALLOWED EXPENDITURES FOR UPDATES BEGINNING WITH 2001.—For purposes of determining the update adjustment factor for a year beginning with 2001, the Secretary shall recompute the allowed expenditures for previous periods beginning on or after April 1, 1999, consistent with subsection (f)(3).

(F) TRANSITIONAL ADJUSTMENT DESIGNED TO PROVIDE FOR BUDGET NEUTRALITY.—Under this subparagraph the Secretary shall provide for an adjustment to the update under subparagraph (A)—

(i) for each of 2001, 2002, 2003, and 2004, of −0.2 percent; and

(ii) for 2005 of +0.8 percent.

(5) UPDATE FOR 2004 AND 2005.—The update to the single conversion factor established in paragraph (1)(C) for each of 2004 and 2005 shall be not less than 1.5 percent.

(6) UPDATE FOR 2006.—The update to the single conversion factor established in paragraph (1)(C) for 2006 shall be 0 percent.

(7) CONVERSION FACTOR FOR 2007.—

(A) IN GENERAL.—The conversion factor that would otherwise be applicable under this subsection for 2007 shall be the amount of such conversion factor divided by the product of—

(i) 1 plus the Secretary's estimate of the percentage increase in the MEI (as defined in section 1842(i)(3)) for 2007 (divided by 100); and

(ii) 1 plus the Secretary's estimate of the update adjustment factor under paragraph (4)(B) for 2007.

(B) NO EFFECT ON COMPUTATION OF CONVERSION FACTOR FOR 2008.—The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2008 as if subparagraph (A) had never applied.

(8) UPDATE FOR 2008.—

(A) IN GENERAL.—Subject to paragraph (7)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2008, the update to the single conversion factor shall be 0.5 percent.

(B) NO EFFECT ON COMPUTATION OF CONVERSION FACTOR FOR 2009.—The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2009 and

subsequent years as if subparagraph (A) had never applied.

(9) UPDATE FOR 2009.—

(A) IN GENERAL.—Subject to paragraphs (7)(B) and (8)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2009, the update to the single conversion factor shall be 1.1 percent.

(B) NO EFFECT ON COMPUTATION OF CONVERSION FACTOR FOR 2010 AND SUBSEQUENT YEARS.—The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2010 and subsequent years as if subparagraph (A) had never applied.

(10) UPDATE FOR JANUARY THROUGH MAY OF 2010.—

(A) IN GENERAL.—Subject to paragraphs (7)(B), (8)(B), and (9)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2010 for the period beginning on January 1, 2010, and ending on May 31, 2010, the update to the single conversion factor shall be 0 percent for 2010.

(B) NO EFFECT ON COMPUTATION OF CONVERSION FACTOR FOR REMAINING PORTION OF 2010 AND SUBSEQUENT YEARS.—The conversion factor under this subsection shall be computed under paragraph (1)(A) for the period beginning on June 1, 2010, and ending on December 31, 2010, and for 2011 and subsequent years as if subparagraph (A) had never applied.

(11) UPDATE FOR JUNE THROUGH DECEMBER OF 2010.—

(A) IN GENERAL.—Subject to paragraphs (7)(B), (8)(B), (9)(B), and (10)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2010 for the period beginning on June 1, 2010, and ending on December 31, 2010, the update to the single conversion factor shall be 2.2 percent.

(B) NO EFFECT ON COMPUTATION OF CONVERSION FACTOR FOR 2011 AND SUBSEQUENT YEARS.—The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2011 and subsequent years as if subparagraph (A) had never applied.

(12) UPDATE FOR 2011.—

(A) IN GENERAL.—Subject to paragraphs (7)(B), (8)(B), (9)(B), (10)(B), and (11)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2011, the update to the single conversion factor shall be 0 percent.

(B) NO EFFECT ON COMPUTATION OF CONVERSION FACTOR FOR 2012 AND SUBSEQUENT YEARS.—The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2012 and subsequent years as if subparagraph (A) had never applied.

(13) UPDATE FOR 2012.—

(A) IN GENERAL.—Subject to paragraphs (7)(B), (8)(B), (9)(B), (10)(B), (11)(B), and (12)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C)

that would otherwise apply for 2012, the update to the single conversion factor shall be zero percent.

(B) NO EFFECT ON COMPUTATION OF CONVERSION FACTOR FOR 2013 AND SUBSEQUENT YEARS.—The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2013 and subsequent years as if subparagraph (A) had never applied.

(14) UPDATE FOR 2013.—

(A) IN GENERAL.—Subject to paragraphs (7)(B), (8)(B), (9)(B), (10)(B), (11)(B), (12)(B), and (13)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2013, the update to the single conversion factor for such year shall be zero percent.

(B) NO EFFECT ON COMPUTATION OF CONVERSION FACTOR FOR 2014 AND SUBSEQUENT YEARS.—The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2014 and subsequent years as if subparagraph (A) had never applied.

(15) UPDATE FOR 2014.—

(A) IN GENERAL.—Subject to paragraphs (7)(B), (8)(B), (9)(B), (10)(B), (11)(B), (12)(B), (13)(B), and (14)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2014, the update to the single conversion factor shall be 0.5 percent.

(B) NO EFFECT ON COMPUTATION OF CONVERSION FACTOR FOR SUBSEQUENT YEARS.—The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2015 and subsequent years as if subparagraph (A) had never applied.

(16) UPDATE FOR JANUARY THROUGH JUNE OF 2015.—Subject to paragraphs (7)(B), (8)(B), (9)(B), (10)(B), (11)(B), (12)(B), (13)(B), (14)(B), and (15)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2015 for the period beginning on January 1, 2015, and ending on June 30, 2015, the update to the single conversion factor shall be 0.0 percent.

(17) UPDATE FOR JULY THROUGH DECEMBER OF 2015.—The update to the single conversion factor established in paragraph (1)(C) for the period beginning on July 1, 2015, and ending on December 31, 2015, shall be 0.5 percent.

(18) UPDATE FOR 2016 THROUGH 2019.—The update to the single conversion factor established in paragraph (1)(C) for 2016 and each subsequent year through 2019 shall be 0.5 percent.

(19) UPDATE FOR 2020 THROUGH 2025.—The update to the single conversion factor established in paragraph (1)(C) for 2020 and each subsequent year through 2025 shall be 0.0 percent.

(20) UPDATE FOR 2026 AND SUBSEQUENT YEARS.—For 2026 and each subsequent year, the update to the qualifying APM conversion factor established under paragraph (1)(A) is 0.75 percent, and the update to the nonqualifying APM conversion factor established under such paragraph is 0.25 percent.

(e) GEOGRAPHIC ADJUSTMENT FACTORS.—

(1) ESTABLISHMENT OF GEOGRAPHIC INDICES.—

(A) IN GENERAL.—Subject to subparagraphs (B), (C), (E), (G), (H), and (I), the Secretary shall establish—

(i) an index which reflects the relative costs of the mix of goods and services comprising practice expenses (other than malpractice expenses) in the different fee schedule areas compared to the national average of such costs,

(ii) an index which reflects the relative costs of malpractice expenses in the different fee schedule areas compared to the national average of such costs, and

(iii) an index which reflects ¼ of the difference between the relative value of physicians' work effort in each of the different fee schedule areas and the national average of such work effort.

(B) CLASS-SPECIFIC GEOGRAPHIC COST-OF-PRACTICE INDICES.—The Secretary may establish more than one index under subparagraph (A)(i) in the case of classes of physicians' services, if, because of differences in the mix of goods and services comprising practice expenses for the different classes of services, the application of a single index under such clause to different classes of such services would be substantially inequitable.

(C) PERIODIC REVIEW AND ADJUSTMENTS IN GEOGRAPHIC ADJUSTMENT FACTORS.—The Secretary, not less often than every 3 years, shall, in consultation with appropriate representatives of physicians, review the indices established under subparagraph (A) and the geographic index values applied under this subsection for all fee schedule areas. Based on such review, the Secretary may revise such index and adjust such index values, except that, if more than 1 year has elapsed since the date of the last previous adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made.

(D) USE OF RECENT DATA.—In establishing indices and index values under this paragraph, the Secretary shall use the most recent data available relating to practice expenses, malpractice expenses, and physician work effort in different fee schedule areas.

(E) FLOOR AT 1.0 ON WORK GEOGRAPHIC INDEX.—After calculating the work geographic index in subparagraph (A)(iii), for purposes of payment for services furnished on or after January 1, 2004, and before January 1, 2018, the Secretary shall increase the work geographic index to 1.00 for any locality for which such work geographic index is less than 1.00.

(G) FLOOR FOR PRACTICE EXPENSE, MALPRACTICE, AND WORK GEOGRAPHIC INDICES FOR SERVICES FURNISHED IN ALASKA.—For purposes of payment for services furnished in Alaska on or after January 1, 2004, and before January 1, 2006, after calculating the practice expense, malpractice, and work geographic indices in clauses (i), (ii), and (iii) of subparagraph (A) and in subparagraph (B), the Secretary shall increase any such index to 1.67 if such index would otherwise be less than 1.67. For purposes of payment for

services furnished in the State described in the preceding sentence on or after January 1, 2009, after calculating the work geographic index in subparagraph (A)(iii), the Secretary shall increase the work geographic index to 1.5 if such index would otherwise be less than 1.5

(H) PRACTICE EXPENSE GEOGRAPHIC ADJUSTMENT FOR 2010 AND SUBSEQUENT YEARS.—

(i) FOR 2010.—Subject to clause (iii), for services furnished during 2010, the employee wage and rent portions of the practice expense geographic index described in subparagraph (A)(i) shall reflect ½ of the difference between the relative costs of employee wages and rents in each of the different fee schedule areas and the national average of such employee wages and rents.

(ii) FOR 2011.—Subject to clause (iii), for services furnished during 2011, the employee wage and rent portions of the practice expense geographic index described in subparagraph (A)(i) shall reflect ½ of the difference between the relative costs of employee wages and rents in each of the different fee schedule areas and the national average of such employee wages and rents.

(iii) HOLD HARMLESS.—The practice expense portion of the geographic adjustment factor applied in a fee schedule area for services furnished in 2010 or 2011 shall not, as a result of the application of clause (i) or (ii), be reduced below the practice expense portion of the geographic adjustment factor under subparagraph (A)(i) (as calculated prior to the application of such clause (i) or (ii), respectively) for such area for such year.

(iv) ANALYSIS.—The Secretary shall analyze current methods of establishing practice expense geographic adjustments under subparagraph (A)(i) and evaluate data that fairly and reliably establishes distinctions in the costs of operating a medical practice in the different fee schedule areas. Such analysis shall include an evaluation of the following:

(I) The feasibility of using actual data or reliable survey data developed by medical organizations on the costs of operating a medical practice, including office rents and non-physician staff wages, in different fee schedule areas.

(II) The office expense portion of the practice expense geographic adjustment described in subparagraph (A)(i), including the extent to which types of office expenses are determined in local markets instead of national markets.

(III) The weights assigned to each of the categories within the practice expense geographic adjustment described in subparagraph (A)(i).

(v) REVISION FOR 2012 AND SUBSEQUENT YEARS.—As a result of the analysis described in clause (iv), the Secretary shall, not later than January 1, 2012, make

appropriate adjustments to the practice expense geographic adjustment described in subparagraph (A)(i) to ensure accurate geographic adjustments across fee schedule areas, including—

(I) basing the office rents component and its weight on office expenses that vary among fee schedule areas; and

(II) considering a representative range of professional and non-professional personnel employed in a medical office based on the use of the American Community Survey data or other reliable data for wage adjustments.

Such adjustments shall be made without regard to adjustments made pursuant to clauses (i) and (ii) and shall be made in a budget neutral manner.

(I) FLOOR FOR PRACTICE EXPENSE INDEX FOR SERVICES FURNISHED IN FRONTIER STATES.—

(i) IN GENERAL.—Subject to clause (ii), for purposes of payment for services furnished in a frontier State (as defined in section 1886(d)(3)(E)(iii)(II)) on or after January 1, 2011, after calculating the practice expense index in subparagraph (A)(i), the Secretary shall increase any such index to 1.00 if such index would otherwise be less that 1.00. The preceding sentence shall not be applied in a budget neutral manner.

(ii) LIMITATION.—This subparagraph shall not apply to services furnished in a State that receives a non-labor related share adjustment under section 1886(d)(5)(H).

(2) COMPUTATION OF GEOGRAPHIC ADJUSTMENT FACTOR.—For purposes of subsection (b)(1)(C), for all physicians' services for each fee schedule area the Secretary shall establish a geographic adjustment factor equal to the sum of the geographic cost-of-practice adjustment factor (specified in paragraph (3)), the geographic malpractice adjustment factor (specified in paragraph (4)), and the geographic physician work adjustment factor (specified in paragraph (5)) for the service and the area.

(3) GEOGRAPHIC COST-OF-PRACTICE ADJUSTMENT FACTOR.—For purposes of paragraph (2), the "geographic cost-of-practice adjustment factor", for a service for a fee schedule area, is the product of—

(A) the proportion of the total relative value for the service that reflects the relative value units for the practice expense component, and

(B) the geographic cost-of-practice index value for the area for the service, based on the index established under paragraph (1)(A)(i) or (1)(B) (as the case may be).

(4) GEOGRAPHIC MALPRACTICE ADJUSTMENT FACTOR.—For purposes of paragraph (2), the "geographic malpractice adjustment factor", for a service for a fee schedule area, is the product of—

(A) the proportion of the total relative value for the service that reflects the relative value units for the malpractice component, and

(B) the geographic malpractice index value for the area, based on the index established under paragraph (1)(A)(ii).

(5) GEOGRAPHIC PHYSICIAN WORK ADJUSTMENT FACTOR.—For purposes of paragraph (2), the "geographic physician work adjustment factor", for a service for a fee schedule area, is the product of—

(A) the proportion of the total relative value for the service that reflects the relative value units for the work component, and

(B) the geographic physician work index value for the area, based on the index established under paragraph (1)(A)(iii).

(6) USE OF MSAS AS FEE SCHEDULE AREAS IN CALIFORNIA.—

(A) IN GENERAL.—Subject to the succeeding provisions of this paragraph and notwithstanding the previous provisions of this subsection, for services furnished on or after January 1, 2017, the fee schedule areas used for payment under this section applicable to California shall be the following:

(i) Each Metropolitan Statistical Area (each in this paragraph referred to as an "MSA"), as defined by the Director of the Office of Management and Budget as of December 31 of the previous year, shall be a fee schedule area.

(ii) All areas not included in an MSA shall be treated as a single rest-of-State fee schedule area.

(B) TRANSITION FOR MSAS PREVIOUSLY IN REST-OF-STATE PAYMENT LOCALITY OR IN LOCALITY 3.—

(i) IN GENERAL.—For services furnished in California during a year beginning with 2017 and ending with 2021 in an MSA in a transition area (as defined in subparagraph (D)), subject to subparagraph (C), the geographic index values to be applied under this subsection for such year shall be equal to the sum of the following:

(I) CURRENT LAW COMPONENT.—The old weighting factor (described in clause (ii)) for such year multiplied by the geographic index values under this subsection for the fee schedule area that included such MSA that would have applied in such area (as estimated by the Secretary) if this paragraph did not apply.

(II) MSA-BASED COMPONENT.—The MSA-based weighting factor (described in clause (iii)) for such year multiplied by the geographic index values computed for the fee schedule area under subparagraph (A) for the year (determined without regard to this subparagraph).

(ii) OLD WEIGHTING FACTOR.—The old weighting factor described in this clause—

(I) for 2017, is 5/6; and

(II) for each succeeding year, is the old weighting factor described in this clause for the previous year minus 1/6.

(iii) MSA-BASED WEIGHTING FACTOR.—The MSA-based weighting factor described in this clause for a year is 1 minus the old weighting factor under clause (ii) for that year.

(C) HOLD HARMLESS.—For services furnished in a transition area in California during a year beginning with 2017, the geographic index values to be applied under this subsection for such year shall not be less than the corresponding geographic index values that would have applied in such transition area (as estimated by the Secretary) if this paragraph did not apply.

(D) TRANSITION AREA DEFINED.—In this paragraph, the term "transition area" means each of the following fee schedule areas for 2013:

(i) The rest-of-State payment locality.

(ii) Payment locality 3.

(E) REFERENCES TO FEE SCHEDULE AREAS.—Effective for services furnished on or after January 1, 2017, for California, any reference in this section to a fee schedule area shall be deemed a reference to a fee schedule area established in accordance with this paragraph.

(f) SUSTAINABLE GROWTH RATE.—

(1) PUBLICATION.—The Secretary shall cause to have published in the Federal Register not later than—

(A) November 1, 2000, the sustainable growth rate for 2000 and 2001; and

(B) November 1 of each succeeding year through 2014 the sustainable growth rate for such succeeding year and each of the preceding 2 years.

(2) SPECIFICATION OF GROWTH RATE.—The sustainable growth rate for all physicians' services for a fiscal year (beginning with fiscal year 1998 and ending with fiscal year 2000) and a year beginning with 2000 and ending with 2014 shall be equal to the product of—

(A) 1 plus the Secretary's estimate of the weighted average percentage increase (divided by 100) in the fees for all physicians' services in the applicable period involved,

(B) 1 plus the Secretary's estimate of the percentage change (divided by 100) in the average number of individuals enrolled under this part (other than Medicare+Choice plan enrollees) from the previous applicable period to the applicable period involved,

(C) 1 plus the Secretary's estimate of the annual average percentage growth in real gross domestic product per capita (divided by 100) during the 10-year period ending with the applicable period involved, and

(D) 1 plus the Secretary's estimate of the percentage change (divided by 100) in expenditures for all physicians' services in the applicable period (compared with the previous applicable period) which will result from changes in law and regulations, determined without taking into account estimated changes in expenditures resulting from the update adjustment factor determined under subsection (d)(3)(B) or (d)(4)(B), as the case may be,

minus 1 and multiplied by 100.

(3) DATA TO BE USED.—For purposes of determining the update adjustment factor under subsection (d)(4)(B) for a year beginning with 2001, the sustainable growth rates taken into consideration in the determination under paragraph (2) shall be determined as follows:

(A) FOR 2001.—For purposes of such calculations for 2001, the sustainable growth rates for fiscal year 2000 and the years 2000 and 2001 shall be determined on the basis of the best data available to the Secretary as of September 1, 2000.

(B) FOR 2002.—For purposes of such calculations for 2002, the sustainable growth rates for fiscal year 2000 and for years 2000, 2001, and 2002 shall be determined on the basis of the best data available to the Secretary as of September 1, 2001.

(C) FOR 2003 AND SUCCEEDING YEARS.—For purposes of such calculations for a year after 2002—

(i) the sustainable growth rates for that year and the preceding 2 years shall be determined on the basis of the best data available to the Secretary as of September 1 of the year preceding the year for which the calculation is made; and

(ii) the sustainable growth rate for any year before a year described in clause (i) shall be the rate as most recently determined for that year under this subsection.

Nothing in this paragraph shall be construed as affecting the sustainable growth rates established for fiscal year 1998 or fiscal year 1999.

(4) DEFINITIONS.—In this subsection:

(A) SERVICES INCLUDED IN PHYSICIANS' SERVICES.—The term "physicians' services" includes other items and services (such as clinical diagnostic laboratory tests and radiology services), specified by the Secretary, that are commonly performed or furnished by a physician or in a physician's office, but does not include services furnished to a Medicare+Choice plan enrollee.

(B) MEDICARE+CHOICE PLAN ENROLLEE.—The term "Medicare+Choice plan enrollee" means, with respect to a fiscal year, an individual enrolled under this part who has elected to receive benefits under this title for the fiscal year through a Medicare+Choice plan offered under part C, and also includes an individual who is receiving benefits under this part through enrollment with an eligible organization with a risk-sharing contract under section 1876.

(C) APPLICABLE PERIOD.—The term "applicable period" means—

(i) a fiscal year, in the case of fiscal year 1998, fiscal year 1999, and fiscal year 2000; or

(ii) a calendar year with respect to a year beginning with 2000;

as the case may be.

(g) LIMITATION ON BENEFICIARY LIABILITY.—

(1) LIMITATION ON ACTUAL CHARGES.—

(A) IN GENERAL.—In the case of a nonparticipating physician or nonparticipating supplier or other person (as defined in section 1842(i)(2)) who does not accept payment on an assignment-related basis for a physician's service furnished with respect to an individual enrolled under this part, the following rules apply:

(i) APPLICATION OF LIMITING CHARGE.—No person may bill or collect an actual charge for the service in excess of the limiting charge described in paragraph (2) for such service.

(ii) NO LIABILITY FOR EXCESS CHARGES.—No person is liable for payment of any amounts billed for the service in excess of such limiting charge.

(iii) CORRECTION OF EXCESS CHARGES.—If such a physician, supplier, or other person bills, but does not collect, an actual charge for a service in violation of clause (i), the physician, supplier, or other person shall reduce on a timely basis the actual charge billed for the service to an amount not to exceed the limiting charge for the service.

(iv) REFUND OF EXCESS COLLECTIONS.—If such a physician, supplier, or other person collects an actual charge for a service in violation of clause (i), the physician, supplier, or other person shall provide on a timely basis a refund to the individual charged in the amount by which the amount collected exceeded the limiting charge for the service. The amount of such a refund shall be reduced to the extent the individual has an outstanding balance owed by the individual to the physician.

(B) SANCTIONS.—If a physician, supplier, or other person—

(i) knowingly and willfully bills or collects for services in violation of subparagraph (A)(i) on a repeated basis, or

(ii) fails to comply with clause (iii) or (iv) of subparagraph (A) on a timely basis,

the Secretary may apply sanctions against the physician, supplier, or other person in accordance with paragraph (2) of section 1842(j). In applying this subparagraph, paragraph (4) of such section applies in the same manner as such paragraph applies to such section and any reference in such section to a physician is deemed also to include a reference to a supplier or other person under this subparagraph.

(C) TIMELY BASIS.—For purposes of this paragraph, a correction of a bill for an excess charge or refund of an amount with respect to a violation of subparagraph (A)(i) in the case of a service is considered to be provided "on a timely basis", if the reduction or refund is made not later than 30 days after the date the physician, supplier, or other person is notified by the carrier under this part of such violation and of the requirements of subparagraph (A).

(2) LIMITING CHARGE DEFINED.—

(A) FOR 1991.—For physicians' services of a physician furnished during 1991, other than radiologist services subject to section 1834(b), the "limiting charge" shall be the same percentage (or, if less, 25 percent) above the recognized payment amount under this part with respect to the physician (as a nonparticipating physician) as the percentage by which—

(i) the maximum allowable actual charge (as determined under section 1842(j)(1)(C) as of December 31, 1990, or, if less, the maximum actual charge otherwise permitted for the service under this part as of such date) for the service of the physician, exceeds

(ii) the recognized payment amount for the service of the physician (as a nonparticipating physician) as of such date.

In the case of evaluation and management services (as specified in section 1842(b)(16)(B)(ii)), the preceding sentence shall be applied by substituting "40 percent" for "25 percent".

(B) FOR 1992.—For physicians' services furnished during 1992, other than radiologist services subject to section 1834(b), the "limiting charge" shall be the same percentage (or, if less, 20 percent) above the recognized payment amount under this part for nonparticipating physicians as the percentage by which—

(i) the limiting charge (as determined under subparagraph (A) as of December 31, 1991) for the service, exceeds

(ii) the recognized payment amount for the service for nonparticipating physicians as of such date.

(C) AFTER 1992.—For physicians' services furnished in a year after 1992, the "limiting charge" shall be 115 percent of the recognized payment amount under this part for nonparticipating physicians or for nonparticipating suppliers or other persons.

(D) RECOGNIZED PAYMENT AMOUNT.—In this section, the term "recognized payment amount" means, for services furnished on or after January 1, 1992, the fee schedule amount determined under subsection (a) (or, if payment under this part is made on a basis other than the fee schedule under this section, 95 percent of the other payment basis), and, for services furnished during 1991, the applicable percentage (as defined in section 1842(b)(4)(A)(iv)) of the prevailing charge (or fee schedule amount) for nonparticipating physicians for that year.

(3) LIMITATION ON CHARGES FOR MEDICARE BENEFICIARIES ELIGIBLE FOR MEDICAID BENEFITS.—

(A) IN GENERAL.—Payment for physicians' services furnished on or after April 1, 1990, to an individual who is enrolled under this part and eligible for any medical assistance (including as a qualified medicare beneficiary, as defined in section 1905(p)(1)) with respect to such services under a State plan approved under title XIX may only be made on an assignment-related basis and the provisions of section 1902(n)(3)(A) apply to further limit permissible charges under this section.

(B) PENALTY.—A person may not bill for physicians' services subject to subparagraph (A) other than on an assignment-related basis. No person is liable for payment of any amounts billed for such a service in violation of the previous sentence. If a person knowingly and willfully bills for physicians' services in violation of the first sentence, the Secretary may apply sanctions against the person in accordance with section 1842(j)(2).

(4) PHYSICIAN SUBMISSION OF CLAIMS.—

(A) IN GENERAL.—For services furnished on or after September 1, 1990, within 1 year after the date of providing a service for which payment is made under this part on a reasonable charge or fee schedule basis, a physician, supplier, or other person (or an employer or facility in the cases described in section 1842(b)(6)(A))—

(i) shall complete and submit a claim for such service on a standard claim form specified by the Secretary to the carrier on behalf of a beneficiary, and

(ii) may not impose any charge relating to completing and submitting such a form.

(B) PENALTY.—(i) With respect to an assigned claim wherever a physician, provider, supplier or other person (or an employer or facility in the cases described in section 1842(b)(6)(A)) fails to submit such a claim as required in subparagraph (A), the Secretary shall reduce by 10 percent the amount that would otherwise be paid for such claim under this part.

(ii) If a physician, supplier, or other person (or an employer or facility in the cases described in section 1842(b)(6)(A)) fails to submit a claim required to be submitted under subparagraph (A) or imposes a charge in violation of such subparagraph, the Secretary shall apply the sanction with respect to such a violation in the same manner as a sanction may be imposed under section 1842(p)(3) for a violation of section 1842(p)(1).

(5) ELECTRONIC BILLING; DIRECT DEPOSIT.—The Secretary shall encourage and develop a system providing for expedited payment for claims submitted electronically. The Secretary shall also encourage and provide incentives allowing for direct deposit as payments for services furnished by participating physicians. The Secretary shall provide physicians with such technical information as necessary to enable such physicians to submit claims electronically. The Secretary shall submit a plan to Congress on this paragraph by May 1, 1990.

(6) MONITORING OF CHARGES.—

(A) IN GENERAL.—The Secretary shall monitor—

(i) the actual charges of nonparticipating physicians for physicians' services furnished on or after January 1, 1991, to individuals enrolled under this part, and

(ii) changes (by specialty, type of service, and geographic area) in (I) the proportion of expenditures for physicians' services provided under this part by participating physicians, (II) the proportion of expenditures for such services for which payment is made under this part on an assignment-related basis, and

(III) the amounts charged above the recognized payment amounts under this part.

(B) REPORT.—The Secretary shall, by not later than April 15 of each year (beginning in 1992), report to the Congress information on the extent to which actual charges exceed limiting charges, the number and types of services involved, and the average amount of excess charges and information regarding the changes described in subparagraph (A)(ii).

(C) PLAN.—If the Secretary finds that there has been a significant decrease in the proportions described in subclauses (I) and (II) of subparagraph (A)(ii) or an increase in the amounts described in subclause (III) of that subparagraph, the Secretary shall develop a plan to address such a problem and transmit to Congress recommendations regarding the plan. The Medicare Payment Advisory Commission shall review the Secretary's plan and recommendations and transmit to Congress its comments regarding such plan and recommendations.

(7) MONITORING OF UTILIZATION AND ACCESS.—

(A) IN GENERAL.—The Secretary shall monitor—

(i) changes in the utilization of and access to services furnished under this part within geographic, population, and service related categories,

(ii) possible sources of inappropriate utilization of services furnished under this part which contribute to the overall level of expenditures under this part, and

(iii) factors underlying these changes and their interrelationships.

(B) REPORT.—The Secretary shall by not later than April 15, of each year (beginning with 1991) report to the Congress on the changes described in subparagraph (A)(i) and shall include in the report an examination of the factors (including factors relating to different services and specific categories and groups of services and geographic and demographic variations in utilization) which may contribute to such changes.

(C) RECOMMENDATIONS.—The Secretary shall include in each annual report under subparagraph (B) recommendations—

(i) addressing any identified patterns of inappropriate utilization,

(ii) on utilization review,

(iii) on physician education or patient education,

(iv) addressing any problems of beneficiary access to care made evident by the monitoring process, and

(v) on such other matters as the Secretary deems appropriate.

The Medicare Payment Advisory Commission shall comment on the Secretary's recommendations and in developing its comments, the Commission shall convene and consult a panel of physician experts to evaluate the implications of medical utilization patterns for the quality of and access to patient care.

(h) SENDING INFORMATION TO PHYSICIANS.—Before the beginning of each year (beginning with 1992), the Secretary shall send to each physician or nonparticipating supplier or other person furnishing physicians' services (as defined in section 1848(j)(3)) furnishing physicians' services under this part, for services commonly performed by the physician, supplier, or other person, information on fee schedule amounts that apply for the year in the fee schedule area for participating and non-participating physicians, and the maximum amount that may be charged consistent with subsection (g)(2). Such information shall be transmitted in conjunction with notices to physicians, suppliers, and other persons under section 1842(h) (relating to the participating physician program) for a year.

(i) MISCELLANEOUS PROVISIONS.—

(1) RESTRICTION ON ADMINISTRATIVE AND JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869 or otherwise of—

(A) the determination of the adjusted historical payment basis (as defined in subsection (a)(2)(D)(i)),

(B) the determination of relative values and relative value units under subsection (c), including adjustments under subsections (c)(2)(F), (c)(2)(H), and (c)(2)(I) and section 13515(b) of the Omnibus Budget Reconciliation Act of 1993,

(C) the determination of conversion factors under subsection (d), including without limitation a prospective redetermination of the sustainable growth rates for any or all previous fiscal years,

(D) the establishment of geographic adjustment factors under subsection (e),

(E) the establishment of the system for the coding of physicians' services under this section, and

(F) the collection and use of information in the determination of relative values under subsection (c)(2)(M).

(2) ASSISTANTS-AT-SURGERY.—

(A) IN GENERAL.—Subject to subparagraph (B), in the case of a surgical service furnished by a physician, if payment is made separately under this part for the services of a physician serving as an assistant-at-surgery, the fee schedule amount shall not exceed 16 percent of the fee schedule amount otherwise determined under this section for the global surgical service involved.

(B) DENIAL OF PAYMENT IN CERTAIN CASES.—If the Secretary determines, based on the most recent data available, that for a surgical procedure (or class of surgical procedures) the national average percentage of such procedure performed under this part which involve the use of a physician as an assistant at surgery is less than 5 percent, no payment may be made under this part for services of an assistant at surgery involved in the procedure.

(3) NO COMPARABILITY ADJUSTMENT.—For physicians' services for which payment under this part is determined under this section—

(A) a carrier may not make any adjustment in the payment amount under section 1842(b)(3)(B) on the basis that the payment amount is higher than the charge applicable,

for comparable services and under comparable circumstances, to the policyholders and subscribers of the carrier,

(B) no payment adjustment may be made under section 1842(b)(8), and

(C) section 1842(b)(9) shall not apply.

(j) DEFINITIONS.—In this section:

(1) CATEGORY.—For services furnished before January 1, 1998, the term "category" means, with respect to physicians' services, surgical services (as defined by the Secretary and including anesthesia services), primary care services (as defined in section 1842(i)(4)), and all other physicians' services. The Secretary shall define surgical services and publish such definitions in the Federal Register no later than May 1, 1990, after consultation with organizations representing physicians.

(2) FEE SCHEDULE AREA.—Except as provided in subsection (e)(6)(D), the term "fee schedule area" means a locality used under section 1842(b) for purposes of computing payment amounts for physicians' services.

(3) PHYSICIANS' SERVICES.—The term "physicians' services" includes items and services described in paragraphs (1), (2)(A), (2)(D), (2)(G), (2)(P) (with respect to services described in subparagraphs (A) and (C) of section 1861(oo)(2)), (2)(R) (with respect to services described in suparagraphs (B), (C), and (D) of section 1861(pp)(1)), (2)(S), (2)(W), (2)(AA), (2)(DD), (2)(EE), (2)(FF) (including administration of the health risk assessment), (3), (4), (13), (14) (with respect to services described in section 1861(nn)(2)), and (15) of section 1861(s) (other than clinical diagnostic laboratory tests and, except for purposes of subsection (a)(3), (g), and (h) such other items and services as the Secretary may specify).

(4) PRACTICE EXPENSES.—The term "practice expenses" includes all expenses for furnishing physicians' services, excluding malpractice expenses, physician compensation, and other physician fringe benefits.

(k) QUALITY REPORTING SYSTEM.—

(1) IN GENERAL.—The Secretary shall implement a system for the reporting by eligible professionals of data on quality measures specified under paragraph (2). Such data shall be submitted in a form and manner specified by the Secretary (by program instruction or otherwise), which may include submission of such data on claims under this part.

(2) USE OF CONSENSUS-BASED QUALITY MEASURES.—

(A) FOR 2007.—

(i) IN GENERAL.—For purposes of applying this subsection for the reporting of data on quality measures for covered professional services furnished during the period beginning July 1, 2007, and ending December 31, 2007, the quality measures specified under this paragraph are the measures identified as 2007 physician quality measures under the Physician Voluntary Reporting Program as published on the public website of the Centers for Medicare & Medicaid Services as of the date of the enactment of this subsection, except as may be changed by the Secretary based on the results

of a consensus-based process in January of 2007, if such change is published on such website by not later than April 1, 2007.

(ii) SUBSEQUENT REFINEMENTS IN APPLICATION PERMITTED.—The Secretary may, from time to time (but not later than July 1, 2007), publish on such website (without notice or opportunity for public comment) modifications or refinements (such as code additions, corrections, or revisions) for the application of quality measures previously published under clause (i), but may not, under this clause, change the quality measures under the reporting system.

(iii) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement by program instruction or otherwise this subsection for 2007.

(B) FOR 2008 AND 2009.—

(i) IN GENERAL.—For purposes of reporting data on quality measures for covered professional services furnished during 2008 and 2009, the quality measures specified under this paragraph for covered professional services shall be measures that have been adopted or endorsed by a consensus organization (such as the National Quality Forum or AQA), that include measures that have been submitted by a physician specialty, and that the Secretary identifies as having used a consensus-based process for developing such measures. Such measures shall include structural measures, such as the use of electronic health records and electronic prescribing technology.

(ii) PROPOSED SET OF MEASURES.—Not later than August 15 of each of 2007 and 2008, the Secretary shall publish in the Federal Register a proposed set of quality measures that the Secretary determines are described in clause (i) and would be appropriate for eligible professionals to use to submit data to the Secretary in 2008 or 2009, as applicable. The Secretary shall provide for a period of public comment on such set of measures.

(iii) FINAL SET OF MEASURES.—Not later than November 15 of each of 2007 and 2008, the Secretary shall publish in the Federal Register a final set of quality measures that the Secretary determines are described in clause (i) and would be appropriate for eligible professionals to use to submit data to the Secretary in 2008 or 2009, as applicable.

(C) FOR 2010 AND SUBSEQUENT YEARS.—

(i) IN GENERAL.—Subject to clause (ii), for purposes of reporting data on quality measures for covered professional services furnished during 2010 and each subsequent year, subject to subsection (m)(3)(C), the quality measures (including electronic prescribing quality measures) specified under this paragraph shall be such measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a).

(ii) EXCEPTION.—In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary, such as the AQA alliance.

(D) OPPORTUNITY TO PROVIDE INPUT ON MEASURES FOR 2009 AND SUBSEQUENT YEARS.—For each quality measure (including an electronic prescribing quality measure) adopted by the Secretary under subparagraph (B) (with respect to 2009) or subparagraph (C), the Secretary shall ensure that eligible professionals have the opportunity to provide input during the development, endorsement, or selection of measures applicable to services they furnish.

(3) COVERED PROFESSIONAL SERVICES AND ELIGIBLE PROFESSIONALS DEFINED.—For purposes of this subsection:

(A) COVERED PROFESSIONAL SERVICES.—The term "covered professional services" means services for which payment is made under, or is based on, the fee schedule established under this section and which are furnished by an eligible professional.

(B) ELIGIBLE PROFESSIONAL.—The term "eligible professional" means any of the following:

(i) A physician.

(ii) A practitioner described in section 1842(b)(18)(C).

(iii) A physical or occupational therapist or a qualified speech-language pathologist.

(iv) Beginning with 2009, a qualified audiologist (as defined in section 1861(ll)(3)(B)).

(4) USE OF REGISTRY-BASED REPORTING.—As part of the publication of proposed and final quality measures for 2008 under clauses (ii) and (iii) of paragraph (2)(B), the Secretary shall address a mechanism whereby an eligible professional may provide data on quality measures through an appropriate medical registry (such as the Society of Thoracic Surgeons National Database) or through a Maintenance of Certification program operated by a specialty body of the American Board of Medical Specialties that meets the criteria for such a registry, as identified by the Secretary.

(5) IDENTIFICATION UNITS.—For purposes of applying this subsection, the Secretary may identify eligible professionals through billing units, which may include the use of the Provider Identification Number, the unique physician identification number (described in section 1833(q)(1)), the taxpayer identification number, or the National Provider Identifier. For purposes of applying this subsection for 2007, the Secretary shall use the taxpayer identification number as the billing unit.

(6) EDUCATION AND OUTREACH.—The Secretary shall provide for education and outreach to eligible professionals on the operation of this subsection.

(7) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of the development and implementation of the reporting system under paragraph (1), including identification of quality measures under paragraph (2) and the application of paragraphs (4) and (5).

(8) IMPLEMENTATION.—The Secretary shall carry out this subsection acting through the Administrator of the Centers for Medicare & Medicaid Services.

(9) CONTINUED APPLICATION FOR PURPOSES OF MIPS AND FOR CERTAIN PROFESSIONALS VOLUNTEERING TO REPORT.—The Secretary shall, in accordance with subsection (q)(1)(F), carry out the provisions of this subsection—

(A) for purposes of subsection (q); and

(B) for eligible professionals who are not MIPS eligible professionals (as defined in subsection (q)(1)(C)) for the year involved.

(l) PHYSICIAN ASSISTANCE AND QUALITY INITIATIVE FUND.—

(1) ESTABLISHMENT.—The Secretary shall establish under this subsection a Physician Assistance and Quality Initiative Fund (in this subsection referred to as the "Fund") which shall be available to the Secretary for physician payment and quality improvement initiatives, which may include application of an adjustment to the update of the conversion factor under subsection (d).

(2) FUNDING.—

(A) AMOUNT AVAILABLE.—

(i) IN GENERAL.—Subject to clause (ii), there shall be available to the Fund the following amounts:

(I) For expenditures during 2008, an amount equal to $150,500,000.

(II) For expenditures during 2009, an amount equal to $24,500,000.

(ii) LIMITATIONS ON EXPENDITURES.—

(I) 2008.—The amount available for expenditures during 2008 shall be reduced as provided by subparagraph (A) of section 225(c)(1) and section 524 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2008 (division G of the Consolidated Appropriations Act, 2008).

(II) 2009.—The amount available for expenditures during 2009 shall be reduced as provided by subparagraph (B) of such section 225(c)(1).

(B) TIMELY OBLIGATION OF ALL AVAILABLE FUNDS FOR SERVICES.—The Secretary shall provide for expenditures from the Fund in a manner designed to provide (to the maximum extent feasible) for the obligation of the entire amount available for expenditures, after application of subparagraph (A)(ii), during—

(i) 2008 for payment with respect to physicians' services furnished during 2008; and

(ii) 2009 for payment with respect to physicians' services furnished during 2009.

(C) PAYMENT FROM TRUST FUND.—The amount specified in subparagraph (A) shall be available to the Fund, as expenditures are made from the Fund, from the Federal Supplementary Medical Insurance Trust Fund under section 1841.

(D) FUNDING LIMITATION.—Amounts in the Fund shall be available in advance of appropriations in accordance with subparagraph (B) but only if the total amount obligated from the Fund does not exceed the amount available to the Fund under subparagraph (A). The Secretary may obligate funds from the Fund only if the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services and the appropriate budget officer certify) that there are available in the Fund sufficient amounts to cover all such obligations incurred consistent with the previous sentence.

(E) CONSTRUCTION.—In the case that expenditures from the Fund are applied to, or otherwise affect, a conversion factor under subsection (d) for a year, the conversion factor under such subsection shall be computed for a subsequent year as if such application or effect had never occurred.

(m) INCENTIVE PAYMENTS FOR QUALITY REPORTING.—

(1) INCENTIVE PAYMENTS.—

(A) IN GENERAL.—For 2007 through 2014, with respect to covered professional services furnished during a reporting period by an eligible professional, if—

(i) there are any quality measures that have been established under the physician reporting system that are applicable to any such services furnished by such professional for such reporting period;

(ii) the eligible professional satisfactorily submits (as determined under this subsection) to the Secretary data on such quality measures in accordance with such reporting system for such reporting period,

in addition to the amount otherwise paid under this part, there also shall be paid to the eligible professional (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6)) or, in the case of a group practice under paragraph (3)(C), to the group practice, from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 an amount equal to the applicable quality percent of the Secretary's estimate (based on claims submitted not later than 2 months after the end of the reporting period) of the allowed charges under this part for all such covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (3)(C), by the group practice) during the reporting period.

(B) APPLICABLE QUALITY PERCENT.—For purposes of subparagraph (A), the term "applicable quality percent" means—

(i) for 2007 and 2008, 1.5 percent; and

(ii) for 2009 and 2010, 2.0 percent;

(iii) for 2011, 1.0 percent; and

(iv) for 2012, 2013, and 2014, 0.5 percent.

(2) INCENTIVE PAYMENTS FOR ELECTRONIC PRESCRIBING.—

(A) IN GENERAL.—Subject to subparagraph (D), for 2009 through 2013, with respect to covered professional services furnished during a reporting period by an eligible professional, if the eligible professional is a successful electronic prescriber for such reporting period, in addition to the amount otherwise paid under this part, there also shall be paid to the eligible professional (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6)) or, in the case of a group practice under paragraph (3)(C), to the group practice, from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 an amount equal to the applicable electronic prescribing percent of the Secretary's estimate (based on claims submitted not later than 2 months after the end of the reporting period) of the allowed charges under this part for all such covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (3)(C), by the group practice) during the reporting period.

(B) LIMITATION WITH RESPECT TO ELECTRONIC PRESCRIBING QUALITY MEASURES.—The provisions of this paragraph and subsection (a)(5) shall not apply to an eligible professional (or, in the case of a group practice under paragraph (3)(C), to the group practice) if, for the reporting period (or, for purposes of subsection (a)(5), for the reporting period for a year)—

(i) the allowed charges under this part for all covered professional services furnished by the eligible professional (or group, as applicable) for the codes to which the electronic prescribing quality measure applies (as identified by the Secretary and published on the Internet website of the Centers for Medicare & Medicaid Services as of January 1, 2008, and as subsequently modified by the Secretary) are less than 10 percent of the total of the allowed charges under this part for all such covered professional services furnished by the eligible professional (or the group, as applicable); or

(ii) if determined appropriate by the Secretary, the eligible professional does not submit (including both electronically and nonelectronically) a sufficient number (as determined by the Secretary) of prescriptions under part D.

If the Secretary makes the determination to apply clause (ii) for a period, then clause (i) shall not apply for such period.

(C) APPLICABLE ELECTRONIC PRESCRIBING PERCENT.—For purposes of subparagraph (A), the term "applicable electronic prescribing percent" means—

(i) for 2009 and 2010, 2.0 percent;

(ii) for 2011 and 2012, 1.0 percent; and

(iii) for 2013, 0.5 percent.

(D) LIMITATION WITH RESPECT TO EHR INCENTIVE PAYMENTS.—The provisions of this paragraph shall not apply

to an eligible professional (or, in the case of a group practice under paragraph (3)(C), to the group practice) if, for the EHR reporting period the eligible professional (or group practice) receives an incentive payment under subsection (o)(1)(A) with respect to a certified EHR technology (as defined in subsection (o)(4)) that has the capability of electronic prescribing.

(3) SATISFACTORY REPORTING AND SUCCESSFUL ELECTRONIC PRESCRIBER AND DESCRIBED.—

(A) IN GENERAL.—For purposes of paragraph (1), an eligible professional shall be treated as satisfactorily submitting data on quality measures for covered professional services for a reporting period (or, for purposes of subsection (a)(8), for the quality reporting period for the year) if quality measures have been reported as follows:

(i) THREE OR FEWER QUALITY MEASURES APPLICABLE.—If there are no more than 3 quality measures that are provided under the physician reporting system and that are applicable to such services of such professional furnished during the period, each such quality measure has been reported under such system in at least 80 percent of the cases in which such measure is reportable under the system.

(ii) FOUR OR MORE QUALITY MEASURES APPLICABLE.—If there are 4 or more quality measures that are provided under the physician reporting system and that are applicable to such services of such professional furnishedduring the period, at least 3 such quality measures have been reported under such system in at least 80 percent of the cases in which the respective measure is reportable under the system.

For years after 2008, quality measures for purposes of this subparagraph shall not include electronic prescribing quality measures.

(B) SUCCESSFUL ELECTRONIC PRESCRIBER.—

(i) IN GENERAL.—For purposes of paragraph (2) and subsection (a)(5), an eligible professional shall be treated as a successful electronic prescriber for a reporting period (or, for purposes of subsection (a)(5), for the reporting period for a year) if the eligible professional meets the requirement described in clause (ii), or, if the Secretary determines appropriate, the requirement described in clause (iii). If the Secretary makes the determination under the preceding sentence to apply the requirement described in clause (iii) for a period, then the requirement described in clause (ii) shall not apply for such period.

(ii) REQUIREMENT FOR SUBMITTING DATA ON ELECTRONIC PRESCRIBING QUALITY MEASURES.—The requirement described in this clause is that, with respect to covered professional services furnished by an eligible professional during a reporting period (or, for purposes of subsection (a)(5), for the reporting period for a year), if there are any electronic prescribing quality measures that have been established under the physi-

cian reporting system and are applicable to any such services furnished by such professional for the period, such professional reported each such measure under such system in at least 50 percent of the cases in which such measure is reportable by such professional under such system.

(iii) REQUIREMENT FOR ELECTRONICALLY PRESCRIBING UNDER PART D.—The requirement described in this clause is that the eligible professional electronically submitted a sufficient number (as determined by the Secretary) of prescriptions under part D during the reporting period (or, for purposes of subsection (a)(5), for the reporting period for a year).

(iv) USE OF PART D DATA.—Notwithstanding sections 1860D-15(d)(2)(B) and 1860D-15(f)(2), the Secretary may use data regarding drug claims submitted for purposes of section 1860D-15 that are necessary for purposes of clause (iii), paragraph (2)(B)(ii), and paragraph (5)(G).

(v) STANDARDS FOR ELECTRONIC PRESCRIBING.—To the extent practicable, in determining whether eligible professionals meet the requirements under clauses (ii) and (iii) for purposes of clause (i), the Secretary shall ensure that eligible professionals utilize electronic prescribing systems in compliance with standards established for such systems pursuant to the Part D Electronic Prescribing Program under section 1860D–4(e).

(C) SATISFACTORY REPORTING MEASURES FOR GROUP PRACTICES.—

(i) IN GENERAL.—By January 1, 2010, the Secretary shall establish and have in place a process under which eligible professionals in a group practice (as defined by the Secretary) shall be treated as satisfactorily submitting data on quality measures under subparagraph (A) and as meeting the requirement described in subparagraph (B)(ii) for covered professional services for a reporting period (or, for purposes of subsection (a)(5), for a reporting period for a year, or, for purposes of subsection (a)(8), for a quality reporting period for the year) if, in lieu of reporting measures under subsection (k)(2)(C), the group practice reports measures determined appropriate by the Secretary, such as measures that target high-cost chronic conditions and preventive care, in a form and manner, and at a time, specified by the Secretary.

(ii) STATISTICAL SAMPLING MODEL.—The process under clause (i) shall provide and, for 2016 and subsequent years, may provide for the use of a statistical sampling model to submit data on measures, such as the model used under the Physician Group Practice demonstration project under section 1866A.

(iii) NO DOUBLE PAYMENTS.—Payments to a group practice under this subsection by reason of the process under clause (i) shall be in lieu of the payments that would otherwise be made under this subsection to eli-

gible professionals in the group practice for satisfactorily submitting data on quality measures.

(D) SATISFACTORY REPORTING MEASURES THROUGH PARTICIPATION IN A QUALIFIED CLINICAL DATA REGISTRY.—For 2014 and subsequent years, the Secretary shall treat an eligible professional as satisfactorily submitting data on quality measures under subparagraph (A) and, for 2016 and subsequent years, subparagraph (A) or (C) if, in lieu of reporting measures under subsection (k)(2)(C), the eligible professional is satisfactorily participating, as determined by the Secretary, in a qualified clinical data registry (as described in subparagraph (E)) for the year.

(E) QUALIFIED CLINICAL DATA REGISTRY.—

(i) IN GENERAL.—The Secretary shall establish requirements for an entity to be considered a qualified clinical data registry. Such requirements shall include a requirement that the entity provide the Secretary with such information, at such times, and in such manner, as the Secretary determines necessary to carry out this subsection.

(ii) CONSIDERATIONS.—In establishing the requirements under clause (i), the Secretary shall consider whether an entity—

(I) has in place mechanisms for the transparency of data elements and specifications, risk models, and measures;

(II) requires the submission of data from participants with respect to multiple payers;

(III) provides timely performance reports to participants at the individual participant level; and

(IV) supports quality improvement initiatives for participants.

(iii) MEASURES.—With respect to measures used by a qualified clinical data registry—

(I) sections 1890(b)(7) and 1890A(a) shall not apply; and

(II) measures endorsed by the entity with a contract with the Secretary under section 1890(a) may be used.

(iv) CONSULTATION.—In carrying out this subparagraph, the Secretary shall consult with interested parties.

(v) DETERMINATION.—The Secretary shall establish a process to determine whether or not an entity meets the requirements established under clause (i). Such process may involve one or both of the following:

(I) A determination by the Secretary.

(II) A designation by the Secretary of one or more independent organizations to make such determination.

(F) AUTHORITY TO REVISE SATISFACTORILY REPORTING DATA.—For years after 2009, the Secretary, in consultation with stakeholders and experts, may revise the criteria under this subsection for satisfactorily submitting data on quality measures under subparagraph (A) and the criteria

for submitting data on electronic prescribing quality measures under subparagraph (B)(ii).

(4) FORM OF PAYMENT.—The payment under this subsection shall be in the form of a single consolidated payment.

(5) APPLICATION.—

(A) PHYSICIAN REPORTING SYSTEM RULES.—Paragraphs (5), (6),and (8) of subsection (k) shall apply for purposes of this subsection in the same manner as they apply for purposes of such subsection.

(B) COORDINATION WITH OTHER BONUS PAYMENTS.—The provisions of this subsection shall not be taken into account in applying subsections (m) and (u) of section 1833 and any payment under such subsections shall not be taken into account in computing allowable charges under this subsection.

(C) IMPLEMENTATION.—Notwithstanding any other provision of law, for 2007, 2008, and 2009, the Secretary may implement by program instruction or otherwise this subsection.

(D) VALIDATION.—

(i) IN GENERAL.—Subject to the succeeding provisions of this subparagraph, for purposes of determining whether a measure is applicable to the covered professional services of an eligible professional under this subsection for 2007 and 288, the Secretary shall presume that if an eligible professional submits data for a measure, such measure is applicable to such professional.

(ii) METHOD.—The Secretary may establish procedures to validate (by sampling or other means as the Secretary determines to be appropriate) whether measures applicable to covered professional services of an eligible professional have been reported.

(iii) DENIAL OF PAYMENT AUTHORITY.—If the Secretary determines that an eligible professional (or, in the case of a group practice under paragraph (3)(C), the group practice) has not reported measures applicable to covered professional services of such professional, the Secretary shall not pay the incentive payment under this subsection. If such payments for such period have already been made, the Secretary shall recoup such payments from the eligible professional (or the group practice).

(E) LIMITATIONS ON REVIEW.—

Except as provided in subparagraph (I), there shall be no administrative or judicial review under 1869, section 1878, or otherwise of

(i) the determination of measures applicable to services furnished by eligible professionals under this subsection;

(ii) the determination of satisfactory reporting under this subsection;

(iii) the determination of a successful electronic prescriber under paragraph (3), the limitation under

paragraph (2)(B), and the exception under subsection (a)(5)(B); and

(iv) the determination of any incentive payment under this subsection and the payment adjustment under paragraphs (5)(A) and (8)(A) of subsection (a).

(F) EXTENSION.—For 2008 through reporting periods occurring in 2015, the Secretary shall establish and, for reporting periods occurring in 2016 and subsequent years, the Secretary may establish alternative criteria for satisfactorily reporting under this subsection and alternative reporting periods under paragraph (6)(C) for reporting groups of measures under subsection (k)(2)(B) and for reporting using the method specified in subsection (k)(4).

(G) POSTING ON WEBSITE.—The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services, in an easily understandable format, a list of the names of the following:

(i) The eligible professionals (or, in the case of reporting under paragraph (3)(C), the group practices) who satisfactorily submitted data on quality measures under this subsection.

(ii) The eligible professionals (or, in the case of reporting under paragraph (3)(C), the group practices) who are successful electronic prescribers.

(H) FEEDBACK.—The Secretary shall provide timely feedback to eligible professionals on the performance of the eligible professional with respect to satisfactorily submitting data on quality measures under this subsection.

(I) INFORMAL APPEALS PROCESS.—The Secretary shall, by not later than January 1, 2011, establish and have in place an informal process for eligible professionals to seek a review of the determination that an eligible professional did not satisfactorily submit data on quality measures under this subsection.

(6) DEFINITIONS.—For purposes of this subsection:

(A) ELIGIBLE PROFESSIONAL; COVERED PROFESSIONAL SERVICES.—The terms "eligible professional" and "covered professional services" have the meanings given such termsin subsection (k)(3).

(B) PHYSICIAN REPORTING SYSTEM.—The term "physician reporting system" means the system established under subsection (k).

(C) REPORTING PERIOD.—

(i) IN GENERAL.—Subject to clauses (ii) and (iii), the term "reporting period" means—

(I) for 2007, the period beginning on July 1, 2007, and ending on December 31, 2007; and

(II) for 2008 and subsequent years, the entire year.

(ii) AUTHORITY TO REVISE REPORTING PERIOD.—For years after 2009, the Secretary may revise the reporting period under clause (i) if the Secretary determines such revision is appropriate, produces valid results on measures reported, and is consistent with the goals of maximizing scientific validity and reducing adminis-

trative burden. If the Secretary revises such period pursuant to the preceding sentence, the term "reporting period" shall mean such revised period.

(iii) REFERENCE.—Any reference in this subsection to a reporting period with respect to the application of subsection (a)(5) (a)(8) shall be deemed a reference to the reporting period under subsection (a)(5)(D)(iii) or the quality reporting period under subsection (a)(8)(D)(iii), respectively.

(7) INTEGRATION OF PHYSICIAN QUALITY REPORTING AND EHR REPORTING.—Not later than January 1, 2012, the Secretary shall develop a plan to integrate reporting on quality measures under this subsection with reporting requirements under subsection (o) relating to the meaningful use of electronic health records. Such integration shall consist of the following:

(A) The selection of measures, the reporting of which would both demonstrate—

(i) meaningful use of an electronic health record for purposes of subsection (o); and

(ii) quality of care furnished to an individual.

(B) Such other activities as specified by the Secretary.

(8) ADDITIONAL INCENTIVE PAYMENT.—

(A) IN GENERAL.—For 2011 through 2014, if an eligible professional meets the requirements described in subparagraph (B), the applicable quality percent for such year, as described in clauses (iii) and (iv) of paragraph (1)(B), shall be increased by 0.5 percentage points.

(B) REQUIREMENTS DESCRIBED.—In order to qualify for the additional incentive payment described in subparagraph (A), an eligible professional shall meet the following requirements:

(i) The eligible professional shall—

(I) satisfactorily submit data on quality measures for purposes of paragraph (1) for a year; and

(II) have such data submitted on their behalf through a Maintenance of Certification Program (as defined in subparagraph (C)(i)) that meets—

(aa) the criteria for a registry (as described in subsection (k)(4)); or

(bb) an alternative form and manner determined appropriate by the Secretary.

(ii) The eligible professional, more frequently than is required to qualify for or maintain board certification status—

(I) participates in such a Maintenance of Certification program for a year; and

(II) successfully completes a qualified Maintenance of Certification Program practice assessment (as defined in subparagraph (C)(ii)) for such year.

(iii) A Maintenance of Certification program submits to the Secretary, on behalf of the eligible professional, information—

(I) in a form and manner specified by the Secretary, that the eligible professional has success-

fully met the requirements of clause (ii) (which may be in the form of a structural measure);

(II) if requested by the Secretary, on the survey of patient experience with care (as described in subparagraph (C)(ii)(II)); and

(III) as the Secretary may require, on the methods, measures, and data used under the Maintenance of Certification Program and the qualified Maintenance of Certification Program practice assessment.

(C) DEFINITIONS.—For purposes of this paragraph:

(i) The term "Maintenance of Certification Program" means a continuous assessment program, such as qualified American Board of Medical Specialties Maintenance of Certification program or an equivalent program (as determined by the Secretary), that advances quality and the lifelong learning and self-assessment of board certified specialty physicians by focusing on the competencies of patient care, medical knowledge, practice-based learning, interpersonal and communication skills and professionalism. Such a program shall include the following:

(I) The program requires the physician to maintain a valid, unrestricted medical license in the United States.

(II) The program requires a physician to participate in educational and self-assessment programs that require an assessment of what was learned.

(III) The program requires a physician to demonstrate, through a formalized, secure examination, that the physician has the fundamental diagnostic skills, medical knowledge, and clinical judgment to provide quality care in their respective specialty.

(IV) The program requires successful completion of a qualified Maintenance of Certification Program practice assessment as described in clause (ii).

(ii) The term "qualified Maintenance of Certification Program practice assessment" means an assessment of a physician's practice that—

(I) includes an initial assessment of an eligible professional's practice that is designed to demonstrate the physician's use of evidence-based medicine;

(II) includes a survey of patient experience with care; and

(III) requires a physician to implement a quality improvement intervention to address a practice weakness identified in the initial assessment under subclause (I) and then to remeasure to assess performance improvement after such intervention.

(9) CONTINUED APPLICATION FOR PURPOSES OF MIPS AND FOR CERTAIN PROFESSIONALS VOLUNTEERING TO REPORT.—The Sec-

retary shall, in accordance with subsection (q)(1)(F), carry out the processes under this subsection—

(A) for purposes of subsection (q); and

(B) for eligible professionals who are not MIPS eligible professionals (as defined in subsection (q)(1)(C)) for the year involved.

(n) PHYSICIAN FEEDBACK PROGRAM.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—

(i) ESTABLISHMENT.—The Secretary shall establish a Physician Feedback Program (in this subsection referred to as the "Program").

(ii) REPORTS ON RESOURCES.—The Secretary shall use claims data under this title (and may use other data) to provide confidential reports to physicians (and, as determined appropriate by the Secretary, to groups of physicians) that measure the resources involved in furnishing care to individuals under this title.

(iii) INCLUSION OF CERTAIN INFORMATION.—If determined appropriate by the Secretary, the Secretary may include information on the quality of care furnished to individuals under this title by the physician (or group of physicians) in such reports.

(B) RESOURCE USE.—The resources described in subparagraph (A)(ii) may be measured—

(i) on an episode basis;

(ii) on a per capita basis; or

(iii) on both an episode and a per capita basis.

(2) IMPLEMENTATION.—The Secretary shall implement the Program by not later than January 1, 2009.

(3) DATA FOR REPORTS.—To the extent practicable, reports under the Program shall be based on the most recent data available.

(4) AUTHORITY TO FOCUS INITIAL APPLICATION.—The Secretary may focus the initial application of the Program as appropriate, such as focusing the Program on—

(A) physician specialties that account for a certain percentage of all spending for physicians' services under this title;

(B) physicians who treat conditions that have a high cost or a high volume, or both, under this title;

(C) physicians who use a high amount of resources compared to other physicians;

(D) physicians practicing in certain geographic areas; or

(E) physicians who treat a minimum number of individuals under this title.

(5) AUTHORITY TO EXCLUDE CERTAIN INFORMATION IF INSUFFICIENT INFORMATION.—The Secretary may exclude certain information regarding a service from a report under the Program with respect to a physician (or group of physicians) if the Secretary determines that there is insufficient information relating to that service to provide a valid report on that service.

(6) ADJUSTMENT OF DATA.—To the extent practicable, the Secretary shall make appropriate adjustments to the data used

in preparing reports under the Program, such as adjustments to take into account variations in health status and other patient characteristics. For adjustments for reports on utilization under paragraph (9), see subparagraph (D) of such paragraph.

(7) EDUCATION AND OUTREACH.—The Secretary shall provide for education and outreach activities to physicians on the operation of, and methodologies employed under, the Program.

(8) DISCLOSURE EXEMPTION.—Reports under the Program shall be exempt from disclosure under section 552 of title 5, United States Code.

(9) REPORTS ON UTILIZATION.—

(A) DEVELOPMENT OF EPISODE GROUPER.—

(i) IN GENERAL.—The Secretary shall develop an episode grouper that combines separate but clinically related items and services into an episode of care for an individual, as appropriate.

(ii) TIMELINE FOR DEVELOPMENT.—The episode grouper described in subparagraph (A) shall be developed by not later than January 1, 2012.

(iii) PUBLIC AVAILABILITY.—The Secretary shall make the details of the episode grouper described in subparagraph (A) available to the public.

(iv) ENDORSEMENT.—The Secretary shall seek endorsement of the episode grouper described in subparagraph (A) by the entity with a contract under section 1890(a).

(B) REPORTS ON UTILIZATION.—Effective beginning with 2012, the Secretary shall provide reports to physicians that compare, as determined appropriate by the Secretary, patterns of resource use of the individual physician to such patterns of other physicians.

(C) ANALYSIS OF DATA.—The Secretary shall, for purposes of preparing reports under this paragraph, establish methodologies as appropriate, such as to—

(i) attribute episodes of care, in whole or in part, to physicians;

(ii) identify appropriate physicians for purposes of comparison under subparagraph (B); and

(iii) aggregate episodes of care attributed to a physician under clause (i) into a composite measure per individual.

(D) DATA ADJUSTMENT.—In preparing reports under this paragraph, the Secretary shall make appropriate adjustments, including adjustments—

(i) to account for differences in socioeconomic and demographic characteristics, ethnicity, and health status of individuals (such as to recognize that less healthy individuals may require more intensive interventions); and

(ii) to eliminate the effect of geographic adjustments in payment rates (as described in subsection (e)).

(E) PUBLIC AVAILABILITY OF METHODOLOGY.—The Secretary shall make available to the public—

(i) the methodologies established under subparagraph (C);

(ii) information regarding any adjustments made to data under subparagraph (D); and

(iii) aggregate reports with respect to physicians.

(F) DEFINITION OF PHYSICIAN.—In this paragraph:

(i) IN GENERAL.—The term "physician" has the meaning given that term in section 1861(r)(1).

(ii) TREATMENT OF GROUPS.—Such term includes, as the Secretary determines appropriate, a group of physicians.

(G) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the establishment of the methodology under subparagraph (C), including the determination of an episode of care under such methodology.

(10) COORDINATION WITH OTHER VALUE-BASED PURCHASING REFORMS.—The Secretary shall coordinate the Program with the value-based payment modifier established under subsection (p) and, as the Secretary determines appropriate, other similar provisions of this title.

(11) REPORTS ENDING WITH 2017.—Reports under the Program shall not be provided after December 31, 2017. See subsection (q)(12) for reports under the eligible professionals Merit-based Incentive Payment System.

(o) INCENTIVES FOR ADOPTION AND MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY.—

(1) INCENTIVE PAYMENTS.—

(A) IN GENERAL.—

(i) IN GENERAL.—Subject to the succeeding subparagraphs of this paragraph, with respect to covered professional services furnished by an eligible professional during a payment year (as defined in subparagraph (E)), if the eligible professional is a meaningful EHR user (as determined under paragraph (2)) for the EHR reporting period with respect to such year, in addition to the amount otherwise paid under this part, there also shall be paid to the eligible professional (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6)), from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 an amount equal to 75 percent of the Secretary's estimate (based on claims submitted not later than 2 months after the end of the payment year) of the allowed charges under this part for all such covered professional services furnished by the eligible professional during such year.

(ii) NO INCENTIVE PAYMENTS WITH RESPECT TO YEARS AFTER 2016.—No incentive payments may be made under this subsection with respect to a year after 2016.

(B) LIMITATIONS ON AMOUNTS OF INCENTIVE PAYMENTS.—

(i) IN GENERAL.—In no case shall the amount of the incentive payment provided under this paragraph for an eligible professional for a payment year exceed the applicable amount specified under this subparagraph

with respect to such eligible professional and such year.

(ii) AMOUNT.—Subject to clauses (iii) through (v), the applicable amount specified in this subparagraph for an eligible professional is as follows:

(I) For the first payment year for such professional, $15,000 (or, if the first payment year for such eligible professional is 2011 or 2012, $18,000).

(II) For the second payment year for such professional, $12,000.

(III) For the third payment year for such professional, $8,000.

(IV) For the fourth payment year for such professional, $4,000.

(V) For the fifth payment year for such professional, $2,000.

(VI) For any succeeding payment year for such professional, $0.

(iii) PHASE DOWN FOR ELIGIBLE PROFESSIONALS FIRST ADOPTING EHR AFTER 2013.—If the first payment year for an eligible professional is after 2013, then the amount specified in this subparagraph for a payment year for such professional is the same as the amount specified in clause (ii) for such payment year for an eligible professional whose first payment year is 2013.

(iv) INCREASE FOR CERTAIN ELIGIBLE PROFESSIONALS.—In the case of an eligible professional who predominantly furnishes services under this part in an area that is designated by the Secretary (under section 332(a)(1)(A) of the Public Health Service Act) as a health professional shortage area, the amount that would otherwise apply for a payment year for such professional under subclauses (I) through (V) of clause (ii) shall be increased by 10 percent. In implementing the preceding sentence, the Secretary may, as determined appropriate, apply provisions of subsections (m) and (u) of section 1833 in a similar manner as such provisions apply under such subsection.

(v) NO INCENTIVE PAYMENT IF FIRST ADOPTING AFTER 2014.—If the first payment year for an eligible professional is after 2014 then the applicable amount specified in this subparagraph for such professional for such year and any subsequent year shall be $0.

(C) NON-APPLICATION TO HOSPITAL-BASED ELIGIBLE PROFESSIONALS.—

(i) IN GENERAL.—No incentive payment may be made under this paragraph in the case of a hospital-based eligible professional.

(ii) HOSPITAL-BASED ELIGIBLE PROFESSIONAL.—For purposes of clause (i), the term "hospital-based eligible professional" means, with respect to covered professional services furnished by an eligible professional during the EHR reporting period for a payment year, an eligible professional, such as a pathologist, anesthe-

siologist, or emergency physician, who furnishes substantially all of such services in a hospital inpatient or emergency room setting and through the use of the facilities and equipment, including qualified electronic health records, of the hospital. The determination of whether an eligible professional is a hospital-based eligible professional shall be made on the basis of the site of service (as defined by the Secretary) and without regard to any employment or billing arrangement between the eligible professional and any other provider.

(D) PAYMENT.—

(i) FORM OF PAYMENT.—The payment under this paragraph may be in the form of a single consolidated payment or in the form of such periodic installments as the Secretary may specify.

(ii) COORDINATION OF APPLICATION OF LIMITATION FOR PROFESSIONALS IN DIFFERENT PRACTICES.—In the case of an eligible professional furnishing covered professional services in more than one practice (as specified by the Secretary), the Secretary shall establish rules to coordinate the incentive payments, including the application of the limitation on amounts of such incentive payments under this paragraph, among such practices.

(iii) COORDINATION WITH MEDICAID.—The Secretary shall seek, to the maximum extent practicable, to avoid duplicative requirements from Federal and State governments to demonstrate meaningful use of certified EHR technology under this title and title XIX. The Secretary may also adjust the reporting periods under such title and such subsections in order to carry out this clause.

(E) PAYMENT YEAR DEFINED.—

(i) IN GENERAL.—For purposes of this subsection, the term "payment year" means a year beginning with 2011.

(ii) FIRST, SECOND, ETC. PAYMENT YEAR.—The term "first payment year" means, with respect to covered professional services furnished by an eligible professional, the first year for which an incentive payment is made for such services under this subsection. The terms "second payment year", "third payment year", "fourth payment year", and "fifth payment year" mean, with respect to covered professional services furnished by such eligible professional, each successive year immediately following the first payment year for such professional.

(2) MEANINGFUL EHR USER.—

(A) IN GENERAL.—An eligible professional shall be treated as a meaningful EHR user for an EHR reporting period for a payment year (or, for purposes of subsection (a)(7), for an EHR reporting period under such subsection for a year, or pursuant to subparagraph (D) for purposes of sub-

section (q), for a performance period under such subsection for a year) if each of the following requirements is met:

(i) MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY.—The eligible professional demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period the professional is using certified EHR technology in a meaningful manner, which shall include the use of electronic prescribing as determined to be appropriate by the Secretary.

(ii) INFORMATION EXCHANGE.—The eligible professional demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period such certified EHR technology is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination, and the professional demonstrates (through a process specified by the Secretary, such as the use of an attestation) that the professional has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of the certified EHR technology.

(iii) REPORTING ON MEASURES USING EHR.—Subject to subparagraph (B)(ii) and subsection (q)(5)(B)(ii)(II) and using such certified EHR technology, the eligible professional submits information for such period, in a form and manner specified by the Secretary, on such clinical quality measures and such other measures as selected by the Secretary under subparagraph (B)(i).

The Secretary may provide for the use of alternative means for meeting the requirements of clauses (i), (ii), and (iii) in the case of an eligible professional furnishing covered professional services in a group practice (as defined by the Secretary). The Secretary shall seek to improve the use of electronic health records and health care quality over time by requiring more stringent measures of meaningful use selected under this paragraph.

(B) REPORTING ON MEASURES.—

(i) SELECTION.—The Secretary shall select measures for purposes of subparagraph (A)(iii) but only consistent with the following:

(I) The Secretary shall provide preference to clinical quality measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a).

(II) Prior to any measure being selected under this subparagraph, the Secretary shall publish in the Federal Register such measure and provide for a period of public comment on such measure.

(ii) LIMITATION.—The Secretary may not require the electronic reporting of information on clinical quality measures under subparagraph (A)(iii) unless the Sec-

retary has the capacity to accept the information electronically, which may be on a pilot basis.

(iii) COORDINATION OF REPORTING OF INFORMATION.—In selecting such measures, and in establishing the form and manner for reporting measures under subparagraph (A)(iii), the Secretary shall seek to avoid redundant or duplicative reporting otherwise required, including reporting under subsection (k)(2)(C).

(C) DEMONSTRATION OF MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY AND INFORMATION EXCHANGE.—

(i) IN GENERAL.—A professional may satisfy the demonstration requirement of clauses (i) and (ii) of subparagraph (A) through means specified by the Secretary, which may include—

(I) an attestation;

(II) the submission of claims with appropriate coding (such as a code indicating that a patient encounter was documented using certified EHR technology);

(III) a survey response;

(IV) reporting under subparagraph (A)(iii); and

(V) other means specified by the Secretary.

(ii) USE OF PART D DATA.—Notwithstanding sections 1860D–15(d)(2)(B) and 1860D–15(f)(2), the Secretary may use data regarding drug claims submitted for purposes of section 1860D–15 that are necessary for purposes of subparagraph (A).

(iii) INTEROPERABILITY.—With respect to EHR reporting periods for payment years beginning with 2018, the means described in clause (i) specified by the Secretary shall include a demonstration, through means such as an attestation, that the professional has not taken any action described in subsection (a)(2) of section 3010A of the Public Health Service Act, with respect to the use of any certified EHR technology.

(D) CONTINUED APPLICATION FOR PURPOSES OF MIPS.—With respect to 2019 and each subsequent payment year, the Secretary shall, for purposes of subsection (q) and in accordance with paragraph (1)(F) of such subsection, determine whether an eligible professional who is a MIPS eligible professional (as defined in subsection (q)(1)(C)) for such year is a meaningful EHR user under this paragraph for the performance period under subsection (q) for such year.

(3) APPLICATION.—

(A) PHYSICIAN REPORTING SYSTEM RULES.—Paragraphs (5), (6), and (8) of subsection (k) shall apply for purposes of this subsection in the same manner as they apply for purposes of such subsection.

(B) COORDINATION WITH OTHER PAYMENTS.—The provisions of this subsection shall not be taken into account in applying the provisions of subsection (m) of this section and of section 1833(m) and any payment under such provisions shall not be taken into account in computing allowable charges under this subsection.

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

(i) the methodology and standards for determining payment amounts under this subsection and payment adjustments under subsection (a)(7)(A), including the limitation under paragraph (1)(B) and coordination under clauses (ii) and (iii) of paragraph (1)(D);

(ii) the methodology and standards for determining a meaningful EHR user under paragraph (2), including selection of measures under paragraph (2)(B), specification of the means of demonstrating meaningful EHR use under paragraph (2)(C), and the hardship exception under subsection (a)(7)(B);

(iii) the methodology and standards for determining a hospital-based eligible professional under paragraph (1)(C); and

(iv) the specification of reporting periods under paragraph (5) and the selection of the form of payment under paragraph (1)(D)(i).

(D) POSTING ON WEBSITE.—The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services, in an easily understandable format, a list of the names, business addresses, and business phone numbers of the eligible professionals who are meaningful EHR users and, as determined appropriate by the Secretary, of group practices receiving incentive payments under paragraph (1).

(4) CERTIFIED EHR TECHNOLOGY DEFINED.—For purposes of this section, the term "certified EHR technology" means a qualified electronic health record (as defined in section 3000(13) of the Public Health Service Act) that is certified pursuant to section 3001(c)(5) of such Act as meeting standards adopted under section 3004 of such Act that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).

(5) DEFINITIONS.—For purposes of this subsection:

(A) COVERED PROFESSIONAL SERVICES.—The term "covered professional services" has the meaning given such term in subsection (k)(3).

(B) EHR REPORTING PERIOD.—The term "EHR reporting period" means, with respect to a payment year, any period (or periods) as specified by the Secretary.

(C) ELIGIBLE PROFESSIONAL.—The term "eligible professional" means a physician, as defined in section 1861(r).

(p) ESTABLISHMENT OF VALUE-BASED PAYMENT MODIFIER.—

(1) IN GENERAL.—The Secretary shall establish a payment modifier that provides for differential payment to a physician or a group of physicians under the fee schedule established under subsection (b) based upon the quality of care furnished compared to cost (as determined under paragraphs (2) and (3), respectively) during a performance period. Such payment modi-

fier shall be separate from the geographic adjustment factors established under subsection (e).

(2) QUALITY.—

(A) IN GENERAL.—For purposes of paragraph (1), quality of care shall be evaluated, to the extent practicable, based on a composite of measures of the quality of care furnished (as established by the Secretary under subparagraph (B)).

(B) MEASURES.—

(i) The Secretary shall establish appropriate measures of the quality of care furnished by a physician or group of physicians to individuals enrolled under this part, such as measures that reflect health outcomes. Such measures shall be risk adjusted as determined appropriate by the Secretary.

(ii) The Secretary shall seek endorsement of the measures established under this subparagraph by the entity with a contract under section 1890(a).

(C) CONTINUED APPLICATION FOR PURPOSES OF MIPS.—The Secretary shall, in accordance with subsection (q)(1)(F), carry out subparagraph (B) for purposes of subsection (q).

(3) COSTS.—For purposes of paragraph (1), costs shall be evaluated, to the extent practicable, based on a composite of appropriate measures of costs established by the Secretary (such as the composite measure under the methodology established under subsection (n)(9)(C)(iii)) that eliminate the effect of geographic adjustments in payment rates (as described in subsection (e)), and take into account risk factors (such as socioeconomic and demographic characteristics, ethnicity, and health status of individuals (such as to recognize that less healthy individuals may require more intensive interventions) and other factors determined appropriate by the Secretary. With respect to 2019 and each subsequent year, the Secretary shall, in accordance with subsection (q)(1)(F), carry out this paragraph for purposes of subsection (q).

(4) IMPLEMENTATION.—

(A) PUBLICATION OF MEASURES, DATES OF IMPLEMENTATION, PERFORMANCE PERIOD.—Not later than January 1, 2012, the Secretary shall publish the following:

(i) The measures of quality of care and costs established under paragraphs (2) and (3), respectively.

(ii) The dates for implementation of the payment modifier (as determined under subparagraph (B)).

(iii) The initial performance period (as specified under subparagraph (B)(ii)).

(B) DEADLINES FOR IMPLEMENTATION.—

(i) INITIAL IMPLEMENTATION.—Subject to the preceding provisions of this subparagraph, the Secretary shall begin implementing the payment modifier established under this subsection through the rulemaking process during 2013 for the physician fee schedule established under subsection (b).

(ii) INITIAL PERFORMANCE PERIOD.—

(I) IN GENERAL.—The Secretary shall specify an initial performance period for application of the

payment modifier established under this subsection with respect to 2015.

(II) PROVISION OF INFORMATION DURING INITIAL PERFORMANCE PERIOD.—During the initial performance period, the Secretary shall, to the extent practicable, provide information to physicians and groups of physicians about the quality of care furnished by the physician or group of physicians to individuals enrolled under this part compared to cost (as determined under paragraphs (2) and (3), respectively) with respect to the performance period.

(iii) APPLICATION.—The Secretary shall apply the payment modifier established under this subsection for items and services furnished on or after January 1, 2015, with respect to specific physicians and groups of physicians the Secretary determines appropriate, and for services furnished on or after January 1, 2017, with respect to all physicians and groups of physicians. Such payment modifier shall not be applied for items and services furnished on or after January 1, 2019.

(C) BUDGET NEUTRALITY.—The payment modifier established under this subsection shall be implemented in a budget neutral manner.

(5) SYSTEMS-BASED CARE.—The Secretary shall, as appropriate, apply the payment modifier established under this subsection in a manner that promotes systems-based care.

(6) CONSIDERATION OF SPECIAL CIRCUMSTANCES OF CERTAIN PROVIDERS.—In applying the payment modifier under this subsection, the Secretary shall, as appropriate, take into account the special circumstances of physicians or groups of physicians in rural areas and other underserved communities.

(7) APPLICATION.—For purposes of the initial application of the payment modifier established under this subsection during the period beginning on January 1, 2015, and ending on December 31, 2016, the term "physician" has the meaning given such term in section 1861(r). On or after January 1, 2017, the Secretary may apply this subsection to eligible professionals (as defined in subsection (k)(3)(B)) as the Secretary determines appropriate.

(8) DEFINITIONS.—For purposes of this subsection:

(A) COSTS.—The term "costs" means expenditures per individual as determined appropriate by the Secretary. In making the determination under the preceding sentence, the Secretary may take into account the amount of growth in expenditures per individual for a physician compared to the amount of such growth for other physicians.

(B) PERFORMANCE PERIOD.—The term "performance period" means a period specified by the Secretary.

(9) COORDINATION WITH OTHER VALUE-BASED PURCHASING REFORMS.—The Secretary shall coordinate the value-based payment modifier established under this subsection with the Physician Feedback Program under subsection (n) and, as the Sec-

retary determines appropriate, other similar provisions of this title.

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

(A) the establishment of the value-based payment modifier under this subsection;

(B) the evaluation of quality of care under paragraph (2), including the establishment of appropriate measures of the quality of care under paragraph (2)(B);

(C) the evaluation of costs under paragraph (3), including the establishment of appropriate measures of costs under such paragraph;

(D) the dates for implementation of the value-based payment modifier;

(E) the specification of the initial performance period and any other performance period under paragraphs (4)(B)(ii) and (8)(B), respectively;

(F) the application of the value-based payment modifier under paragraph (7); and

(G) the determination of costs under paragraph (8)(A).

(q) MERIT-BASED INCENTIVE PAYMENT SYSTEM.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, the Secretary shall establish an eligible professional Merit-based Incentive Payment System (in this subsection referred to as the "MIPS") under which the Secretary shall—

(i) develop a methodology for assessing the total performance of each MIPS eligible professional according to performance standards under paragraph (3) for a performance period (as established under paragraph (4)) for a year;

(ii) using such methodology, provide for a composite performance score in accordance with paragraph (5) for each such professional for each performance period; and

(iii) use such composite performance score of the MIPS eligible professional for a performance period for a year to determine and apply a MIPS adjustment factor (and, as applicable, an additional MIPS adjustment factor) under paragraph (6) to the professional for the year.

Notwithstanding subparagraph (C)(ii), under the MIPS, the Secretary shall permit any eligible professional (as defined in subsection (k)(3)(B)) to report on applicable measures and activities described in paragraph (2)(B).

(B) PROGRAM IMPLEMENTATION.—The MIPS shall apply to payments for items and services furnished on or after January 1, 2019.

(C) MIPS ELIGIBLE PROFESSIONAL DEFINED.—

(i) IN GENERAL.—For purposes of this subsection, subject to clauses (ii) and (iv), the term "MIPS eligible professional" means—

(I) for the first and second years for which the MIPS applies to payments (and for the performance period for such first and second year), a physician (as defined in section 1861(r)), a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5)), a certified registered nurse anesthetist (as defined in section 1861(bb)(2)), and a group that includes such professionals; and

(II) for the third year for which the MIPS applies to payments (and for the performance period for such third year) and for each succeeding year (and for the performance period for each such year), the professionals described in subclause (I), such other eligible professionals (as defined in subsection (k)(3)(B)) as specified by the Secretary, and a group that includes such professionals.

(ii) EXCLUSIONS.—For purposes of clause (i), the term "MIPS eligible professional" does not include, with respect to a year, an eligible professional (as defined in subsection (k)(3)(B)) who—

(I) is a qualifying APM participant (as defined in section 1833(z)(2));

(II) subject to clause (vii), is a partial qualifying APM participant (as defined in clause (iii)) for the most recent period for which data are available and who, for the performance period with respect to such year, does not report on applicable measures and activities described in paragraph (2)(B) that are required to be reported by such a professional under the MIPS; or

(III) for the performance period with respect to such year, does not exceed the low-volume threshold measurement selected under clause (iv).

(iii) PARTIAL QUALIFYING APM PARTICIPANT.—For purposes of this subparagraph, the term "partial qualifying APM participant" means, with respect to a year, an eligible professional for whom the Secretary determines the minimum payment percentage (or percentages), as applicable, described in paragraph (2) of section 1833(z) for such year have not been satisfied, but who would be considered a qualifying APM participant (as defined in such paragraph) for such year if—

(I) with respect to 2019 and 2020, the reference in subparagraph (A) of such paragraph to 25 percent was instead a reference to 20 percent;

(II) with respect to 2021 and 2022—

(aa) the reference in subparagraph (B)(i) of such paragraph to 50 percent was instead a reference to 40 percent; and

(bb) the references in subparagraph (B)(ii) of such paragraph to 50 percent and 25 percent of such paragraph were instead references to 40 percent and 20 percent, respectively; and

(III) with respect to 2023 and subsequent years—

(aa) the reference in subparagraph (C)(i) of such paragraph to 75 percent was instead a reference to 50 percent; and

(bb) the references in subparagraph (C)(ii) of such paragraph to 75 percent and 25 percent of such paragraph were instead references to 50 percent and 20 percent, respectively.

(iv) SELECTION OF LOW-VOLUME THRESHOLD MEASUREMENT.—The Secretary shall select a low-volume threshold to apply for purposes of clause (ii)(III), which may include one or more or a combination of the following:

(I) The minimum number (as determined by the Secretary) of individuals enrolled under this part who are treated by the eligible professional for the performance period involved.

(II) The minimum number (as determined by the Secretary) of items and services furnished to individuals enrolled under this part by such professional for such performance period.

(III) The minimum amount (as determined by the Secretary) of allowed charges billed by such professional under this part for such performance period.

(v) TREATMENT OF NEW MEDICARE ENROLLED ELIGIBLE PROFESSIONALS.—In the case of a professional who first becomes a Medicare enrolled eligible professional during the performance period for a year (and had not previously submitted claims under this title such as a person, an entity, or a part of a physician group or under a different billing number or tax identifier), such professional shall not be treated under this subsection as a MIPS eligible professional until the subsequent year and performance period for such subsequent year.

(vi) CLARIFICATION.—In the case of items and services furnished during a year by an individual who is not a MIPS eligible professional (including pursuant to clauses (ii) and (v)) with respect to a year, in no case shall a MIPS adjustment factor (or additional MIPS adjustment factor) under paragraph (6) apply to such individual for such year.

(vii) PARTIAL QUALIFYING APM PARTICIPANT CLARIFICATIONS.—

(I) TREATMENT AS MIPS ELIGIBLE PROFESSIONAL.—In the case of an eligible professional who is a partial qualifying APM participant, with respect to a year, and who, for the performance period for such year, reports on applicable measures and activities described in paragraph (2)(B) that are required to be reported by such a professional under the MIPS, such eligible professional

is considered to be a MIPS eligible professional with respect to such year.

(II) NOT ELIGIBLE FOR QUALIFYING APM PARTICIPANT PAYMENTS.—In no case shall an eligible professional who is a partial qualifying APM participant, with respect to a year, be considered a qualifying APM participant (as defined in paragraph (2) of section 1833(z)) for such year or be eligible for the additional payment under paragraph (1) of such section for such year.

(D) APPLICATION TO GROUP PRACTICES.—

(i) IN GENERAL.—Under the MIPS:

(I) QUALITY PERFORMANCE CATEGORY.—The Secretary shall establish and apply a process that includes features of the provisions of subsection (m)(3)(C) for MIPS eligible professionals in a group practice with respect to assessing performance of such group with respect to the performance category described in clause (i) of paragraph (2)(A).

(II) OTHER PERFORMANCE CATEGORIES.—The Secretary may establish and apply a process that includes features of the provisions of subsection (m)(3)(C) for MIPS eligible professionals in a group practice with respect to assessing the performance of such group with respect to the performance categories described in clauses (ii) through (iv) of such paragraph.

(ii) ENSURING COMPREHENSIVENESS OF GROUP PRACTICE ASSESSMENT.—The process established under clause (i) shall to the extent practicable reflect the range of items and services furnished by the MIPS eligible professionals in the group practice involved.

(E) USE OF REGISTRIES.—Under the MIPS, the Secretary shall encourage the use of qualified clinical data registries pursuant to subsection (m)(3)(E) in carrying out this subsection.

(F) APPLICATION OF CERTAIN PROVISIONS.—In applying a provision of subsection (k), (m), (o), or (p) for purposes of this subsection, the Secretary shall—

(i) adjust the application of such provision to ensure the provision is consistent with the provisions of this subsection; and

(ii) not apply such provision to the extent that the provision is duplicative with a provision of this subsection.

(G) ACCOUNTING FOR RISK FACTORS.—

(i) RISK FACTORS.—Taking into account the relevant studies conducted and recommendations made in reports under section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014, and, as appropriate, other information, including information collected before completion of such studies and recommendations, the Secretary, on an ongoing basis, shall, as the Secretary determines appropriate and

based on an individual's health status and other risk factors—

(I) assess appropriate adjustments to quality measures, resource use measures, and other measures used under the MIPS; and

(II) assess and implement appropriate adjustments to payment adjustments, composite performance scores, scores for performance categories, or scores for measures or activities under the MIPS.

(2) MEASURES AND ACTIVITIES UNDER PERFORMANCE CATEGORIES.—

(A) PERFORMANCE CATEGORIES.—Under the MIPS, the Secretary shall use the following performance categories (each of which is referred to in this subsection as a performance category) in determining the composite performance score under paragraph (5):

(i) Quality.

(ii) Resource use.

(iii) Clinical practice improvement activities.

(iv) Meaningful use of certified EHR technology.

(B) MEASURES AND ACTIVITIES SPECIFIED FOR EACH CATEGORY.—For purposes of paragraph (3)(A) and subject to subparagraph (C), measures and activities specified for a performance period (as established under paragraph (4)) for a year are as follows:

(i) QUALITY.—For the performance category described in subparagraph (A)(i), the quality measures included in the final measures list published under subparagraph (D)(i) for such year and the list of quality measures described in subparagraph (D)(vi) used by qualified clinical data registries under subsection (m)(3)(E).

(ii) RESOURCE USE.—For the performance category described in subparagraph (A)(ii), the measurement of resource use for such period under subsection (p)(3), using the methodology under subsection (r) as appropriate, and, as feasible and applicable, accounting for the cost of drugs under part D.

(iii) CLINICAL PRACTICE IMPROVEMENT ACTIVITIES.—For the performance category described in subparagraph (A)(iii), clinical practice improvement activities (as defined in subparagraph (C)(v)(III)) under subcategories specified by the Secretary for such period, which shall include at least the following:

(I) The subcategory of expanded practice access, such as same day appointments for urgent needs and after hours access to clinician advice.

(II) The subcategory of population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a qualified clinical data registry.

(III) The subcategory of care coordination, such as timely communication of test results, timely exchange of clinical information to patients and

other providers, and use of remote monitoring or telehealth.

(IV) The subcategory of beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision-making mechanisms.

(V) The subcategory of patient safety and practice assessment, such as through use of clinical or surgical checklists and practice assessments related to maintaining certification.

(VI) The subcategory of participation in an alternative payment model (as defined in section 1833(z)(3)(C)).

In establishing activities under this clause, the Secretary shall give consideration to the circumstances of small practices (consisting of 15 or fewer professionals) and practices located in rural areas and in health professional shortage areas (as designated under section 332(a)(1)(A) of the Public Health Service Act).

(iv) MEANINGFUL EHR USE.—For the performance category described in subparagraph (A)(iv), the requirements established for such period under subsection (o)(2) for determining whether an eligible professional is a meaningful EHR user.

(C) ADDITIONAL PROVISIONS.—

(i) EMPHASIZING OUTCOME MEASURES UNDER THE QUALITY PERFORMANCE CATEGORY.—In applying subparagraph (B)(i), the Secretary shall, as feasible, emphasize the application of outcome measures.

(ii) APPLICATION OF ADDITIONAL SYSTEM MEASURES.—The Secretary may use measures used for a payment system other than for physicians, such as measures for inpatient hospitals, for purposes of the performance categories described in clauses (i) and (ii) of subparagraph (A). For purposes of the previous sentence, the Secretary may not use measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists.

(iii) GLOBAL AND POPULATION-BASED MEASURES.—The Secretary may use global measures, such as global outcome measures, and population-based measures for purposes of the performance category described in subparagraph (A)(i).

(iv) APPLICATION OF MEASURES AND ACTIVITIES TO NON-PATIENT-FACING PROFESSIONALS.—In carrying out this paragraph, with respect to measures and activities specified in subparagraph (B) for performance categories described in subparagraph (A), the Secretary—

(I) shall give consideration to the circumstances of professional types (or subcategories of those types determined by practice characteristics) who typically furnish services that do not involve face-to-face interaction with a patient; and

(II) may, to the extent feasible and appropriate, take into account such circumstances and apply under this subsection with respect to MIPS eligible professionals of such professional types or subcategories, alternative measures or activities that fulfill the goals of the applicable performance category.

In carrying out the previous sentence, the Secretary shall consult with professionals of such professional types or subcategories.

(v) CLINICAL PRACTICE IMPROVEMENT ACTIVITIES.—

(I) REQUEST FOR INFORMATION.—In initially applying subparagraph (B)(iii), the Secretary shall use a request for information to solicit recommendations from stakeholders to identify activities described in such subparagraph and specifying criteria for such activities.

(II) CONTRACT AUTHORITY FOR CLINICAL PRACTICE IMPROVEMENT ACTIVITIES PERFORMANCE CATEGORY.—In applying subparagraph (B)(iii), the Secretary may contract with entities to assist the Secretary in—

(aa) identifying activities described in subparagraph (B)(iii);

(bb) specifying criteria for such activities; and

(cc) determining whether a MIPS eligible professional meets such criteria.

(III) CLINICAL PRACTICE IMPROVEMENT ACTIVITIES DEFINED.—For purposes of this subsection, the term "clinical practice improvement activity" means an activity that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.

(D) ANNUAL LIST OF QUALITY MEASURES AVAILABLE FOR MIPS ASSESSMENT.—

(i) IN GENERAL.—Under the MIPS, the Secretary, through notice and comment rulemaking and subject to the succeeding clauses of this subparagraph, shall, with respect to the performance period for a year, establish an annual final list of quality measures from which MIPS eligible professionals may choose for purposes of assessment under this subsection for such performance period. Pursuant to the previous sentence, the Secretary shall—

(I) not later than November 1 of the year prior to the first day of the first performance period under the MIPS, establish and publish in the Federal Register a final list of quality measures; and

(II) not later than November 1 of the year prior to the first day of each subsequent performance period, update the final list of quality measures

from the previous year (and publish such updated final list in the Federal Register), by—

(aa) removing from such list, as appropriate, quality measures, which may include the removal of measures that are no longer meaningful (such as measures that are topped out);

(bb) adding to such list, as appropriate, new quality measures; and

(cc) determining whether or not quality measures on such list that have undergone substantive changes should be included in the updated list.

(ii) CALL FOR QUALITY MEASURES.—

(I) IN GENERAL.—Eligible professional organizations and other relevant stakeholders shall be requested to identify and submit quality measures to be considered for selection under this subparagraph in the annual list of quality measures published under clause (i) and to identify and submit updates to the measures on such list. For purposes of the previous sentence, measures may be submitted regardless of whether such measures were previously published in a proposed rule or endorsed by an entity with a contract under section 1890(a).

(II) ELIGIBLE PROFESSIONAL ORGANIZATION DEFINED.—In this subparagraph, the term "eligible professional organization" means a professional organization as defined by nationally recognized specialty boards of certification or equivalent certification boards.

(iii) REQUIREMENTS.—In selecting quality measures for inclusion in the annual final list under clause (i), the Secretary shall—

(I) provide that, to the extent practicable, all quality domains (as defined in subsection (s)(1)(B)) are addressed by such measures; and

(II) ensure that such selection is consistent with the process for selection of measures under subsections (k), (m), and (p)(2).

(iv) PEER REVIEW.—Before including a new measure in the final list of measures published under clause (i) for a year, the Secretary shall submit for publication in applicable specialty-appropriate, peer-reviewed journals such measure and the method for developing and selecting such measure, including clinical and other data supporting such measure.

(v) MEASURES FOR INCLUSION.—The final list of quality measures published under clause (i) shall include, as applicable, measures under subsections (k), (m), and (p)(2), including quality measures from among—

(I) measures endorsed by a consensus-based entity;

(II) measures developed under subsection (s); and

(III) measures submitted under clause (ii)(I).

Any measure selected for inclusion in such list that is not endorsed by a consensus-based entity shall have a focus that is evidence-based.

(vi) EXCEPTION FOR QUALIFIED CLINICAL DATA REGISTRY MEASURES.—Measures used by a qualified clinical data registry under subsection (m)(3)(E) shall not be subject to the requirements under clauses (i), (iv), and (v). The Secretary shall publish the list of measures used by such qualified clinical data registries on the Internet website of the Centers for Medicare & Medicaid Services.

(vii) EXCEPTION FOR EXISTING QUALITY MEASURES.—Any quality measure specified by the Secretary under subsection (k) or (m), including under subsection (m)(3)(E), and any measure of quality of care established under subsection (p)(2) for the reporting period or performance period under the respective subsection beginning before the first performance period under the MIPS—

(I) shall not be subject to the requirements under clause (i) (except under items (aa) and (cc) of subclause (II) of such clause) or to the requirement under clause (iv); and

(II) shall be included in the final list of quality measures published under clause (i) unless removed under clause (i)(II)(aa).

(viii) CONSULTATION WITH RELEVANT ELIGIBLE PROFESSIONAL ORGANIZATIONS AND OTHER RELEVANT STAKEHOLDERS.—Relevant eligible professional organizations and other relevant stakeholders, including State and national medical societies, shall be consulted in carrying out this subparagraph.

(ix) OPTIONAL APPLICATION.—The process under section 1890A is not required to apply to the selection of measures under this subparagraph.

(3) PERFORMANCE STANDARDS.—

(A) ESTABLISHMENT.—Under the MIPS, the Secretary shall establish performance standards with respect to measures and activities specified under paragraph (2)(B) for a performance period (as established under paragraph (4)) for a year.

(B) CONSIDERATIONS IN ESTABLISHING STANDARDS.—In establishing such performance standards with respect to measures and activities specified under paragraph (2)(B), the Secretary shall consider the following:

(i) Historical performance standards.

(ii) Improvement.

(iii) The opportunity for continued improvement.

(4) PERFORMANCE PERIOD.—The Secretary shall establish a performance period (or periods) for a year (beginning with 2019). Such performance period (or periods) shall begin and end prior to the beginning of such year and be as close as pos-

sible to such year. In this subsection, such performance period (or periods) for a year shall be referred to as the performance period for the year.

(5) COMPOSITE PERFORMANCE SCORE.—

(A) IN GENERAL.—Subject to the succeeding provisions of this paragraph and taking into account, as available and applicable, paragraph (1)(G), the Secretary shall develop a methodology for assessing the total performance of each MIPS eligible professional according to performance standards under paragraph (3) with respect to applicable measures and activities specified in paragraph (2)(B) with respect to each performance category applicable to such professional for a performance period (as established under paragraph (4)) for a year. Using such methodology, the Secretary shall provide for a composite assessment (using a scoring scale of 0 to 100) for each such professional for the performance period for such year. In this subsection such a composite assessment for such a professional with respect to a performance period shall be referred to as the "composite performance score" for such professional for such performance period.

(B) INCENTIVE TO REPORT; ENCOURAGING USE OF CERTIFIED EHR TECHNOLOGY FOR REPORTING QUALITY MEASURES.—

(i) INCENTIVE TO REPORT.—Under the methodology established under subparagraph (A), the Secretary shall provide that in the case of a MIPS eligible professional who fails to report on an applicable measure or activity that is required to be reported by the professional, the professional shall be treated as achieving the lowest potential score applicable to such measure or activity.

(ii) ENCOURAGING USE OF CERTIFIED EHR TECHNOLOGY AND QUALIFIED CLINICAL DATA REGISTRIES FOR REPORTING QUALITY MEASURES.—Under the methodology established under subparagraph (A), the Secretary shall—

(I) encourage MIPS eligible professionals to report on applicable measures with respect to the performance category described in paragraph (2)(A)(i) through the use of certified EHR technology and qualified clinical data registries; and

(II) with respect to a performance period, with respect to a year, for which a MIPS eligible professional reports such measures through the use of such EHR technology, treat such professional as satisfying the clinical quality measures reporting requirement described in subsection (o)(2)(A)(iii) for such year.

(C) CLINICAL PRACTICE IMPROVEMENT ACTIVITIES PERFORMANCE SCORE.—

(i) RULE FOR CERTIFICATION.—A MIPS eligible professional who is in a practice that is certified as a patient-centered medical home or comparable specialty practice, as determined by the Secretary, with respect

to a performance period shall be given the highest potential score for the performance category described in paragraph (2)(A)(iii) for such period.

(ii) APM PARTICIPATION.—Participation by a MIPS eligible professional in an alternative payment model (as defined in section 1833(z)(3)(C)) with respect to a performance period shall earn such eligible professional a minimum score of one-half of the highest potential score for the performance category described in paragraph (2)(A)(iii) for such performance period.

(iii) SUBCATEGORIES.—A MIPS eligible professional shall not be required to perform activities in each subcategory under paragraph (2)(B)(iii) or participate in an alternative payment model in order to achieve the highest potential score for the performance category described in paragraph (2)(A)(iii).

(D) ACHIEVEMENT AND IMPROVEMENT.—

(i) TAKING INTO ACCOUNT IMPROVEMENT.—Beginning with the second year to which the MIPS applies, in addition to the achievement of a MIPS eligible professional, if data sufficient to measure improvement is available, the methodology developed under subparagraph (A)—

(I) in the case of the performance score for the performance category described in clauses (i) and (ii) of paragraph (2)(A), shall take into account the improvement of the professional; and

(II) in the case of performance scores for other performance categories, may take into account the improvement of the professional.

(ii) ASSIGNING HIGHER WEIGHT FOR ACHIEVEMENT.—Subject to clause (i), under the methodology developed under subparagraph (A), the Secretary may assign a higher scoring weight under subparagraph (F) with respect to the achievement of a MIPS eligible professional than with respect to any improvement of such professional applied under clause (i) with respect to a measure, activity, or category described in paragraph (2).

(E) WEIGHTS FOR THE PERFORMANCE CATEGORIES.—

(i) IN GENERAL.—Under the methodology developed under subparagraph (A), subject to subparagraph (F)(i) and clause (ii), the composite performance score shall be determined as follows:

(I) QUALITY.—

(aa) IN GENERAL.—Subject to item (bb), thirty percent of such score shall be based on performance with respect to the category described in clause (i) of paragraph (2)(A). In applying the previous sentence, the Secretary shall, as feasible, encourage the application of outcome measures within such category.

(bb) FIRST 2 YEARS.—For the first and second years for which the MIPS applies to payments, the percentage applicable under item

(aa) shall be increased in a manner such that the total percentage points of the increase under this item for the respective year equals the total number of percentage points by which the percentage applied under subclause (II)(bb) for the respective year is less than 30 percent.

(II) RESOURCE USE.—

(aa) IN GENERAL.—Subject to item (bb), thirty percent of such score shall be based on performance with respect to the category described in clause (ii) of paragraph (2)(A).

(bb) FIRST 2 YEARS.—For the first year for which the MIPS applies to payments, not more than 10 percent of such score shall be based on performance with respect to the category described in clause (ii) of paragraph (2)(A). For the second year for which the MIPS applies to payments, not more than 15 percent of such score shall be based on performance with respect to the category described in clause (ii) of paragraph (2)(A).

(III) CLINICAL PRACTICE IMPROVEMENT ACTIVITIES.—Fifteen percent of such score shall be based on performance with respect to the category described in clause (iii) of paragraph (2)(A).

(IV) MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY.—Twenty-five percent of such score shall be based on performance with respect to the category described in clause (iv) of paragraph (2)(A).

(ii) AUTHORITY TO ADJUST PERCENTAGES IN CASE OF HIGH EHR MEANINGFUL USE ADOPTION.—In any year in which the Secretary estimates that the proportion of eligible professionals (as defined in subsection (o)(5)) who are meaningful EHR users (as determined under subsection (o)(2)) is 75 percent or greater, the Secretary may reduce the percent applicable under clause (i)(IV), but not below 15 percent. If the Secretary makes such reduction for a year, subject to subclauses (I)(bb) and (II)(bb) of clause (i), the percentages applicable under one or more of subclauses (I), (II), and (III) of clause (i) for such year shall be increased in a manner such that the total percentage points of the increase under this clause for such year equals the total number of percentage points reduced under the preceding sentence for such year.

(F) CERTAIN FLEXIBILITY FOR WEIGHTING PERFORMANCE CATEGORIES, MEASURES, AND ACTIVITIES.—Under the methodology under subparagraph (A), if there are not sufficient measures and activities (described in paragraph (2)(B)) applicable and available to each type of eligible professional involved, the Secretary shall assign different scoring weights (including a weight of 0)—

(i) which may vary from the scoring weights specified in subparagraph (E), for each performance cat-

egory based on the extent to which the category is applicable to the type of eligible professional involved; and

(ii) for each measure and activity specified under paragraph (2)(B) with respect to each such category based on the extent to which the measure or activity is applicable and available to the type of eligible professional involved.

(G) RESOURCE USE.—Analysis of the performance category described in paragraph (2)(A)(ii) shall include results from the methodology described in subsection (r)(5), as appropriate.

(H) INCLUSION OF QUALITY MEASURE DATA FROM OTHER PAYERS.—In applying subsections (k), (m), and (p) with respect to measures described in paragraph (2)(B)(i), analysis of the performance category described in paragraph (2)(A)(i) may include data submitted by MIPS eligible professionals with respect to items and services furnished to individuals who are not individuals entitled to benefits under part A or enrolled under part B.

(I) USE OF VOLUNTARY VIRTUAL GROUPS FOR CERTAIN ASSESSMENT PURPOSES.—

(i) IN GENERAL.—In the case of MIPS eligible professionals electing to be a virtual group under clause (ii) with respect to a performance period for a year, for purposes of applying the methodology under subparagraph (A) with respect to the performance categories described in clauses (i) and (ii) of paragraph (2)(A)—

(I) the assessment of performance provided under such methodology with respect to such performance categories that is to be applied to each such professional in such group for such performance period shall be with respect to the combined performance of all such professionals in such group for such period; and

(II) with respect to the composite performance score provided under this paragraph for such performance period for each such MIPS eligible professional in such virtual group, the components of the composite performance score that assess performance with respect to such performance categories shall be based on the assessment of the combined performance under subclause (I) for such performance categories and performance period.

(ii) ELECTION OF PRACTICES TO BE A VIRTUAL GROUP.—The Secretary shall, in accordance with the requirements under clause (iii), establish and have in place a process to allow an individual MIPS eligible professional or a group practice consisting of not more than 10 MIPS eligible professionals to elect, with respect to a performance period for a year to be a virtual group under this subparagraph with at least one other such individual MIPS eligible professional or group practice. Such a virtual group may be based on appro-

priate classifications of providers, such as by geographic areas or by provider specialties defined by nationally recognized specialty boards of certification or equivalent certification boards.

(iii) REQUIREMENTS.—The requirements for the process under clause (ii) shall—

(I) provide that an election under such clause, with respect to a performance period, shall be made before the beginning of such performance period and may not be changed during such performance period;

(II) provide that an individual MIPS eligible professional and a group practice described in clause (ii) may elect to be in no more than one virtual group for a performance period and that, in the case of such a group practice that elects to be in such virtual group for such performance period, such election applies to all MIPS eligible professionals in such group practice;

(III) provide that a virtual group be a combination of tax identification numbers;

(IV) provide for formal written agreements among MIPS eligible professionals electing to be a virtual group under this subparagraph; and

(V) include such other requirements as the Secretary determines appropriate.

(6) MIPS PAYMENTS.—

(A) MIPS ADJUSTMENT FACTOR.—Taking into account paragraph (1)(G), the Secretary shall specify a MIPS adjustment factor for each MIPS eligible professional for a year. Such MIPS adjustment factor for a MIPS eligible professional for a year shall be in the form of a percent and shall be determined—

(i) by comparing the composite performance score of the eligible professional for such year to the performance threshold established under subparagraph (D)(i) for such year;

(ii) in a manner such that the adjustment factors specified under this subparagraph for a year result in differential payments under this paragraph reflecting that—

(I) MIPS eligible professionals with composite performance scores for such year at or above such performance threshold for such year receive zero or positive payment adjustment factors for such year in accordance with clause (iii), with such professionals having higher composite performance scores receiving higher adjustment factors; and

(II) MIPS eligible professionals with composite performance scores for such year below such performance threshold for such year receive negative payment adjustment factors for such year in accordance with clause (iv), with such professionals having lower composite performance scores receiving lower adjustment factors;

(iii) in a manner such that MIPS eligible professionals with composite scores described in clause (ii)(I) for such year, subject to clauses (i) and (ii) of subparagraph (F), receive a zero or positive adjustment factor on a linear sliding scale such that an adjustment factor of 0 percent is assigned for a score at the performance threshold and an adjustment factor of the applicable percent specified in subparagraph (B) is assigned for a score of 100; and

(iv) in a manner such that—

(I) subject to subclause (II), MIPS eligible professionals with composite performance scores described in clause (ii)(II) for such year receive a negative payment adjustment factor on a linear sliding scale such that an adjustment factor of 0 percent is assigned for a score at the performance threshold and an adjustment factor of the negative of the applicable percent specified in subparagraph (B) is assigned for a score of 0; and

(II) MIPS eligible professionals with composite performance scores that are equal to or greater than 0, but not greater than ¼ of the performance threshold specified under subparagraph (D)(i) for such year, receive a negative payment adjustment factor that is equal to the negative of the applicable percent specified in subparagraph (B) for such year.

(B) APPLICABLE PERCENT DEFINED.—For purposes of this paragraph, the term "applicable percent" means—

(i) for 2019, 4 percent;

(ii) for 2020, 5 percent;

(iii) for 2021, 7 percent; and

(iv) for 2022 and subsequent years, 9 percent.

(C) ADDITIONAL MIPS ADJUSTMENT FACTORS FOR EXCEPTIONAL PERFORMANCE.—For 2019 and each subsequent year through 2024, in the case of a MIPS eligible professional with a composite performance score for a year at or above the additional performance threshold under subparagraph (D)(ii) for such year, in addition to the MIPS adjustment factor under subparagraph (A) for the eligible professional for such year, subject to subparagraph (F)(iv), the Secretary shall specify an additional positive MIPS adjustment factor for such professional and year. Such additional MIPS adjustment factors shall be in the form of a percent and determined by the Secretary in a manner such that professionals having higher composite performance scores above the additional performance threshold receive higher additional MIPS adjustment factors.

(D) ESTABLISHMENT OF PERFORMANCE THRESHOLDS.—

(i) PERFORMANCE THRESHOLD.—For each year of the MIPS, the Secretary shall compute a performance threshold with respect to which the composite performance score of MIPS eligible professionals shall be compared for purposes of determining adjustment factors under subparagraph (A) that are positive, nega-

tive, and zero. Such performance threshold for a year shall be the mean or median (as selected by the Secretary) of the composite performance scores for all MIPS eligible professionals with respect to a prior period specified by the Secretary. The Secretary may reassess the selection of the mean or median under the previous sentence every 3 years.

(ii) ADDITIONAL PERFORMANCE THRESHOLD FOR EXCEPTIONAL PERFORMANCE.—In addition to the performance threshold under clause (i), for each year of the MIPS, the Secretary shall compute an additional performance threshold for purposes of determining the additional MIPS adjustment factors under subparagraph (C). For each such year, the Secretary shall apply either of the following methods for computing such additional performance threshold for such a year:

(I) The threshold shall be the score that is equal to the 25th percentile of the range of possible composite performance scores above the performance threshold determined under clause (i).

(II) The threshold shall be the score that is equal to the 25th percentile of the actual composite performance scores for MIPS eligible professionals with composite performance scores at or above the performance threshold with respect to the prior period described in clause (i).

(iii) SPECIAL RULE FOR INITIAL 2 YEARS.—With respect to each of the first two years to which the MIPS applies, the Secretary shall, prior to the performance period for such years, establish a performance threshold for purposes of determining MIPS adjustment factors under subparagraph (A) and a threshold for purposes of determining additional MIPS adjustment factors under subparagraph (C). Each such performance threshold shall—

(I) be based on a period prior to such performance periods; and

(II) take into account—

(aa) data available with respect to performance on measures and activities that may be used under the performance categories under subparagraph (2)(B); and

(bb) other factors determined appropriate by the Secretary.

(E) APPLICATION OF MIPS ADJUSTMENT FACTORS.—In the case of items and services furnished by a MIPS eligible professional during a year (beginning with 2019), the amount otherwise paid under this part with respect to such items and services and MIPS eligible professional for such year, shall be multiplied by—

(i) 1, plus

(ii) the sum of—

(I) the MIPS adjustment factor determined under subparagraph (A) divided by 100, and

(II) as applicable, the additional MIPS adjustment factor determined under subparagraph (C) divided by 100.

(F) AGGREGATE APPLICATION OF MIPS ADJUSTMENT FACTORS.—

(i) APPLICATION OF SCALING FACTOR.—

(I) IN GENERAL.—With respect to positive MIPS adjustment factors under subparagraph (A)(ii)(I) for eligible professionals whose composite performance score is above the performance threshold under subparagraph (D)(i) for such year, subject to subclause (II), the Secretary shall increase or decrease such adjustment factors by a scaling factor in order to ensure that the budget neutrality requirement of clause (ii) is met.

(II) SCALING FACTOR LIMIT.—In no case may the scaling factor applied under this clause exceed 3.0.

(ii) BUDGET NEUTRALITY REQUIREMENT.—

(I) IN GENERAL.—Subject to clause (iii), the Secretary shall ensure that the estimated amount described in subclause (II) for a year is equal to the estimated amount described in subclause (III) for such year.

(II) AGGREGATE INCREASES.—The amount described in this subclause is the estimated increase in the aggregate allowed charges resulting from the application of positive MIPS adjustment factors under subparagraph (A) (after application of the scaling factor described in clause (i)) to MIPS eligible professionals whose composite performance score for a year is above the performance threshold under subparagraph (D)(i) for such year.

(III) AGGREGATE DECREASES.—The amount described in this subclause is the estimated decrease in the aggregate allowed charges resulting from the application of negative MIPS adjustment factors under subparagraph (A) to MIPS eligible professionals whose composite performance score for a year is below the performance threshold under subparagraph (D)(i) for such year.

(iii) EXCEPTIONS.—

(I) In the case that all MIPS eligible professionals receive composite performance scores for a year that are below the performance threshold under subparagraph (D)(i) for such year, the negative MIPS adjustment factors under subparagraph (A) shall apply with respect to such MIPS eligible professionals and the budget neutrality requirement of clause (ii) and the additional adjustment factors under clause (iv) shall not apply for such year.

(II) In the case that, with respect to a year, the application of clause (i) results in a scaling factor equal to the maximum scaling factor specified in clause (i)(II), such scaling factor shall apply and

the budget neutrality requirement of clause (ii) shall not apply for such year.

(iv) ADDITIONAL INCENTIVE PAYMENT ADJUSTMENTS.—

(I) IN GENERAL.—Subject to subclause (II), in specifying the MIPS additional adjustment factors under subparagraph (C) for each applicable MIPS eligible professional for a year, the Secretary shall ensure that the estimated aggregate increase in payments under this part resulting from the application of such additional adjustment factors for MIPS eligible professionals in a year shall be equal (as estimated by the Secretary) to $500,000,000 for each year beginning with 2019 and ending with 2024.

(II) LIMITATION ON ADDITIONAL INCENTIVE PAYMENT ADJUSTMENTS.—The MIPS additional adjustment factor under subparagraph (C) for a year for an applicable MIPS eligible professional whose composite performance score is above the additional performance threshold under subparagraph (D)(ii) for such year shall not exceed 10 percent. The application of the previous sentence may result in an aggregate amount of additional incentive payments that are less than the amount specified in subclause (I).

(7) ANNOUNCEMENT OF RESULT OF ADJUSTMENTS.—Under the MIPS, the Secretary shall, not later than 30 days prior to January 1 of the year involved, make available to MIPS eligible professionals the MIPS adjustment factor (and, as applicable, the additional MIPS adjustment factor) under paragraph (6) applicable to the eligible professional for items and services furnished by the professional for such year. The Secretary may include such information in the confidential feedback under paragraph (12).

(8) NO EFFECT IN SUBSEQUENT YEARS.—The MIPS adjustment factors and additional MIPS adjustment factors under paragraph (6) shall apply only with respect to the year involved, and the Secretary shall not take into account such adjustment factors in making payments to a MIPS eligible professional under this part in a subsequent year.

(9) PUBLIC REPORTING.—

(A) IN GENERAL.—The Secretary shall, in an easily understandable format, make available on the Physician Compare Internet website of the Centers for Medicare & Medicaid Services the following:

(i) Information regarding the performance of MIPS eligible professionals under the MIPS, which—

(I) shall include the composite score for each such MIPS eligible professional and the performance of each such MIPS eligible professional with respect to each performance category; and

(II) may include the performance of each such MIPS eligible professional with respect to each measure or activity specified in paragraph (2)(B).

(ii) The names of eligible professionals in eligible alternative payment models (as defined in section 1833(z)(3)(D)) and, to the extent feasible, the names of such eligible alternative payment models and performance of such models.

(B) DISCLOSURE.—The information made available under this paragraph shall indicate, where appropriate, that publicized information may not be representative of the eligible professional's entire patient population, the variety of services furnished by the eligible professional, or the health conditions of individuals treated.

(C) OPPORTUNITY TO REVIEW AND SUBMIT CORRECTIONS.—The Secretary shall provide for an opportunity for a professional described in subparagraph (A) to review, and submit corrections for, the information to be made public with respect to the professional under such subparagraph prior to such information being made public.

(D) AGGREGATE INFORMATION.—The Secretary shall periodically post on the Physician Compare Internet website aggregate information on the MIPS, including the range of composite scores for all MIPS eligible professionals and the range of the performance of all MIPS eligible professionals with respect to each performance category.

(10) CONSULTATION.—The Secretary shall consult with stakeholders in carrying out the MIPS, including for the identification of measures and activities under paragraph (2)(B) and the methodologies developed under paragraphs (5)(A) and (6) and regarding the use of qualified clinical data registries. Such consultation shall include the use of a request for information or other mechanisms determined appropriate.

(11) TECHNICAL ASSISTANCE TO SMALL PRACTICES AND PRACTICES IN HEALTH PROFESSIONAL SHORTAGE AREAS.—

(A) IN GENERAL.—The Secretary shall enter into contracts or agreements with appropriate entities (such as quality improvement organizations, regional extension centers (as described in section 3012(c) of the Public Health Service Act), or regional health collaboratives) to offer guidance and assistance to MIPS eligible professionals in practices of 15 or fewer professionals (with priority given to such practices located in rural areas, health professional shortage areas (as designated under in section 332(a)(1)(A) of such Act), and medically underserved areas, and practices with low composite scores) with respect to—

(i) the performance categories described in clauses (i) through (iv) of paragraph (2)(A); or

(ii) how to transition to the implementation of and participation in an alternative payment model as described in section 1833(z)(3)(C).

(B) FUNDING FOR TECHNICAL ASSISTANCE.—For purposes of implementing subparagraph (A), the Secretary shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 to the Centers for Medicare & Medicaid Services Program Management Account of $20,000,000 for each of fiscal years 2016 through 2020. Amounts transferred under this

subparagraph for a fiscal year shall be available until expended.

(12) FEEDBACK AND INFORMATION TO IMPROVE PERFORMANCE.—

(A) PERFORMANCE FEEDBACK.—

(i) IN GENERAL.—Beginning July 1, 2017, the Secretary—

(I) shall make available timely (such as quarterly) confidential feedback to MIPS eligible professionals on the performance of such professionals with respect to the performance categories under clauses (i) and (ii) of paragraph (2)(A); and

(II) may make available confidential feedback to such professionals on the performance of such professionals with respect to the performance categories under clauses (iii) and (iv) of such paragraph.

(ii) MECHANISMS.—The Secretary may use one or more mechanisms to make feedback available under clause (i), which may include use of a web-based portal or other mechanisms determined appropriate by the Secretary. With respect to the performance category described in paragraph (2)(A)(i), feedback under this subparagraph shall, to the extent an eligible professional chooses to participate in a data registry for purposes of this subsection (including registries under subsections (k) and (m)), be provided based on performance on quality measures reported through the use of such registries. With respect to any other performance category described in paragraph (2)(A), the Secretary shall encourage provision of feedback through qualified clinical data registries as described in subsection (m)(3)(E)).

(iii) USE OF DATA.—For purposes of clause (i), the Secretary may use data, with respect to a MIPS eligible professional, from periods prior to the current performance period and may use rolling periods in order to make illustrative calculations about the performance of such professional.

(iv) DISCLOSURE EXEMPTION.—Feedback made available under this subparagraph shall be exempt from disclosure under section 552 of title 5, United States Code.

(v) RECEIPT OF INFORMATION.—The Secretary may use the mechanisms established under clause (ii) to receive information from professionals, such as information with respect to this subsection.

(B) ADDITIONAL INFORMATION.—

(i) IN GENERAL.—Beginning July 1, 2018, the Secretary shall make available to MIPS eligible professionals information, with respect to individuals who are patients of such MIPS eligible professionals, about items and services for which payment is made under this title that are furnished to such individuals by other suppliers and providers of services, which may

include information described in clause (ii). Such information may be made available under the previous sentence to such MIPS eligible professionals by mechanisms determined appropriate by the Secretary, which may include use of a web-based portal. Such information may be made available in accordance with the same or similar terms as data are made available to accountable care organizations participating in the shared savings program under section 1899.

(ii) TYPE OF INFORMATION.—For purposes of clause (i), the information described in this clause, is the following:

(I) With respect to selected items and services (as determined appropriate by the Secretary) for which payment is made under this title and that are furnished to individuals, who are patients of a MIPS eligible professional, by another supplier or provider of services during the most recent period for which data are available (such as the most recent three-month period), such as the name of such providers furnishing such items and services to such patients during such period, the types of such items and services so furnished, and the dates such items and services were so furnished.

(II) Historical data, such as averages and other measures of the distribution if appropriate, of the total, and components of, allowed charges (and other figures as determined appropriate by the Secretary).

(13) REVIEW.—

(A) TARGETED REVIEW.—The Secretary shall establish a process under which a MIPS eligible professional may seek an informal review of the calculation of the MIPS adjustment factor (or factors) applicable to such eligible professional under this subsection for a year. The results of a review conducted pursuant to the previous sentence shall not be taken into account for purposes of paragraph (6) with respect to a year (other than with respect to the calculation of such eligible professional's MIPS adjustment factor for such year or additional MIPS adjustment factor for such year) after the factors determined in subparagraph (A) and subparagraph (C) of such paragraph have been determined for such year.

(B) LIMITATION.—Except as provided for in subparagraph (A), there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

(i) The methodology used to determine the amount of the MIPS adjustment factor under paragraph (6)(A) and the amount of the additional MIPS adjustment factor under paragraph (6)(C) and the determination of such amounts.

(ii) The establishment of the performance standards under paragraph (3) and the performance period under paragraph (4).

(iii) The identification of measures and activities specified under paragraph (2)(B) and information made public or posted on the Physician Compare Internet website of the Centers for Medicare & Medicaid Services under paragraph (9).

(iv) The methodology developed under paragraph (5) that is used to calculate performance scores and the calculation of such scores, including the weighting of measures and activities under such methodology.

(r) COLLABORATING WITH THE PHYSICIAN, PRACTITIONER, AND OTHER STAKEHOLDER COMMUNITIES TO IMPROVE RESOURCE USE MEASUREMENT.—

(1) IN GENERAL.—In order to involve the physician, practitioner, and other stakeholder communities in enhancing the infrastructure for resource use measurement, including for purposes of the Merit-based Incentive Payment System under subsection (q) and alternative payment models under section 1833(z), the Secretary shall undertake the steps described in the succeeding provisions of this subsection.

(2) DEVELOPMENT OF CARE EPISODE AND PATIENT CONDITION GROUPS AND CLASSIFICATION CODES.—

(A) IN GENERAL.—In order to classify similar patients into care episode groups and patient condition groups, the Secretary shall undertake the steps described in the succeeding provisions of this paragraph.

(B) PUBLIC AVAILABILITY OF EXISTING EFFORTS TO DESIGN AN EPISODE GROUPER.—Not later than 180 days after the date of the enactment of this subsection, the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a list of the episode groups developed pursuant to subsection (n)(9)(A) and related descriptive information.

(C) STAKEHOLDER INPUT.—The Secretary shall accept, through the date that is 120 days after the day the Secretary posts the list pursuant to subparagraph (B), suggestions from physician specialty societies, applicable practitioner organizations, and other stakeholders for episode groups in addition to those posted pursuant to such subparagraph, and specific clinical criteria and patient characteristics to classify patients into—

(i) care episode groups; and

(ii) patient condition groups.

(D) DEVELOPMENT OF PROPOSED CLASSIFICATION CODES.—

(i) IN GENERAL.—Taking into account the information described in subparagraph (B) and the information received under subparagraph (C), the Secretary shall—

(I) establish care episode groups and patient condition groups, which account for a target of an estimated ½ of expenditures under parts A and B (with such target increasing over time as appropriate); and

(II) assign codes to such groups.

(ii) CARE EPISODE GROUPS.—In establishing the care episode groups under clause (i), the Secretary shall take into account—

(I) the patient's clinical problems at the time items and services are furnished during an episode of care, such as the clinical conditions or diagnoses, whether or not inpatient hospitalization occurs, and the principal procedures or services furnished; and

(II) other factors determined appropriate by the Secretary.

(iii) PATIENT CONDITION GROUPS.—In establishing the patient condition groups under clause (i), the Secretary shall take into account—

(I) the patient's clinical history at the time of a medical visit, such as the patient's combination of chronic conditions, current health status, and recent significant history (such as hospitalization and major surgery during a previous period, such as 3 months); and

(II) other factors determined appropriate by the Secretary, such as eligibility status under this title (including eligibility under section 226(a), 226(b), or 226A, and dual eligibility under this title and title XIX).

(E) DRAFT CARE EPISODE AND PATIENT CONDITION GROUPS AND CLASSIFICATION CODES.—Not later than 270 days after the end of the comment period described in subparagraph (C), the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a draft list of the care episode and patient condition codes established under subparagraph (D) (and the criteria and characteristics assigned to such code).

(F) SOLICITATION OF INPUT.—The Secretary shall seek, through the date that is 120 days after the Secretary posts the list pursuant to subparagraph (E), comments from physician specialty societies, applicable practitioner organizations, and other stakeholders, including representatives of individuals entitled to benefits under part A or enrolled under this part, regarding the care episode and patient condition groups (and codes) posted under subparagraph (E). In seeking such comments, the Secretary shall use one or more mechanisms (other than notice and comment rulemaking) that may include use of open door forums, town hall meetings, or other appropriate mechanisms.

(G) OPERATIONAL LIST OF CARE EPISODE AND PATIENT CONDITION GROUPS AND CODES.—Not later than 270 days after the end of the comment period described in subparagraph (F), taking into account the comments received under such subparagraph, the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services an operational list of care episode and patient condition codes (and the criteria and characteristics assigned to such code).

(H) SUBSEQUENT REVISIONS.—Not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, make revisions to the operational lists of care episode and patient condition codes as the Secretary determines may be appropriate. Such revisions may be based on experience, new information developed pursuant to subsection (n)(9)(A), and input from the physician specialty societies, applicable practitioner organizations, and other stakeholders, including representatives of individuals entitled to benefits under part A or enrolled under this part.

(3) ATTRIBUTION OF PATIENTS TO PHYSICIANS OR PRACTITIONERS.—

(A) IN GENERAL.—In order to facilitate the attribution of patients and episodes (in whole or in part) to one or more physicians or applicable practitioners furnishing items and services, the Secretary shall undertake the steps described in the succeeding provisions of this paragraph.

(B) DEVELOPMENT OF PATIENT RELATIONSHIP CATEGORIES AND CODES.—The Secretary shall develop patient relationship categories and codes that define and distinguish the relationship and responsibility of a physician or applicable practitioner with a patient at the time of furnishing an item or service. Such patient relationship categories shall include different relationships of the physician or applicable practitioner to the patient (and the codes may reflect combinations of such categories), such as a physician or applicable practitioner who—

(i) considers themself to have the primary responsibility for the general and ongoing care for the patient over extended periods of time;

(ii) considers themself to be the lead physician or practitioner and who furnishes items and services and coordinates care furnished by other physicians or practitioners for the patient during an acute episode;

(iii) furnishes items and services to the patient on a continuing basis during an acute episode of care, but in a supportive rather than a lead role;

(iv) furnishes items and services to the patient on an occasional basis, usually at the request of another physician or practitioner; or

(v) furnishes items and services only as ordered by another physician or practitioner.

(C) DRAFT LIST OF PATIENT RELATIONSHIP CATEGORIES AND CODES.—Not later than one year after the date of the enactment of this subsection, the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a draft list of the patient relationship categories and codes developed under subparagraph (B).

(D) STAKEHOLDER INPUT.—The Secretary shall seek, through the date that is 120 days after the Secretary posts the list pursuant to subparagraph (C), comments from physician specialty societies, applicable practitioner organizations, and other stakeholders, including representatives of individuals entitled to benefits under part A or en-

rolled under this part, regarding the patient relationship categories and codes posted under subparagraph (C). In seeking such comments, the Secretary shall use one or more mechanisms (other than notice and comment rulemaking) that may include open door forums, town hall meetings, web-based forums, or other appropriate mechanisms.

(E) OPERATIONAL LIST OF PATIENT RELATIONSHIP CATEGORIES AND CODES.—Not later than 240 days after the end of the comment period described in subparagraph (D), taking into account the comments received under such subparagraph, the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services an operational list of patient relationship categories and codes.

(F) SUBSEQUENT REVISIONS.—Not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, make revisions to the operational list of patient relationship categories and codes as the Secretary determines appropriate. Such revisions may be based on experience, new information developed pursuant to subsection (n)(9)(A), and input from the physician specialty societies, applicable practitioner organizations, and other stakeholders, including representatives of individuals entitled to benefits under part A or enrolled under this part.

(4) REPORTING OF INFORMATION FOR RESOURCE USE MEASUREMENT.—Claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018, shall, as determined appropriate by the Secretary, include—

(A) applicable codes established under paragraphs (2) and (3); and

(B) the national provider identifier of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner).

(5) METHODOLOGY FOR RESOURCE USE ANALYSIS.—

(A) IN GENERAL.—In order to evaluate the resources used to treat patients (with respect to care episode and patient condition groups), the Secretary shall, as the Secretary determines appropriate—

(i) use the patient relationship codes reported on claims pursuant to paragraph (4) to attribute patients (in whole or in part) to one or more physicians and applicable practitioners;

(ii) use the care episode and patient condition codes reported on claims pursuant to paragraph (4) as a basis to compare similar patients and care episodes and patient condition groups; and

(iii) conduct an analysis of resource use (with respect to care episodes and patient condition groups of such patients).

(B) ANALYSIS OF PATIENTS OF PHYSICIANS AND PRACTITIONERS.—In conducting the analysis described in subparagraph (A)(iii) with respect to patients attributed to

physicians and applicable practitioners, the Secretary shall, as feasible—

(i) use the claims data experience of such patients by patient condition codes during a common period, such as 12 months; and

(ii) use the claims data experience of such patients by care episode codes—

(I) in the case of episodes without a hospitalization, during periods of time (such as the number of days) determined appropriate by the Secretary; and

(II) in the case of episodes with a hospitalization, during periods of time (such as the number of days) before, during, and after the hospitalization.

(C) MEASUREMENT OF RESOURCE USE.—In measuring such resource use, the Secretary—

(i) shall use per patient total allowed charges for all services under part A and this part (and, if the Secretary determines appropriate, part D) for the analysis of patient resource use, by care episode codes and by patient condition codes; and

(ii) may, as determined appropriate, use other measures of allowed charges (such as subtotals for categories of items and services) and measures of utilization of items and services (such as frequency of specific items and services and the ratio of specific items and services among attributed patients or episodes).

(D) STAKEHOLDER INPUT.—The Secretary shall seek comments from the physician specialty societies, applicable practitioner organizations, and other stakeholders, including representatives of individuals entitled to benefits under part A or enrolled under this part, regarding the resource use methodology established pursuant to this paragraph. In seeking comments the Secretary shall use one or more mechanisms (other than notice and comment rulemaking) that may include open door forums, town hall meetings, web-based forums, or other appropriate mechanisms.

(6) IMPLEMENTATION.—To the extent that the Secretary contracts with an entity to carry out any part of the provisions of this subsection, the Secretary may not contract with an entity or an entity with a subcontract if the entity or subcontracting entity currently makes recommendations to the Secretary on relative values for services under the fee schedule for physicians' services under this section.

(7) LIMITATION.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of—

(A) care episode and patient condition groups and codes established under paragraph (2);

(B) patient relationship categories and codes established under paragraph (3); and

(C) measurement of, and analyses of resource use with respect to, care episode and patient condition codes and patient relationship codes pursuant to paragraph (5).

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

(9) DEFINITIONS.—In this subsection:

(A) PHYSICIAN.—The term "physician" has the meaning given such term in section 1861(r)(1).

(B) APPLICABLE PRACTITIONER.—The term "applicable practitioner" means—

(i) a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5)), and a certified registered nurse anesthetist (as defined in section 1861(bb)(2)); and

(ii) beginning January 1, 2019, such other eligible professionals (as defined in subsection (k)(3)(B)) as specified by the Secretary.

(10) CLARIFICATION.—The provisions of sections 1890(b)(7) and 1890A shall not apply to this subsection.

(s) PRIORITIES AND FUNDING FOR MEASURE DEVELOPMENT.—

(1) PLAN IDENTIFYING MEASURE DEVELOPMENT PRIORITIES AND TIMELINES.—

(A) DRAFT MEASURE DEVELOPMENT PLAN.—Not later than January 1, 2016, the Secretary shall develop, and post on the Internet website of the Centers for Medicare & Medicaid Services, a draft plan for the development of quality measures for application under the applicable provisions (as defined in paragraph (5)). Under such plan the Secretary shall—

(i) address how measures used by private payers and integrated delivery systems could be incorporated under title XVIII;

(ii) describe how coordination, to the extent possible, will occur across organizations developing such measures; and

(iii) take into account how clinical best practices and clinical practice guidelines should be used in the development of quality measures.

(B) QUALITY DOMAINS.—For purposes of this subsection, the term "quality domains" means at least the following domains:

(i) Clinical care.

(ii) Safety.

(iii) Care coordination.

(iv) Patient and caregiver experience.

(v) Population health and prevention.

(C) CONSIDERATION.—In developing the draft plan under this paragraph, the Secretary shall consider—

(i) gap analyses conducted by the entity with a contract under section 1890(a) or other contractors or entities;

(ii) whether measures are applicable across health care settings;

(iii) clinical practice improvement activities submitted under subsection (q)(2)(C)(iv) for identifying possible areas for future measure development and identifying existing gaps with respect to such measures; and

(iv) the quality domains applied under this subsection.

(D) PRIORITIES.—In developing the draft plan under this paragraph, the Secretary shall give priority to the following types of measures:

(i) Outcome measures, including patient reported outcome and functional status measures.

(ii) Patient experience measures.

(iii) Care coordination measures.

(iv) Measures of appropriate use of services, including measures of over use.

(E) STAKEHOLDER INPUT.—The Secretary shall accept through March 1, 2016, comments on the draft plan posted under paragraph (1)(A) from the public, including health care providers, payers, consumers, and other stakeholders.

(F) FINAL MEASURE DEVELOPMENT PLAN.—Not later than May 1, 2016, taking into account the comments received under this subparagraph, the Secretary shall finalize the plan and post on the Internet website of the Centers for Medicare & Medicaid Services an operational plan for the development of quality measures for use under the applicable provisions. Such plan shall be updated as appropriate.

(2) CONTRACTS AND OTHER ARRANGEMENTS FOR QUALITY MEASURE DEVELOPMENT.—

(A) IN GENERAL.—The Secretary shall enter into contracts or other arrangements with entities for the purpose of developing, improving, updating, or expanding in accordance with the plan under paragraph (1) quality measures for application under the applicable provisions. Such entities shall include organizations with quality measure development expertise.

(B) PRIORITIZATION.—

(i) IN GENERAL.—In entering into contracts or other arrangements under subparagraph (A), the Secretary shall give priority to the development of the types of measures described in paragraph (1)(D).

(ii) CONSIDERATION.—In selecting measures for development under this subsection, the Secretary shall consider—

(I) whether such measures would be electronically specified; and

(II) clinical practice guidelines to the extent that such guidelines exist.

(3) ANNUAL REPORT BY THE SECRETARY.—

(A) IN GENERAL.—Not later than May 1, 2017, and annually thereafter, the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a report on the progress made in developing quality measures for application under the applicable provisions.

(B) REQUIREMENTS.—Each report submitted pursuant to subparagraph (A) shall include the following:

(i) A description of the Secretary's efforts to implement this paragraph.

(ii) With respect to the measures developed during the previous year—

(I) a description of the total number of quality measures developed and the types of such measures, such as an outcome or patient experience measure;

(II) the name of each measure developed;

(III) the name of the developer and steward of each measure;

(IV) with respect to each type of measure, an estimate of the total amount expended under this title to develop all measures of such type; and

(V) whether the measure would be electronically specified.

(iii) With respect to measures in development at the time of the report—

(I) the information described in clause (ii), if available; and

(II) a timeline for completion of the development of such measures.

(iv) A description of any updates to the plan under paragraph (1) (including newly identified gaps and the status of previously identified gaps) and the inventory of measures applicable under the applicable provisions.

(v) Other information the Secretary determines to be appropriate.

(4) STAKEHOLDER INPUT.—With respect to paragraph (1), the Secretary shall seek stakeholder input with respect to—

(A) the identification of gaps where no quality measures exist, particularly with respect to the types of measures described in paragraph (1)(D);

(B) prioritizing quality measure development to address such gaps; and

(C) other areas related to quality measure development determined appropriate by the Secretary.

(5) DEFINITION OF APPLICABLE PROVISIONS.—In this subsection, the term "applicable provisions" means the following provisions:

(A) Subsection (q)(2)(B)(i).

(B) Section 1833(z)(2)(C).

(6) FUNDING.—For purposes of carrying out this subsection, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of $15,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for each of fiscal years 2015 through 2019. Amounts transferred under this paragraph shall remain available through the end of fiscal year 2022.

(7) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the collection of information for the development of quality measures.

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PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

Subpart 1—Part D Eligible Individuals and Prescription Drug Benefits

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BENEFICIARY PROTECTIONS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE

SEC. 1860D–4. (a) DISSEMINATION OF INFORMATION.—

(1) GENERAL INFORMATION.—

(A) APPLICATION OF MA INFORMATION.—A PDP sponsor shall disclose, in a clear, accurate, and standardized form to each enrollee with a prescription drug plan offered by the sponsor under this part at the time of enrollment and at least annually thereafter, the information described in section 1852(c)(1) relating to such plan, insofar as the Secretary determines appropriate with respect to benefits provided under this part, and including the information described in subparagraph (B).

(B) DRUG SPECIFIC INFORMATION.—The information described in this subparagraph is information concerning the following:

(i) Access to specific covered part D drugs, including access through pharmacy networks.

(ii) How any formulary (including any tiered formulary structure) used by the sponsor functions, including a description of how a part D eligible individual may obtain information on the formulary consistent with paragraph (3).

(iii) Beneficiary cost-sharing requirements and how a part D eligible individual may obtain information on such requirements, including tiered or other copayment level applicable to each drug (or class of drugs), consistent with paragraph (3).

(iv) The medication therapy management program required under subsection (c).

(v) The drug management program for at-risk beneficiaries under subsection (c)(5).

(2) DISCLOSURE UPON REQUEST OF GENERAL COVERAGE, UTILIZATION, AND GRIEVANCE INFORMATION.—Upon request of a part D eligible individual who is eligible to enroll in a prescription drug plan, the PDP sponsor offering such plan shall provide information similar (as determined by the Secretary) to the information described in subparagraphs (A), (B), and (C) of section 1852(c)(2) to such individual.

(3) PROVISION OF SPECIFIC INFORMATION.—

(A) RESPONSE TO BENEFICIARY QUESTIONS.—Each PDP sponsor offering a prescription drug plan shall have a mechanism for providing specific information on a timely basis to enrollees upon request. Such mechanism shall include access to information through the use of a toll-free telephone number and, upon request, the provision of such information in writing.

(B) AVAILABILITY OF INFORMATION ON CHANGES IN FORMULARY THROUGH THE INTERNET.—A PDP sponsor offering a prescription drug plan shall make available on a timely basis through an Internet website information on specific changes in the formulary under the plan (including changes to tiered or preferred status of covered part D drugs).

(4) CLAIMS INFORMATION.—A PDP sponsor offering a prescription drug plan must furnish to each enrollee in a form easily understandable to such enrollees—

(A) an explanation of benefits (in accordance with section 1806(a) or in a comparable manner); and

(B) when prescription drug benefits are provided under this part, a notice of the benefits in relation to—

(i) the initial coverage limit for the current year; and

(ii) the annual out-of-pocket threshold for the current year.

Notices under subparagraph (B) need not be provided more often than as specified by the Secretary and notices under subparagraph (B)(ii) shall take into account the application of section 1860D–2(b)(4)(C) to the extent practicable, as specified by the Secretary.

(b) ACCESS TO COVERED PART D DRUGS.—

(1) ASSURING PHARMACY ACCESS.—

(A) PARTICIPATION OF ANY WILLING PHARMACY.—A prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.

(B) DISCOUNTS ALLOWED FOR NETWORK PHARMACIES.—For covered part D drugs dispensed through in-network pharmacies, a prescription drug plan may, notwithstanding subparagraph (A), reduce coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required. In no case shall such a reduction result in an increase in payments made by the Secretary under section 1860D–15 to a plan.

(C) CONVENIENT ACCESS FOR NETWORK PHARMACIES.—

(i) IN GENERAL.—The PDP sponsor of the prescription drug plan shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary).

(ii) APPLICATION OF TRICARE STANDARDS.—The Secretary shall establish rules for convenient access to in-network pharmacies under this subparagraph that are no less favorable to enrollees than the rules for convenient access to pharmacies included in the statement of work of solicitation (#MDA906–03–R–0002) of the Department of Defense under the TRICARE Retail Pharmacy (TRRx) as of March 13, 2003.

(iii) ADEQUATE EMERGENCY ACCESS.—Such rules shall include adequate emergency access for enrollees.

(iv) CONVENIENT ACCESS IN LONG-TERM CARE FACILITIES.—Such rules may include standards with respect

to access for enrollees who are residing in long-term care facilities and for pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (as defined in section 4 of the Indian Health Care Improvement Act).

(D) LEVEL PLAYING FIELD.—Such a sponsor shall permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a pharmacy (other than a mail order pharmacy), with any differential in charge paid by such enrollees.

(E) NOT REQUIRED TO ACCEPT INSURANCE RISK.—The terms and conditions under subparagraph (A) may not require participating pharmacies to accept insurance risk as a condition of participation.

(2) USE OF STANDARDIZED TECHNOLOGY.—

(A) IN GENERAL.—The PDP sponsor of a prescription drug plan shall issue (and reissue, as appropriate) such a card (or other technology) that may be used by an enrollee to assure access to negotiated prices under section 1860D–2(d).

(B) STANDARDS.—

(i) IN GENERAL.—The Secretary shall provide for the development, adoption, or recognition of standards relating to a standardized format for the card or other technology required under subparagraph (A). Such standards shall be compatible with part C of title XI and may be based on standards developed by an appropriate standard setting organization.

(ii) CONSULTATION.—In developing the standards under clause (i), the Secretary shall consult with the National Council for Prescription Drug Programs and other standard setting organizations determined appropriate by the Secretary.

(iii) IMPLEMENTATION.—The Secretary shall develop, adopt, or recognize the standards under clause (i) by such date as the Secretary determines shall be sufficient to ensure that PDP sponsors utilize such standards beginning January 1, 2006.

(3) REQUIREMENTS ON DEVELOPMENT AND APPLICATION OF FORMULARIES.—If a PDP sponsor of a prescription drug plan uses a formulary (including the use of tiered cost-sharing), the following requirements must be met:

(A) DEVELOPMENT AND REVISION BY A PHARMACY AND THERAPEUTIC (P&T) COMMITTEE.—

(i) IN GENERAL.—The formulary must be developed and reviewed by a pharmacy and therapeutic committee. A majority of the members of such committee shall consist of individuals who are practicing physicians or practicing pharmacists (or both).

(ii) INCLUSION OF INDEPENDENT EXPERTS.—Such committee shall include at least one practicing physician and at least one practicing pharmacist, each of whom—

(I) is independent and free of conflict with respect to the sponsor and plan; and

(II) has expertise in the care of elderly or disabled persons.

(B) FORMULARY DEVELOPMENT.—In developing and reviewing the formulary, the committee shall—

(i) base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and on such other information as the committee determines to be appropriate; and

(ii) take into account whether including in the formulary (or in a tier in such formulary) particular covered part D drugs has therapeutic advantages in terms of safety and efficacy.

(C) INCLUSION OF DRUGS IN ALL THERAPEUTIC CATEGORIES AND CLASSES.—

(i) IN GENERAL.—Subject to subparagraph (G), the formulary must include drugs within each therapeutic category and class of covered part D drugs, although not necessarily all drugs within such categories and classes.

(ii) MODEL GUIDELINES.—The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and the additions of new covered part D drugs.

(iii) LIMITATION ON CHANGES IN THERAPEUTIC CLASSIFICATION.—The PDP sponsor of a prescription drug plan may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year except as the Secretary may permit to take into account new therapeutic uses and newly approved covered part D drugs.

(D) PROVIDER AND PATIENT EDUCATION.—The PDP sponsor shall establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary.

(E) NOTICE BEFORE REMOVING DRUG FROM FORMULARY OR CHANGING PREFERRED OR TIER STATUS OF DRUG.—Any removal of a covered part D drug from a formulary and any change in the preferred or tiered cost-sharing status of such a drug shall take effect only after appropriate notice is made available (such as under subsection (a)(3)) to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists.

(F) PERIODIC EVALUATION OF PROTOCOLS.—In connection with the formulary, the sponsor of a prescription drug plan shall provide for the periodic evaluation and analysis of treatment protocols and procedures.

(G) REQUIRED INCLUSION OF DRUGS IN CERTAIN CATEGORIES AND CLASSES.—

(i) FORMULARY REQUIREMENTS.—

(I) IN GENERAL.—Subject to subclause (II), a PDP sponsor offering a prescription drug plan shall be required to include all covered part D drugs in the categories and classes identified by the Secretary under clause (ii)(I).

(II) EXCEPTIONS.—The Secretary may establish exceptions that permit a PDP sponsor offering a prescription drug plan to exclude from its formulary a particular covered part D drug in a category or class that is otherwise required to be included in the formulary under subclause (I) (or to otherwise limit access to such a drug, including through prior authorization or utilization management).

(ii) IDENTIFICATION OF DRUGS IN CERTAIN CATEGORIES AND CLASSES.—

(I) IN GENERAL.—Subject to clause (iv), the Secretary shall identify, as appropriate, categories and classes of drugs for which the Secretary determines are of clinical concern.

(II) CRITERIA.—The Secretary shall use criteria established by the Secretary in making any determination under subclause (I).

(iii) IMPLEMENTATION.—The Secretary shall establish the criteria under clause (ii)(II) and any exceptions under clause (i)(II) through the promulgation of a regulation which includes a public notice and comment period.

(iv) REQUIREMENT FOR CERTAIN CATEGORIES AND CLASSES UNTIL CRITERIA ESTABLISHED.—Until such time as the Secretary establishes the criteria under clause (ii)(II) the following categories and classes of drugs shall be identified under clause (ii)(I):

(I) Anticonvulsants.

(II) Antidepressants.

(III) Antineoplastics.

(IV) Antipsychotics.

(V) Antiretrovirals.

(VI) Immunosuppressants for the treatment of transplant rejection.

(H) USE OF SINGLE, UNIFORM EXCEPTIONS AND APPEALS PROCESS.—Notwithstanding any other provision of this part, each PDP sponsor of a prescription drug plan shall—

(i) use a single, uniform exceptions and appeals process (including, to the extent the Secretary determines feasible, a single, uniform model form for use under such process) with respect to the determination of prescription drug coverage for an enrollee under the plan; and

(ii) provide instant access to such process by enrollees through a toll-free telephone number and an Internet website.

(c) COST AND UTILIZATION MANAGEMENT; QUALITY ASSURANCE; MEDICATION THERAPY MANAGEMENT PROGRAM.—

(1) IN GENERAL.—The PDP sponsor shall have in place, directly or through appropriate arrangements, with respect to covered part D drugs, the following:

(A) A cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs (as defined in section 1927(k)(7)(A)(i)).

(B) Quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use.

(C) A medication therapy management program described in paragraph (2).

(D) A program to control fraud, abuse, and waste.

(E) A utilization management tool to prevent drug abuse (as described in paragraph (6)(A)).

Nothing in this section shall be construed as impairing a PDP sponsor from utilizing cost management tools (including differential payments) under all methods of operation.

(2) MEDICATION THERAPY MANAGEMENT PROGRAM.—

(A) DESCRIPTION.—

(i) IN GENERAL.—A medication therapy management program described in this paragraph is a program of drug therapy management that may be furnished by a pharmacist and that is designed to assure, with respect to targeted beneficiaries described in clause (ii), that covered part D drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions. Such a program may distinguish between services in ambulatory and institutional settings.

(ii) TARGETED BENEFICIARIES DESCRIBED.—Targeted beneficiaries described in this clause are part D eligible individuals who—

(I) have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure);

(II) are taking multiple covered part D drugs; and

(III) are identified as likely to incur annual costs for covered part D drugs that exceed a level specified by the Secretary.

(B) ELEMENTS.—Such program may include elements that promote—

(i) enhanced enrollee understanding to promote the appropriate use of medications by enrollees and to reduce the risk of potential adverse events associated with medications, through beneficiary education, counseling, and other appropriate means;

(ii) increased enrollee adherence with prescription medication regimens through medication refill reminders, special packaging, and other compliance programs and other appropriate means; and

(iii) detection of adverse drug events and patterns of overuse and underuse of prescription drugs.

(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—

(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.

(E) DEVELOPMENT OF PROGRAM IN COOPERATION WITH LICENSED PHARMACISTS.—Such program shall be developed in cooperation with licensed and practicing pharmacists and physicians.

(F) COORDINATION WITH CARE MANAGEMENT PLANS.—The Secretary shall establish guidelines for the coordination of any medication therapy management program under this paragraph with respect to a targeted beneficiary with any care management plan established with respect to such beneficiary under a chronic care improvement program under section 1807.

(G) CONSIDERATIONS IN PHARMACY FEES.—The PDP sponsor of a prescription drug plan shall take into account, in establishing fees for pharmacists and others providing services under such plan, the resources used, and time required to, implement the medication therapy management program under this paragraph. Each such sponsor shall disclose to the Secretary upon request the amount of any such management or dispensing fees. The provisions of section 1927(b)(3)(D) apply to information disclosed under this subparagraph.

(3) REDUCING WASTEFUL DISPENSING OF OUTPATIENT PRESCRIPTION DRUGS IN LONG-TERM CARE FACILITIES.—The Secretary shall require PDP sponsors of prescription drug plans to utilize specific, uniform dispensing techniques, as determined by the Secretary, in consultation with relevant stakeholders (including representatives of nursing facilities, residents of nursing facilities, pharmacists, the pharmacy industry (including retail and long-term care pharmacy), prescription drug plans, MA–PD plans, and any other stakeholders the Secretary determines appropriate), such as weekly, daily, or automated dose dispensing, when dispensing covered part D drugs to enrollees who reside in a long-term care facility in order to reduce waste associated with 30-day fills.

(4) REQUIRING VALID PRESCRIBER NATIONAL PROVIDER IDENTIFIERS ON PHARMACY CLAIMS.—

(A) IN GENERAL.—For plan year 2016 and subsequent plan years, the Secretary shall require a claim for a covered part D drug for a part D eligible individual enrolled in a prescription drug plan under this part or an MA–PD plan under part C to include a prescriber National Provider Identifier that is determined to be valid under the procedures established under subparagraph (B)(i).

(B) PROCEDURES.—

(i) VALIDITY OF PRESCRIBER NATIONAL PROVIDER IDENTIFIERS.—The Secretary, in consultation with appropriate stakeholders, shall establish procedures for determining the validity of prescriber National Provider Identifiers under subparagraph (A).

(ii) INFORMING BENEFICIARIES OF REASON FOR DENIAL.—The Secretary shall establish procedures to ensure that, in the case that a claim for a covered part D drug of an individual described in subparagraph (A) is denied because the claim does not meet the requirements of this paragraph, the individual is properly informed at the point of service of the reason for the denial.

(C) REPORT.—Not later than January 1, 2018, the Inspector General of the Department of Health and Human

Services shall submit to Congress a report on the effectiveness of the procedures established under subparagraph (B)(i).

(5) DRUG MANAGEMENT PROGRAM FOR AT-RISK BENEFICIARIES.—

(A) AUTHORITY TO ESTABLISH.—A PDP sponsor may establish a drug management program for at-risk beneficiaries under which, subject to subparagraph (B), the PDP sponsor may, in the case of an at-risk beneficiary for prescription drug abuse who is an enrollee in a prescription drug plan of such PDP sponsor, limit such beneficiary's access to coverage for frequently abused drugs under such plan to frequently abused drugs that are prescribed for such beneficiary by one or more prescribers selected under subparagraph (D), and dispensed for such beneficiary by one or more pharmacies selected under such subparagraph.

(B) REQUIREMENT FOR NOTICES.—

(i) IN GENERAL.—A PDP sponsor may not limit the access of an at-risk beneficiary for prescription drug abuse to coverage for frequently abused drugs under a prescription drug plan until such sponsor—

(I) provides to the beneficiary an initial notice described in clause (ii) and a second notice described in clause (iii); and

(II) verifies with the providers of the beneficiary that the beneficiary is an at-risk beneficiary for prescription drug abuse.

(ii) INITIAL NOTICE.—An initial notice described in this clause is a notice that provides to the beneficiary—

(I) notice that the PDP sponsor has identified the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse;

(II) information describing all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health services and other counseling services;

(III) notice of, and information about, the right of the beneficiary to appeal such identification under subsection (h) and the option of an automatic escalation to external review;

(IV) a request for the beneficiary to submit to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would prefer the PDP sponsor to select under subparagraph (D) in the case that the beneficiary is identified as an at-risk beneficiary for prescription drug abuse as described in clause (iii)(I);

(V) an explanation of the meaning and consequences of the identification of the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse, including an explanation of the drug management program established by the PDP sponsor pursuant to subparagraph (A);

(VI) clear instructions that explain how the beneficiary can contact the PDP sponsor in order to submit to the PDP sponsor the preferences described in subclause (IV) and any other communications relating to the drug management program for at-risk beneficiaries established by the PDP sponsor; and

(VII) contact information for other organizations that can provide the beneficiary with assistance regarding such drug management program (similar to the information provided by the Secretary in other standardized notices provided to part D eligible individuals enrolled in prescription drug plans under this part).

(iii) SECOND NOTICE.—A second notice described in this clause is a notice that provides to the beneficiary notice—

(I) that the PDP sponsor has identified the beneficiary as an at-risk beneficiary for prescription drug abuse;

(II) that such beneficiary is subject to the requirements of the drug management program for at-risk beneficiaries established by such PDP sponsor for such plan;

(III) of the prescriber (or prescribers) and pharmacy (or pharmacies) selected for such individual under subparagraph (D);

(IV) of, and information about, the beneficiary's right to appeal such identification under subsection (h) and the option of an automatic escalation to external review;

(V) that the beneficiary can, in the case that the beneficiary has not previously submitted to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would prefer the PDP sponsor select under subparagraph (D), submit such preferences to the PDP sponsor; and

(VI) that includes clear instructions that explain how the beneficiary can contact the PDP sponsor.

(iv) TIMING OF NOTICES.—

(I) IN GENERAL.—Subject to subclause (II), a second notice described in clause (iii) shall be provided to the beneficiary on a date that is not less than 60 days after an initial notice described in clause (ii) is provided to the beneficiary.

(II) EXCEPTION.—In the case that the PDP sponsor, in conjunction with the Secretary, determines that concerns identified through rulemaking by the Secretary regarding the health or safety of the beneficiary or regarding significant drug diversion activities require the PDP sponsor to provide a second notice described in clause (iii) to the beneficiary on a date that is earlier than the date described in subclause (I), the PDP sponsor may provide such second notice on such earlier date.

(C) AT-RISK BENEFICIARY FOR PRESCRIPTION DRUG ABUSE.—

(i) IN GENERAL.—For purposes of this paragraph, the term "at-risk beneficiary for prescription drug abuse" means a part D eligible individual who is not an exempted individual described in clause (ii) and—

(I) who is identified through the use of clinical guidelines developed by the Secretary in consultation with PDP sponsors and other stakeholders described in section 3141(f)(2)(A) of the 21st Century Cures Act; or

(II) with respect to whom the PDP sponsor of a prescription drug plan, upon enrolling such individual in such plan, received notice from the Secretary that such individual was identified under this paragraph to be an at-risk beneficiary for prescription drug abuse under the prescription drug plan in which such individual was most recently previously enrolled and such identification has not been terminated under subparagraph (F).

(ii) EXEMPTED INDIVIDUAL DESCRIBED.—An exempted individual described in this clause is an individual who—

(I) receives hospice care under this title;

(II) is a resident of a long-term care facility, of an intermediate care facility for the mentally retarded, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or

(III) the Secretary elects to treat as an exempted individual for purposes of clause (i).

(D) SELECTION OF PRESCRIBERS AND PHARMACIES.—

(i) IN GENERAL.—With respect to each at-risk beneficiary for prescription drug abuse enrolled in a prescription drug plan offered by such sponsor, a PDP sponsor shall, based on the preferences submitted to the PDP sponsor by the beneficiary pursuant to clauses (ii)(IV) and (iii)(V) of subparagraph (B), select—

(I) one or more individuals who are authorized to prescribe frequently abused drugs (referred to in this paragraph as "prescribers") who may write prescriptions for such drugs for such beneficiary; and

(II) one or more pharmacies that may dispense such drugs to such beneficiary.

(ii) REASONABLE ACCESS.—In making the selections under this subparagraph—

(I) a PDP sponsor shall ensure that the beneficiary continues to have reasonable access to frequently abused drugs (as defined in subparagraph (G)), taking into account geographic location, beneficiary preference, impact on costsharing, and reasonable travel time; and

(II) a PDP sponsor shall ensure such access (including access to prescribers and pharmacies with

respect to frequently abused drugs) in the case of individuals with multiple residences and in the case of natural disasters and similar emergency situations.

(iii) BENEFICIARY PREFERENCES.—

(I) IN GENERAL.—If an at-risk beneficiary for prescription drug abuse submits preferences for which in-network prescribers and pharmacies the beneficiary would prefer the PDP sponsor select in response to a notice under subparagraph (B), the PDP sponsor shall—

(aa) review such preferences;

(bb) select or change the selection of prescribers and pharmacies for the beneficiary based on such preferences; and

(cc) inform the beneficiary of such selection or change of selection.

(II) EXCEPTION.—In the case that the PDP sponsor determines that a change to the selection of prescriber or pharmacy under item (bb) by the PDP sponsor is contributing or would contribute to prescription drug abuse or drug diversion by the beneficiary, the PDP sponsor may change the selection of prescriber or pharmacy for the beneficiary without regard to the preferences of the beneficiary described in subclause (I).

(iv) CONFIRMATION.—Before selecting a prescriber (or prescribers) or pharmacy (or pharmacies) under this subparagraph, a PDP sponsor must request and receive confirmation from such a prescriber or pharmacy acknowledging and accepting that the beneficiary involved is in the drug management program for at-risk beneficiaries.

(E) TERMINATIONS AND APPEALS.—The identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph, a coverage determination made under a drug management program for at-risk beneficiaries, and the selection of prescriber or pharmacy under subparagraph (D) with respect to such individual shall be subject to reconsideration and appeal under subsection (h) and the option of an automatic escalation to external review to the extent provided by the Secretary.

(F) TERMINATION OF IDENTIFICATION.—

(i) IN GENERAL.—The Secretary shall develop standards for the termination of identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph. Under such standards such identification shall terminate as of the earlier of—

(I) the date the individual demonstrates that the individual is no longer likely, in the absence of the restrictions under this paragraph, to be an at-risk beneficiary for prescription drug abuse described in subparagraph (C)(i); and

(II) the end of such maximum period of identification as the Secretary may specify.

(ii) RULE OF CONSTRUCTION.—Nothing in clause (i) shall be construed as preventing a plan from identifying an individual as an at-risk beneficiary for prescription drug abuse under subparagraph (C)(i) after such termination on the basis of additional information on drug use occurring after the date of notice of such termination.

(G) FREQUENTLY ABUSED DRUG.—For purposes of this subsection, the term "frequently abused drug" means a drug that is a controlled substance that the Secretary determines to be frequently abused or diverted.

(H) DATA DISCLOSURE.—In the case of an at-risk beneficiary for prescription drug abuse whose access to coverage for frequently abused drugs under a prescription drug plan has been limited by a PDP sponsor under this paragraph, such PDP sponsor shall disclose data, including any necessary individually identifiable health information, in a form and manner specified by the Secretary, about the decision to impose such limitations and the limitations imposed by the sponsor under this part.

(I) EDUCATION.—The Secretary shall provide education to enrollees in prescription drug plans of PDP sponsors and providers regarding the drug management program for at-risk beneficiaries described in this paragraph, including education—

(i) provided by medicare administrative contractors through the improper payment outreach and education program described in section 1874A(h); and

(ii) through current education efforts (such as State health insurance assistance programs described in subsection (a)(1)(A) of section 119 of the Medicare Improvements for Patients and Providers Act of 2008 (42 U.S.C. 1395b–3 note)) and materials directed toward such enrollees.

(J) APPLICATION UNDER MA–PD PLANS.—Pursuant to section 1860D—21(c)(1), the provisions of this paragraph apply under part D to MA organizations offering MA–PD plans to MA eligible individuals in the same manner as such provisions apply under this part to a PDP sponsor offering a prescription drug plan to a part D eligible individual.

(6) UTILIZATION MANAGEMENT TOOL TO PREVENT DRUG ABUSE.—

(A) IN GENERAL.—A tool described in this paragraph is any of the following:

(i) A utilization tool designed to prevent the abuse of frequently abused drugs by individuals and to prevent the diversion of such drugs at pharmacies.

(ii) Retrospective utilization review to identify—

(I) individuals that receive frequently abused drugs at a frequency or in amounts that are not clinically appropriate; and

(II) providers of services or suppliers that may facilitate the abuse or diversion of frequently abused drugs by beneficiaries.

(iii) Consultation with the contractor described in subparagraph (B) to verify if an individual enrolling in a prescription drug plan offered by a PDP sponsor has been previously identified by another PDP sponsor as an individual described in clause (ii)(I).

(B) REPORTING.—A PDP sponsor offering a prescription drug plan (and an MA organization offering an MA–PD plan) in a State shall submit to the Secretary and the Medicare drug integrity contractor with which the Secretary has entered into a contract under section 1893 with respect to such State a report, on a monthly basis, containing information on—

(i) any provider of services or supplier described in subparagraph (A)(ii)(II) that is identified by such plan sponsor (or organization) during the 30-day period before such report is submitted; and

(ii) the name and prescription records of individuals described in paragraph (5)(C).

(d) CONSUMER SATISFACTION SURVEYS.—In order to provide for comparative information under section 1860D–1(c)(3)(A)(v), the Secretary shall conduct consumer satisfaction surveys with respect to PDP sponsors and prescription drug plans in a manner similar to the manner such surveys are conducted for MA organizations and MA plans under part C.

(e) ELECTRONIC PRESCRIPTION PROGRAM.—

(1) APPLICATION OF STANDARDS.—As of such date as the Secretary may specify, but not later than 1 year after the date of promulgation of final standards under paragraph (4)(D), prescriptions and other information described in paragraph (2)(A) for covered part D drugs prescribed for part D eligible individuals that are transmitted electronically shall be transmitted only in accordance with such standards under an electronic prescription drug program that meets the requirements of paragraph (2).

(2) PROGRAM REQUIREMENTS.—Consistent with uniform standards established under paragraph (3)—

(A) PROVISION OF INFORMATION TO PRESCRIBING HEALTH CARE PROFESSIONAL AND DISPENSING PHARMACIES AND PHARMACISTS.—An electronic prescription drug program shall provide for the electronic transmittal to the prescribing health care professional and to the dispensing pharmacy and pharmacist of the prescription and information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) and of the following information with respect to the prescribing and dispensing of a covered part D drug:

(i) Information on the drug being prescribed or dispensed and other drugs listed on the medication history, including information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments.

(ii) Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed.

(B) APPLICATION TO MEDICAL HISTORY INFORMATION.—Effective on and after such date as the Secretary specifies and after the establishment of appropriate standards to carry out this subparagraph, the program shall provide for the electronic transmittal in a manner similar to the manner under subparagraph (A) of information that relates to the medical history concerning the individual and related to a covered part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

(C) LIMITATIONS.—Information shall only be disclosed under subparagraph (A) or (B) if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

(D) TIMING.—To the extent feasible, the information exchanged under this paragraph shall be on an interactive, real-time basis.

(3) STANDARDS.—

(A) IN GENERAL.—The Secretary shall provide consistent with this subsection for the promulgation of uniform standards relating to the requirements for electronic prescription drug programs under paragraph (2).

(B) OBJECTIVES.—Such standards shall be consistent with the objectives of improving—

(i) patient safety;

(ii) the quality of care provided to patients; and

(iii) efficiencies, including cost savings, in the delivery of care.

(C) DESIGN CRITERIA.—Such standards shall—

(i) be designed so that, to the extent practicable, the standards do not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and pharmacists;

(ii) be compatible with standards established under part C of title XI, standards established under subsection (b)(2)(B)(i), and with general health information technology standards; and

(iii) be designed so that they permit electronic exchange of drug labeling and drug listing information maintained by the Food and Drug Administration and the National Library of Medicine.

(D) PERMITTING USE OF APPROPRIATE MESSAGING.—Such standards shall allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems referred to in subsection (c)(1)(B).

(E) PERMITTING PATIENT DESIGNATION OF DISPENSING PHARMACY.—

(i) IN GENERAL.—Consistent with clause (ii), such standards shall permit a part D eligible individual to designate a particular pharmacy to dispense a prescribed drug.

(ii) NO CHANGE IN BENEFITS.—Clause (i) shall not be construed as affecting—

(I) the access required to be provided to pharmacies by a prescription drug plan; or

(II) the application of any differences in benefits or payments under such a plan based on the pharmacy dispensing a covered part D drug.

(4) DEVELOPMENT, PROMULGATION, AND MODIFICATION OF STANDARDS.—

(A) INITIAL STANDARDS.—Not later than September 1, 2005, the Secretary shall develop, adopt, recognize, or modify initial uniform standards relating to the requirements for electronic prescription drug programs described in paragraph (2) taking into consideration the recommendations (if any) from the National Committee on Vital and Health Statistics (as established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k))) under subparagraph (B).

(B) ROLE OF NCVHS.—The National Committee on Vital and Health Statistics shall develop recommendations for uniform standards relating to such requirements in consultation with the following:

(i) Standard setting organizations (as defined in section 1171(8))

(ii) Practicing physicians.

(iii) Hospitals.

(iv) Pharmacies.

(v) Practicing pharmacists.

(vi) Pharmacy benefit managers.

(vii) State boards of pharmacy.

(viii) State boards of medicine.

(ix) Experts on electronic prescribing.

(x) Other appropriate Federal agencies.

(C) PILOT PROJECT TO TEST INITIAL STANDARDS.—

(i) IN GENERAL.—During the 1-year period that begins on January 1, 2006, the Secretary shall conduct a pilot project to test the initial standards developed under subparagraph (A) prior to the promulgation of the final uniform standards under subparagraph (D) in order to provide for the efficient implementation of the requirements described in paragraph (2).

(ii) EXCEPTION.—Pilot testing of standards is not required under clause (i) where there already is adequate industry experience with such standards, as determined by the Secretary after consultation with effected standard setting organizations and industry users.

(iii) VOLUNTARY PARTICIPATION OF PHYSICIANS AND PHARMACIES.—In order to conduct the pilot project under clause (i), the Secretary shall enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with such standards.

(iv) EVALUATION AND REPORT.—

(I) EVALUATION.—The Secretary shall conduct an evaluation of the pilot project conducted under clause (i).

(II) REPORT TO CONGRESS.—Not later than April 1, 2007, the Secretary shall submit to Congress a report on the evaluation conducted under subclause (I).

(D) FINAL STANDARDS.—Based upon the evaluation of the pilot project under subparagraph (C)(iv)(I) and not later than April 1, 2008, the Secretary shall promulgate uniform standards relating to the requirements described in paragraph (2).

(5) RELATION TO STATE LAWS.—The standards promulgated under this subsection shall supersede any State law or regulation that—

(A) is contrary to the standards or restricts the ability to carry out this part; and

(B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

(6) ESTABLISHMENT OF SAFE HARBOR.—The Secretary, in consultation with the Attorney General, shall promulgate regulations that provide for a safe harbor from sanctions under paragraphs (1) and (2) of section 1128B(b) and an exception to the prohibition under subsection (a)(1) of section 1877 with respect to the provision of nonmonetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information in accordance with the standards promulgated under this subsection—

(A) in the case of a hospital, by the hospital to members of its medical staff;

(B) in the case of a group practice (as defined in section 1877(h)(4)), by the practice to prescribing health care professionals who are members of such practice; and

(C) in the case of a PDP sponsor or MA organization, by the sponsor or organization to pharmacists and pharmacies participating in the network of such sponsor or organization, and to prescribing health care professionals.

(f) GRIEVANCE MECHANISM.—Each PDP sponsor shall provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor provides covered benefits) and enrollees with prescription drug plans of the sponsor under this part in accordance with section 1852(f).

(g) COVERAGE DETERMINATIONS AND RECONSIDERATIONS.—

(1) APPLICATION OF COVERAGE DETERMINATION AND RECONSIDERATION PROVISIONS.—A PDP sponsor shall meet the requirements of paragraphs (1) through (3) of section 1852(g) with respect to covered benefits under the prescription drug plan it offers under this part in the same manner as such requirements apply to an MA organization with respect to benefits it offers under an MA plan under part C.

(2) REQUEST FOR A DETERMINATION FOR THE TREATMENT OF TIERED FORMULARY DRUG.—In the case of a prescription drug plan offered by a PDP sponsor that provides for tiered cost-sharing for drugs included within a formulary and provides lower cost-sharing for preferred drugs included within the formulary, a part D eligible individual who is enrolled in the plan may request an exception to the tiered cost-sharing structure. Under such an exception, a nonpreferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both. A PDP sponsor shall have an exceptions process under this paragraph consistent with guidelines established by the Secretary for making a determination with respect to such a request. Denial of such an exception shall be treated as a coverage denial for purposes of applying subsection (h).

(h) APPEALS.—

(1) IN GENERAL.—Subject to paragraph (2), a PDP sponsor shall meet the requirements of paragraphs (4) and (5) of section 1852(g) with respect to benefits (including a determination related to the application of tiered cost-sharing described in subsection (g)(2)) in a manner similar (as determined by the Secretary) to the manner such requirements apply to an MA organization with respect to benefits under the original medicare fee-for-service program option it offers under an MA plan under part C. In applying this paragraph only the part D eligible individual shall be entitled to bring such an appeal.

(2) LIMITATION IN CASES ON NONFORMULARY DETERMINATIONS.—A part D eligible individual who is enrolled in a prescription drug plan offered by a PDP sponsor may appeal under paragraph (1) a determination not to provide for coverage of a covered part D drug that is not on the formulary under the plan only if the prescribing physician determines that all covered part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the nonformulary drug, would have adverse effects for the individual, or both.

(3) TREATMENT OF NONFORMULARY DETERMINATIONS.—If a PDP sponsor determines that a plan provides coverage for a covered part D drug that is not on the formulary of the plan, the drug shall be treated as being included on the formulary for purposes of section 1860D–2(b)(4)(C)(i).

(i) PRIVACY, CONFIDENTIALITY, AND ACCURACY OF ENROLLEE RECORDS.—The provisions of section 1852(h) shall apply to a PDP sponsor and prescription drug plan in the same manner as it applies to an MA organization and an MA plan.

(j) TREATMENT OF ACCREDITATION.—Subparagraph (A) of section 1852(e)(4) (relating to treatment of accreditation) shall apply to a PDP sponsor under this part with respect to the following requirements, in the same manner as it applies to an MA organization with respect to the requirements in subparagraph (B) (other than clause (vii) thereof) of such section:

(1) Subsection (b) of this section (relating to access to covered part D drugs).

(2) Subsection (c) of this section (including quality assurance and medication therapy management).

(3) Subsection (i) of this section (relating to confidentiality and accuracy of enrollee records).

(k) PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS.—

(1) IN GENERAL.—A PDP sponsor offering a prescription drug plan shall provide that each pharmacy that dispenses a covered part D drug shall inform an enrollee of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered part D drug under the plan that is therapeutically equivalent and bioequivalent and available at such pharmacy.

(2) TIMING OF NOTICE.—

(A) IN GENERAL.—Subject to subparagraph (B), the information under paragraph (1) shall be provided at the time of purchase of the drug involved, or, in the case of dispensing by mail order, at the time of delivery of such drug.

(B) WAIVER.—The Secretary may waive subparagraph (A) in such circumstances as the Secretary may specify.

(l) REQUIREMENTS WITH RESPECT TO SALES AND MARKETING ACTIVITIES.—The following provisions shall apply to a PDP sponsor (and the agents, brokers, and other third parties representing such sponsor) in the same manner as such provisions apply to a Medicare Advantage organization (and the agents, brokers, and other third parties representing such organization):

(1) The prohibition under section 1851(h)(4)(C) on conducting activities described in section 1851(j)(1).

(2) The requirement under section 1851(h)(4)(D) to conduct activities described in section 1851(j)(2) in accordance with the limitations established under such subsection.

(3) The inclusion of the plan type in the plan name under section 1851(h)(6).

(4) The requirements regarding the appointment of agents and brokers and compliance with State information requests under subparagraphs (A) and (B), respectively, of section 1851(h)(7).

Subpart 2—Prescription Drug Plans; PDP Sponsors; Financing

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SUBSIDIES FOR PART D ELIGIBLE INDIVIDUALS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE

SEC. 1860D–15. (a) SUBSIDY PAYMENT.—In order to reduce premium levels applicable to qualified prescription drug coverage for part D eligible individuals consistent with an overall subsidy level of 74.5 percent for basic prescription drug coverage, to reduce adverse selection among prescription drug plans and MA–PD plans, and to promote the participation of PDP sponsors under this part and MA organizations under part C, the Secretary shall provide for payment to a PDP sponsor that offers a prescription drug plan and an MA organization that offers an MA–PD plan of the following subsidies in accordance with this section:

(1) DIRECT SUBSIDY.—A direct subsidy for each part D eligible individual enrolled in a prescription drug plan or MA–PD plan for a month equal to—

(A) the amount of the plan's standardized bid amount (as defined in section 1860D–13(a)(5)), adjusted under subsection (c)(1), reduced by

(B) the base beneficiary premium (as computed under paragraph (2) of section 1860D–13(a) and as adjusted under paragraph (1)(B) of such section).

(2) SUBSIDY THROUGH REINSURANCE.—The reinsurance payment amount (as defined in subsection (b)).

This section constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this section.

(b) REINSURANCE PAYMENT AMOUNT.—

(1) IN GENERAL.—The reinsurance payment amount under this subsection for a part D eligible individual enrolled in a prescription drug plan or MA–PD plan for a coverage year is an amount equal to 80 percent of the allowable reinsurance costs (as specified in paragraph (2)) attributable to that portion of gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B).

(2) ALLOWABLE REINSURANCE COSTS.—For purposes of this section, the term "allowable reinsurance costs" means, with respect to gross covered prescription drug costs under a prescription drug plan offered by a PDP sponsor or an MA–PD plan offered by an MA organization, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization or by (or on behalf of) an enrollee under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were basic prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were standard prescription drug coverage.

(3) GROSS COVERED PRESCRIPTION DRUG COSTS.—For purposes of this section, the term "gross covered prescription drug costs" means, with respect to a part D eligible individual enrolled in a prescription drug plan or MA–PD plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible. Such costs shall be determined whether they are paid by the individual or under the plan, regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

(4) COVERAGE YEAR DEFINED.—For purposes of this section, the term "coverage year" means a calendar year in which covered part D drugs are dispensed if the claim for such drugs (and payment on such claim) is made not later than such period after the end of such year as the Secretary specifies.

(c) ADJUSTMENTS RELATING TO BIDS.—

(1) HEALTH STATUS RISK ADJUSTMENT.—

(A) ESTABLISHMENT OF RISK ADJUSTORS.—The Secretary shall establish an appropriate methodology for adjusting the standardized bid amount under subsection (a)(1)(A) to take into account variation in costs for basic prescription drug coverage among prescription drug plans and MA–PD plans based on the differences in actuarial risk of different enrollees being served. Any such risk adjustment shall be designed in a manner so as not to result in a change in the aggregate amounts payable to such plans under subsection (a)(1) and through that portion of the monthly beneficiary prescription drug premiums described in subsection (a)(1)(B) and MA monthly prescription drug beneficiary premiums.

(B) CONSIDERATIONS.—In establishing the methodology under subparagraph (A), the Secretary may take into account the similar methodologies used under section 1853(a)(3) to adjust payments to MA organizations for benefits under the original medicare fee-for-service program option.

(C) DATA COLLECTION.—In order to carry out this paragraph, the Secretary shall require—

(i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to part A and part B data and such other information as the Secretary determines necessary; and

(ii) MA organizations that offer MA–PD plans to submit data regarding drug claims that can be linked at the individual level to other data that such organizations are required to submit to the Secretary and such other information as the Secretary determines necessary.

(D) PUBLICATION.—At the time of publication of risk adjustment factors under section 1853(b)(1)(B)(i)(II), the Secretary shall publish the risk adjusters established under this paragraph for the succeeding year.

(2) GEOGRAPHIC ADJUSTMENT.—

(A) IN GENERAL.—Subject to subparagraph (B), for purposes of section 1860D–13(a)(1)(B)(iii), the Secretary shall establish an appropriate methodology for adjusting the national average monthly bid amount (computed under section 1860D–13(a)(4)) to take into account differences in prices for covered part D drugs among PDP regions.

(B) DE MINIMIS RULE.—If the Secretary determines that the price variations described in subparagraph (A) among PDP regions are de minimis, the Secretary shall not provide for adjustment under this paragraph.

(C) BUDGET NEUTRAL ADJUSTMENT.—Any adjustment under this paragraph shall be applied in a manner so as to not result in a change in the aggregate payments made under this part that would have been made if the Secretary had not applied such adjustment.

(d) PAYMENT METHODS.—

(1) IN GENERAL.—Payments under this section shall be based on such a method as the Secretary determines. The Secretary may establish a payment method by which interim payments

of amounts under this section are made during a year based on the Secretary's best estimate of amounts that will be payable after obtaining all of the information.

(2) REQUIREMENT FOR PROVISION OF INFORMATION.—

(A) REQUIREMENT.—Payments under this section to a PDP sponsor or MA organization are conditioned upon the furnishing to the Secretary, in a form and manner specified by the Secretary, of such information as may be required to carry out this section.

(B) RESTRICTION ON USE OF INFORMATION.—Information disclosed or obtained pursuant to subparagraph (A) may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section.

(3) SOURCE OF PAYMENTS.—Payments under this section shall be made from the Medicare Prescription Drug Account.

(4) APPLICATION OF ENROLLEE ADJUSTMENT.—The provisions of section 1853(a)(2) shall apply to payments to PDP sponsors under this section in the same manner as they apply to payments to MA organizations under section 1853(a).

(5) TIMING OF PAYMENTS.—With respect to monthly reinsurance payment amounts under this section to a PDP sponsor for months in a year (beginning with 2020), such payment amounts for a month shall be made on the first business day occurring on or after the following date for that month:

(A) For the month of January, January 2nd.

(B) For the month of February, February 5th.

(C) For the month of March, March 10th.

(D) For the month of April, April 15th.

(E) For the month of May, May 20th.

(F) For the month of June, June 25th.

(G) For the month of July and each succeeding month (other than December) in a year, the first day of the next month.

(H) For the month of December, December 24th.

(e) PORTION OF TOTAL PAYMENTS TO A SPONSOR OR ORGANIZATION SUBJECT TO RISK (APPLICATION OF RISK CORRIDORS).—

(1) COMPUTATION OF ADJUSTED ALLOWABLE RISK CORRIDOR COSTS.—

(A) IN GENERAL.—For purposes of this subsection, the term "adjusted allowable risk corridor costs" means, for a plan for a coverage year (as defined in subsection (b)(4))—

(i) the allowable risk corridor costs (as defined in subparagraph (B)) for the plan for the year, reduced by

(ii) the sum of (I) the total reinsurance payments made under subsection (b) to the sponsor of the plan for the year, and (II) the total subsidy payments made under section 1860D–14 to the sponsor of the plan for the year.

(B) ALLOWABLE RISK CORRIDOR COSTS.—For purposes of this subsection, the term "allowable risk corridor costs" means, with respect to a prescription drug plan offered by a PDP sponsor or an MA–PD plan offered by an MA orga-

nization, the part of costs (not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year) incurred by the sponsor or organization under the plan that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were basic prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were basic prescription drug coverage taking into account the adjustment under section 1860D–11(c)(2). In computing allowable costs under this paragraph, the Secretary shall compute such costs based upon imposition under paragraphs (1)(D) and (2)(E) of section 1860D–14(a) of the maximum amount of copayments permitted under such paragraphs.

(2) ADJUSTMENT OF PAYMENT.—

(A) NO ADJUSTMENT IF ADJUSTED ALLOWABLE RISK CORRIDOR COSTS WITHIN RISK CORRIDOR.—If the adjusted allowable risk corridor costs (as defined in paragraph (1)) for the plan for the year are at least equal to the first threshold lower limit of the risk corridor (specified in paragraph (3)(A)(i)), but not greater than the first threshold upper limit of the risk corridor (specified in paragraph (3)(A)(iii)) for the plan for the year, then no payment adjustment shall be made under this subsection.

(B) INCREASE IN PAYMENT IF ADJUSTED ALLOWABLE RISK CORRIDOR COSTS ABOVE UPPER LIMIT OF RISK CORRIDOR.—

(i) COSTS BETWEEN FIRST AND SECOND THRESHOLD UPPER LIMITS.—If the adjusted allowable risk corridor costs for the plan for the year are greater than the first threshold upper limit, but not greater than the second threshold upper limit, of the risk corridor for the plan for the year, the Secretary shall increase the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in clause (iii) are met for the year) of the difference between such adjusted allowable risk corridor costs and the first threshold upper limit of the risk corridor.

(ii) COSTS ABOVE SECOND THRESHOLD UPPER LIMITS.—If the adjusted allowable risk corridor costs for the plan for the year are greater than the second threshold upper limit of the risk corridor for the plan for the year, the Secretary shall increase the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to the sum of—

(I) 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in clause (iii) are met for the year) of the difference between

the second threshold upper limit and the first threshold upper limit; and

(II) 80 percent of the difference between such adjusted allowable risk corridor costs and the second threshold upper limit of the risk corridor.

(iii) CONDITIONS FOR APPLICATION OF HIGHER PERCENTAGE FOR 2006 AND 2007.—The conditions described in this clause are met for 2006 or 2007 if the Secretary determines with respect to such year that—

(I) at least 60 percent of prescription drug plans and MA–PD plans to which this subsection applies have adjusted allowable risk corridor costs for the plan for the year that are more than the first threshold upper limit of the risk corridor for the plan for the year; and

(II) such plans represent at least 60 percent of part D eligible individuals enrolled in any prescription drug plan or MA–PD plan.

(C) REDUCTION IN PAYMENT IF ADJUSTED ALLOWABLE RISK CORRIDOR COSTS BELOW LOWER LIMIT OF RISK CORRIDOR.—

(i) COSTS BETWEEN FIRST AND SECOND THRESHOLD LOWER LIMITS.—If the adjusted allowable risk corridor costs for the plan for the year are less than the first threshold lower limit, but not less than the second threshold lower limit, of the risk corridor for the plan for the year, the Secretary shall reduce the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recover from the sponsor or organization an amount) equal to 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit of the risk corridor and such adjusted allowable risk corridor costs.

(ii) COSTS BELOW SECOND THRESHOLD LOWER LIMIT.—If the adjusted allowable risk corridor costs for the plan for the year are less the second threshold lower limit of the risk corridor for the plan for the year, the Secretary shall reduce the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recover from the sponsor or organization an amount) equal to the sum of—

(I) 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit and the second threshold lower limit; and

(II) 80 percent of the difference between the second threshold upper limit of the risk corridor and such adjusted allowable risk corridor costs.

(3) ESTABLISHMENT OF RISK CORRIDORS.—

(A) IN GENERAL.—For each plan year the Secretary shall establish a risk corridor for each prescription drug plan and each MA–PD plan. The risk corridor for a plan for a year shall be equal to a range as follows:

(i) FIRST THRESHOLD LOWER LIMIT.—The first threshold lower limit of such corridor shall be equal to—

(I) the target amount described in subparagraph (B) for the plan; minus

(II) an amount equal to the first threshold risk percentage for the plan (as determined under subparagraph (C)(i)) of such target amount.

(ii) SECOND THRESHOLD LOWER LIMIT.—The second threshold lower limit of such corridor shall be equal to—

(I) the target amount described in subparagraph (B) for the plan; minus

(II) an amount equal to the second threshold risk percentage for the plan (as determined under subparagraph (C)(ii)) of such target amount.

(iii) FIRST THRESHOLD UPPER LIMIT.—The first threshold upper limit of such corridor shall be equal to the sum of—

(I) such target amount; and

(II) the amount described in clause (i)(II).

(iv) SECOND THRESHOLD UPPER LIMIT.—The second threshold upper limit of such corridor shall be equal to the sum of—

(I) such target amount; and

(II) the amount described in clause (ii)(II).

(B) TARGET AMOUNT DESCRIBED.—The target amount described in this paragraph is, with respect to a prescription drug plan or an MA–PD plan in a year, the total amount of payments paid to the PDP sponsor or MA–PD organization for the plan for the year, taking into account amounts paid by the Secretary and enrollees, based upon the standardized bid amount (as defined in section 1860D–13(a)(5) and as risk adjusted under subsection (c)(1)), reduced by the total amount of administrative expenses for the year assumed in such standardized bid.

(C) FIRST AND SECOND THRESHOLD RISK PERCENTAGE DEFINED.—

(i) FIRST THRESHOLD RISK PERCENTAGE.—Subject to clause (iii), for purposes of this section, the first threshold risk percentage is—

(I) for 2006 and 2007, and 2.5 percent;

(II) for 2008 through 2011, 5 percent; and

(III) for 2012 and subsequent years, a percentage established by the Secretary, but in no case less than 5 percent.

(ii) SECOND THRESHOLD RISK PERCENTAGE.—Subject to clause (iii), for purposes of this section, the second threshold risk percentage is—

(I) for 2006 and 2007, 5 percent;

(II) for 2008 through 2011, 10 percent; and

(III) for 2012 and subsequent years, a percentage established by the Secretary that is greater than the percent established for the year under clause (i)(III), but in no case less than 10 percent.

(iii) REDUCTION OF RISK PERCENTAGE TO ENSURE 2 PLANS IN AN AREA.—Pursuant to section 1860D–11(b)(2)(E)(ii), a PDP sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (2).

(4) PLANS AT RISK FOR ENTIRE AMOUNT OF SUPPLEMENTAL PRESCRIPTION DRUG COVERAGE.—A PDP sponsor and MA organization that offers a plan that provides supplemental prescription drug benefits shall be at full financial risk for the provision of such supplemental benefits.

(5) NO EFFECT ON MONTHLY PREMIUM.—No adjustment in payments made by reason of this subsection shall affect the monthly beneficiary premium or the MA monthly prescription drug beneficiary premium.

(f) DISCLOSURE OF INFORMATION.—

(1) IN GENERAL.—Each contract under this part and under part C shall provide that—

(A) the PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan shall provide the Secretary with such information as the Secretary determines is necessary to carry out this section; and

(B) the Secretary shall have the right in accordance with section 1857(d)(2)(B) (as applied under section 1860D–12(b)(3)(C)) to inspect and audit any books and records of a PDP sponsor or MA organization that pertain to the information regarding costs provided to the Secretary under subparagraph (A).

(2) RESTRICTION ON USE OF INFORMATION.—Information disclosed or obtained pursuant to the provisions of this section may be used—

(A) by officers, employees, and contractors of the Department of Health and Human Services for the purposes of, and to the extent necessary in—

(i) carrying out this section; and

(ii) conducting oversight, evaluation, and enforcement under this title; and

(B) by the Attorney General and the Comptroller General of the United States for the purposes of, and to the extent necessary in, carrying out health oversight activities.

(g) PAYMENT FOR FALLBACK PRESCRIPTION DRUG PLANS.—In lieu of the amounts otherwise payable under this section to a PDP sponsor offering a fallback prescription drug plan (as defined in section 1860D–3(c)(4)), the amount payable shall be the amounts determined under the contract for such plan pursuant to section 1860D–11(g)(5).

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Subpart 5—Definitions and Miscellaneous Provisions

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MISCELLANEOUS PROVISIONS

SEC. 1860D–42. (a) ACCESS TO COVERAGE IN TERRITORIES.—The Secretary may waive such requirements of this part, including section 1860D–3(a)(1), insofar as the Secretary determines it is necessary to secure access to qualified prescription drug coverage for part D eligible individuals residing in a State (other than the 50 States and the District of Columbia).

(b) APPLICATION OF DEMONSTRATION AUTHORITY.—The provisions of section 402 of the Social Security Amendments of 1967 (Public Law 90–248) shall apply with respect to this part and part C in the same manner it applies with respect to parts A and B, except that any reference with respect to a Trust Fund in relation to an experiment or demonstration project relating to prescription drug coverage under this part shall be deemed a reference to the Medicare Prescription Drug Account within the Federal Supplementary Medical Insurance Trust Fund.

(c) COVERAGE GAP REBATE FOR 2010.—

(1) IN GENERAL.—In the case of an individual described in subparagraphs (A) through (D) of section 1860D–14A(g)(1) who as of the last day of a calendar quarter in 2010 has incurred costs for covered part D drugs so that the individual has exceeded the initial coverage limit under section 1860D–2(b)(3) for 2010, the Secretary shall provide for payment from the Medicare Prescription Drug Account of $250 to the individual by not later than the 15th day of the third month following the end of such quarter.

(2) LIMITATION.—The Secretary shall provide only 1 payment under this subsection with respect to any individual.

(d) TREATMENT OF CERTAIN COMPLAINTS FOR PURPOSES OF QUALITY OR PERFORMANCE ASSESSMENT.—In conducting a quality or performance assessment of a PDP sponsor, the Secretary shall develop or utilize existing screening methods for reviewing and considering complaints that are received from enrollees in a prescription drug plan offered by such PDP sponsor and that are complaints regarding the lack of access by the individual to prescription drugs due to a drug management program for at-risk beneficiaries.

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PART E—MISCELLANEOUS PROVISIONS

DEFINITIONS OF SERVICES, INSTITUTIONS, ETC.

SEC. 1861. For purposes of this title—

Spell of Illness

(a) The term "spell of illness" with respect to any individual means a period of consecutive days—

(1) beginning with the first day (not included in a previous spell of illness) (A) on which such individual is furnished inpatient hospital services, inpatient critical access hospital services or extended care services, and (B) which occurs in a month for which he is entitled to benefits under part A, and

(2) ending with the close of the first period of 60 consecutive days thereafter on each of which he is neither an inpatient of

a hospital or critical access hospital nor an inpatient of a facility described in section 1819(a)(1) or subsection (y)(1).

Inpatient Hospital Services

(b) The term "inpatient hospital services" means the following items and services furnished to an inpatient of a hospital and (except as provided in paragraph (3)) by the hospital—

(1) bed and board;

(2) such nursing services and other related services, such use of hospital facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients, and such drugs, biologicals, supplies, appliances, and equipment, for use in the hospital, as are ordinarily furnished by such hospital for the care and treatment of inpatients; and

(3) such other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangements with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements;

excluding, however—

(4) medical or surgical services provided by a physician, resident, or intern, services described by subsection (s)(2)(K), certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist; and

(5) the services of a private-duty nurse or other private-duty attendant.

Paragraph (4) shall not apply to services provided in a hospital by—

(6) an intern or a resident-in-training under a teaching program approved by the Council on Medical Education of the American Medical Association or, in the case of an osteopathic hospital, approved by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association, or, in the case of services in a hospital or osteopathic hospital by an intern or resident-in-training in the field of dentistry, approved by the Council on Dental Education of the American Dental Association, or in the case of services in a hospital or osteopathic hospital by an intern or resident-in-training in the field of podiatry, approved by the Council on Podiatric Medical Education of the American Podiatric Medical Association; or

(7) a physician where the hospital has a teaching program approved as specified in paragraph (6), if (A) the hospital elects to receive any payment due under this title for reasonable costs of such services, and (B) all physicians in such hospital agree not to bill charges for professional services rendered in such hospital to individuals covered under the insurance program established by this title.

Inpatient Psychiatric Hospital Services

(c) The term "inpatient psychiatric hospital services" means inpatient hospital services furnished to an inpatient of a psychiatric hospital.

Supplier

(d) The term "supplier" means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.

Hospital

(e) The term "hospital" (except for purposes of sections 1814(d), 1814(f), and 1835(b), subsection (a)(2) of this section, paragraph (7) of this subsection, and subsection (i) of this section) means an institution which—

(1) is primarily engaged in providing, by or under the supervision of physicians, to inpatients (A) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons;

(2) maintains clinical records on all patients;

(3) has bylaws in effect with respect to its staff of physicians;

(4) has a requirement that every patient with respect to whom payment may be made under this title must be under the care of a physician, except that a patient receiving qualified psychologist services (as defined in subsection (ii)) may be under the care of a clinical psychologist with respect to such services to the extent permitted under State law;

(5) provides 24-hour nursing service rendered or supervised by a registered professional nurse, and has a licensed practical nurse or registered professional nurse on duty at all times; except that until January 1, 1979, the Secretary is authorized to waive the requirement of this paragraph for any one-year period with respect to any institution, insofar as such requirement relates to the provision of twenty-four-hour nursing service rendered or supervised by a registered professional nurse (except that in any event a registered professional nurse must be present on the premises to render or supervise the nursing service provided, during at least the regular daytime shift), where immediately preceding such one-year period he finds that—

(A) such institution is located in a rural area and the supply of hospital services in such area is not sufficient to meet the needs of individuals residing therein,

(B) the failure of such institution to qualify as a hospital would seriously reduce the availability of such services to such individuals, and

(C) such institution has made and continues to make a good faith effort to comply with this paragraph, but such compliance is impeded by the lack of qualified nursing personnel in such area;

(6)(A) has in effect a hospital utilization review plan which meets the requirements of subsection (k) and (B) has in place a discharge planning process that meets the requirements of subsection (ee);

(7) in the case of an institution in any State in which State or applicable local law provides for the licensing of hospitals, (A) is licensed pursuant to such law or (B) is approved, by the

agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing;

(8) has in effect an overall plan and budget that meets the requirements of subsection (z); and

(9) meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.

For purposes of subsection (a)(2), such term includes any institution which meets the requirements of paragraph (1) of this subsection. For purposes of sections 1814(d) and 1835(b) (including determination of whether an individual received inpatient hospital services or diagnostic services for purposes of such sections), section 1814(f)(2), and subsection (i) of this section, such term includes any institution which (i) meets the requirements of paragraphs (5) and (7) of this subsection, (ii) is not primarily engaged in providing the services described in section 1861(j)(1)(A) and (iii) is primarily engaged in providing, by or under the supervision of individuals referred to in paragraph (1) of section 1861(r), to inpatients diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. For purposes of section 1814(f)(1), such term includes an institution which (i) is a hospital for purposes of sections 1814(d), 1814(f)(2), and 1835(b) and (ii) is accredited by a national accreditation body recognized by the Secretary under section 1865(a), or is accredited by or approved by a program of the country in which such institution is located if the Secretary finds the accreditation or comparable approval standards of such program to be essentially equivalent to those of such a national accreditation body.. Notwithstanding the preceding provisions of this subsection, such term shall not, except for purposes of subsection (a)(2), include any institution which is primarily for the care and treatment of mental diseases unless it is a psychiatric hospital (as defined in subsection (f)). The term "hospital" also includes a religious nonmedical health care institution (as defined in subsection (ss)(1)), but only with respect to items and services ordinarily furnished by such institution to inpatients, and payment may be made with respect to services provided by or in such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise applicable) as may be provided in regulations consistent with section 1821. For provisions deeming certain requirements of this subsection to be met in the case of accredited institutions, see section 1865. The term "hospital" also includes a facility of fifty beds or less which is located in an area determined by the Secretary to meet the definition relating to a rural area described in subparagraph (A) of paragraph (5) of this subsection and which meets the other requirements of this subsection, except that—

(A) with respect to the requirements for nursing services applicable after December 31, 1978, such requirements shall provide for temporary waiver of the requirements, for such period as the Secretary deems appropriate, where (i) the facility's failure to fully comply with the requirements is attributable to a temporary shortage of qualified nursing personnel in the area in which the facility is located, (ii) a registered professional

nurse is present on the premises to render or supervise the nursing service provided during at least the regular daytime shift, and (iii) the Secretary determines that the employment of such nursing personnel as are available to the facility during such temporary period will not adversely affect the health and safety of patients;

(B) with respect to the health and safety requirements promulgated under paragraph (9), such requirements shall be applied by the Secretary to a facility herein defined in such manner as to assure that personnel requirements take into account the availability of technical personnel and the educational opportunities for technical personnel in the area in which such facility is located, and the scope of services rendered by such facility; and the Secretary, by regulations, shall provide for the continued participation of such a facility where such personnel requirements are not fully met, for such period as the Secretary determines that (i) the facility is making good faith efforts to fully comply with the personnel requirements, (ii) the employment by the facility of such personnel as are available to the facility will not adversely affect the health and safety of patients, and (iii) if the Secretary has determined that because of the facility's waiver under this subparagraph the facility should limit its scope of services in order not to adversely affect the health and safety of the facility's patients, the facility is so limiting the scope of services it provides; and

(C) with respect to the fire and safety requirements promulgated under paragraph (9), the Secretary (i) may waive, for such period as he deems appropriate, specific provisions of such requirements which if rigidly applied would result in unreasonable hardship for such a facility and which, if not applied, would not jeopardize the health and safety of patients, and (ii) may accept a facility's compliance with all applicable State codes relating to fire and safety in lieu of compliance with the fire and safety requirements promulgated under paragraph (9), if he determines that such State has in effect fire and safety codes, imposed by State law, which adequately protect patients.

The term "hospital" does not include, unless the context otherwise requires, a critical access hospital (as defined in section 1861(mm)(1)).

Psychiatric Hospital

(f) The term "psychiatric hospital" means an institution which—

(1) is primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons;

(2) satisfies the requirements of paragraphs (3) through (9) of subsection (e);

(3) maintains clinical records on all patients and maintains such records as the Secretary finds to be necessary to determine the degree and intensity of the treatment provided to individuals entitled to hospital insurance benefits under part A; and

(4) meets such staffing requirements as the Secretary finds necessary for the institution to carry out an active program of

treatment for individuals who are furnished services in the institution.

In the case of an institution which satisfies paragraphs (1) and (2) of the preceding sentence and which contains a distinct part which also satisfies paragraphs (3) and (4) of such sentence, such distinct part shall be considered to be a "psychiatric hospital".

Outpatient Occupational Therapy Services

(g) The term "outpatient occupational therapy services" has the meaning given the term "outpatient physical therapy services" in subsection (p), except that "occupational" shall be substituted for "physical" each place it appears therein.

Extended Care Services

(h) The term "extended care services" means the following items and services furnished to an inpatient of a skilled nursing facility and (except as provided in paragraphs (3), (6) and (7)) by such skilled nursing facility—

(1) nursing care provided by or under the supervision of a registered professional nurse;

(2) bed and board in connection with the furnishing of such nursing care;

(3) physical or occupational therapy or speech-language pathology services furnished by the skilled nursing facility or by others under arrangements with them made by the facility;

(4) medical social services;

(5) such drugs, biologicals, supplies, appliances, and equipment, furnished for use in the skilled nursing facility, as are ordinarily furnished by such facility for the care and treatment of inpatients;

(6) medical services provided by an intern or resident-in-training of a hospital with which the facility has in effect a transfer agreement (meeting the requirements of subsection (l)), under a teaching program of such hospital approved as provided in the last sentence of subsection (b), and other diagnostic or therapeutic services provided by a hospital with which the facility has such an agreement in effect; and

(7) such other services necessary to the health of the patients as are generally provided by skilled nursing facilities, or by others under arrangements with them made by the facility;

excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital.

Post-Hospital Extended Care Services

(i) The term "post-hospital extended care services" means extended care services furnished an individual after transfer from a hospital in which he was an inpatient for not less than 3 consecutive days before his discharge from the hospital in connection with such transfer. For purposes of the preceding sentence, items and services shall be deemed to have been furnished to an individual after transfer from a hospital, and he shall be deemed to have been an inpatient in the hospital immediately before transfer therefrom, if he is admitted to the skilled nursing facility (A) within 30 days after discharge from such hospital, or (B) within such time as it

would be medically appropriate to begin an active course of treatment, in the case of an individual whose condition is such that skilled nursing facility care would not be medically appropriate within 30 days after discharge from a hospital; and an individual shall be deemed not to have been discharged from a skilled nursing facility if, within 30 days after discharge therefrom, he is admitted to such facility or any other skilled nursing facility.

Skilled Nursing Facility

(j) The term "skilled nursing facility" has the meaning given such term in section 1819(a).

Utilization Review

(k) A utilization review plan of a hospital or skilled nursing facility shall be considered sufficient if it is applicable to services furnished by the institution to individuals entitled to insurance benefits under this title and if it provides—

(1) for the review, on a sample or other basis, of admissions to the institution, the duration of stays therein, and the professional services (including drugs and biologicals) furnished, (A) with respect to the medical necessity of the services, and (B) for the purpose of promoting the most efficient use of available health facilities and services;

(2) for such review to be made by either (A) a staff committee of the institution composed of two or more physicians (of which at least two must be physicians described in subsection (r)(1) of this section), with or without participation of other professional personnel, or (B) a group outside the institution which is similarly composed and (i) which is established by the local medical society and some or all of the hospitals and skilled nursing facilities in the locality, or (ii) if (and for as long as) there has not been established such a group which serves such institution, which is established in such other manner as may be approved by the Secretary;

(3) for such review, in each case of inpatient hospital services or extended care services furnished to such an individual during a continuous period of extended duration, as of such days of such period (which may differ for different classes of cases) as may be specified in regulations, with such review to be made as promptly as possible, after each day so specified, and in no event later than one week following such day; and

(4) for prompt notification to the institution, the individual, and his attending physician of any finding (made after opportunity for consultation to such attending physician) by the physician members of such committee or group that any further stay in the institution is not medically necessary.

The review committee must be composed as provided in clause (B) of paragraph (2) rather than as provided in clause (A) of such paragraph in the case of any hospital or skilled nursing facility where, because of the small size of the institution, or (in the case of a skilled nursing facility) because of lack of an organized medical staff, or for such other reason or reasons as may be included in regulations, it is impracticable for the institution to have a properly functioning staff committee for the purposes of this subsection. If

the Secretary determines that the utilization review procedures established pursuant to title XIX are superior in their effectiveness to the procedures required under this section, he may, to the extent that he deems it appropriate, require for purposes of this title that the procedures established pursuant to title XIX be utilized instead of the procedures required by this section.

Agreements for Transfer Between Skilled Nursing Facilities and Hospitals

(l) A hospital and a skilled nursing facility shall be considered to have a transfer agreement in effect if, by reason of a written agreement between them or (in case the two institutions are under common control) by reason of a written undertaking by the person or body which controls them, there is reasonable assurance that—

(1) transfer of patients will be effected between the hospital and the skilled nursing facility whenever such transfer is medically appropriate as determined by the attending physician; and

(2) there will be interchange of medical and other information necessary or useful in the care and treatment of individuals transferred between the institutions, or in determining whether such individuals can be adequately cared for otherwise than in either of such institutions.

Any skilled nursing facility which does not have such an agreement in effect, but which is found by a State agency (of the State in which such facility is situated) with which an agreement under section 1864 is in effect (or, in the case of a State in which no such agency has an agreement under section 1864, by the Secretary) to have attempted in good faith to enter into such an agreement with a hospital sufficiently close to the facility to make feasible the transfer between them of patients and the information referred to in paragraph (2), shall be considered to have such an agreement in effect if and for so long as such agency (or the Secretary, as the case may be) finds that to do so is in the public interest and essential to assuring extended care services for persons in the community who are eligible for payments with respect to such services under this title.

Home Health Services

(m) The term "home health services" means the following items and services furnished to an individual, who is under the care of a physician, by a home health agency or by others under arrangements with them made by such agency, under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician, which items and services are, except as provided in paragraph (7), provided on a visiting basis in a place of residence used as such individual's home—

(1) part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse;

(2) physical or occupational therapy or speech-language pathology services;

(3) medical social services under the direction of a physician;

(4) to the extent permitted in regulations, part-time or intermittent services of a home health aide who has successfully completed a training program approved by the Secretary;

(5) medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care, and a covered osteoporosis drug (as defined in subsection (kk)), but excluding other drugs and biologicals) and durable medical equipment *and devices described in section 1834(r)(2)* while under such a plan;

(6) in the case of a home health agency which is affiliated or under common control with a hospital, medical services provided by an intern or resident-in-training of such hospital, under a teaching program of such hospital approved as provided in the last sentence of subsection (b); and

(7) any of the foregoing items and services which are provided on an outpatient basis, under arrangements made by the home health agency, at a hospital or skilled nursing facility, or at a rehabilitation center which meets such standards as may be prescribed in regulations, and—

(A) the furnishing of which involves the use of equipment of such a nature that the items and services cannot readily be made available to the individual in such place of residence, or

(B) which are furnished at such facility while he is there to receive any such item or service described in clause (A),

but not including transportation of the individual in connection with any such item or service;

excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital. For purposes of paragraphs (1) and (4), the term "part-time or intermittent services" means skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours per week). For purposes of sections 1814(a)(2)(C) and 1835(a)(2)(A), "intermittent" means skilled nursing care that is either provided or needed on fewer than 7 days each week, or less than 8 hours of each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable).

Durable Medical Equipment

(n) The term "durable medical equipment" includes iron lungs, oxygen tents, hospital beds, and wheelchairs (which may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condition and the vehicle meets such safety requirements as the Secretary may prescribe) used in the patient's home (including an institution used as his home other than an institution that meets the requirements of subsection (e)(1) of this section or section 1819(a)(1)), whether furnished on a rental basis or purchased, and includes blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has

Type I or Type II diabetes or to the individual's use of insulin (as determined under standards established by the Secretary in consultation with the appropriate organizations); except that such term does not include such equipment furnished by a supplier who has used, for the demonstration and use of specific equipment, an individual who has not met such minimum training standards as the Secretary may establish with respect to the demonstration and use of such specific equipment. With respect to a seat-lift chair, such term includes only the seat-lift mechanism and does not include the chair.

Home Health Agency

(o) The term "home health agency" means a public agency or private organization, or a subdivision of such an agency or organization, which—

(1) is primarily engaged in providing skilled nursing services and other therapeutic services;

(2) has policies, established by a group of professional personnel (associated with the agency or organization), including one or more physicians and one or more registered professional nurses, to govern the services (referred to in paragraph (1)) which it provides, and provides for supervision of such services by a physician or registered professional nurse;

(3) maintains clinical records on all patients;

(4) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing agencies or organizations of this nature, as meeting the standards established for such licensing;

(5) has in effect an overall plan and budget that meets the requirements of subsection (z);

(6) meets the conditions of participation specified in section 1891(a) and such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization;

(7) provides the Secretary with a surety bond—

(A) in a form specified by the Secretary and in an amount that is not less than the minimum of $50,000; and

(B) that the Secretary determines is commensurate with the volume of payments to the home health agency; and

(8) meets such additional requirements (including conditions relating to bonding or establishing of escrow accounts as the Secretary finds necessary for the financial security of the program) as the Secretary finds necessary for the effective and efficient operation of the program;

except that for purposes of part A such term shall not include any agency or organization which is primarily for the care and treatment of mental diseases. The Secretary may waive the requirement of a surety bond under paragraph (7) in the case of an agency or organization that provides a comparable surety bond under State law.

Outpatient Physical Therapy Services

(p) The term "outpatient physical therapy services" means physical therapy services furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient—

(1) who is under the care of a physician (as defined in paragraph (1), (3), or (4) of section 1861(r)), and

(2) with respect to whom a plan prescribing the type, amount, and duration of physical therapy services that are to be furnished such individual has been established by a physician (as so defined) or by a qualified physical therapist and is periodically reviewed by a physician (as so defined);

excluding, however—

(3) any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital; and

(4) any such service—

(A) if furnished by a clinic or rehabilitation agency, or by others under arrangements with such clinic or agency, unless such clinic or rehabilitation agency—

(i) provides an adequate program of physical therapy services for outpatients and has the facilities and personnel required for such program or required for the supervision of such a program, in accordance with such requirements as the Secretary may specify,

(ii) has policies, established by a group of professional personnel, including one or more physicians (associated with the clinic or rehabilitation agency) and one or more qualified physical therapists, to govern the services (referred to in clause (i)) it provides,

(iii) maintains clinical records on all patients,

(iv) if such clinic or agency is situated in a State in which State or applicable local law provides for the licensing of institutions of this nature, (I) is licensed pursuant to such law, or (II) is approved by the agency of such State or locality responsible for licensing institutions of this nature, as meeting the standards established for such licensing; and

(v) meets such other conditions relating to the health and safety of individuals who are furnished services by such clinic or agency on an outpatient basis, as the Secretary may find necessary, and provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000, or

(B) if furnished by a public health agency, unless such agency meets such other conditions relating to health and safety of individuals who are furnished services by such agency on an outpatient basis, as the Secretary may find necessary.

The term "outpatient physical therapy services" also includes physical therapy services furnished an individual by a physical therapist (in his office or in such individual's home) who meets licensing

and other standards prescribed by the Secretary in regulations, otherwise than under an arrangement with and under the supervision of a provider of services, clinic, rehabilitation agency, or public health agency, if the furnishing of such services meets such conditions relating to health and safety as the Secretary may find necessary. In addition, such term includes physical therapy services which meet the requirements of the first sentence of this subsection except that they are furnished to an individual as an inpatient of a hospital or extended care facility. Nothing in this subsection shall be construed as requiring, with respect to outpatients who are not entitled to benefits under this title, a physical therapist to provide outpatient physical therapy services only to outpatients who are under the care of a physician or pursuant to a plan of care established by a physician. The Secretary may waive the requirement of a surety bond under paragraph (4)(A)(v) in the case of a clinic or agency that provides a comparable surety bond under State law.

Physicians' Services

(q) The term "physicians' services" means professional services performed by physicians, including surgery, consultation, and home, office, and institutional calls (but not including services described in subsection (b)(6)).

Physician

(r) The term "physician", when used in connection with the performance of any function or action, means (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1101(a)(7)), (2) a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions, (3) a doctor of podiatric medicine for the purposes of subsections (k), (m), (p)(1), and (s) of this section and sections 1814(a), 1832(a)(2)(F)(ii), and 1835 but only with respect to functions which he is legally authorized to perform as such by the State in which he performs them, (4) a doctor of optometry, but only for purposes of subsection (p)(1) and with respect to the provision of items or services described in subsection (s) which he is legally authorized to perform as a doctor of optometry by the State in which he performs them, or (5) a chiropractor who is licensed as such by the State (or in a State which does not license chiropractors as such, is legally authorized to perform the services of a chiropractor in the jurisdiction in which he performs such services), and who meets uniform minimum standards promulgated by the Secretary, but only for the purpose of sections 1861(s)(1) and 1861(s)(2)(A) and only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation) which he is legally authorized to perform by the State or jurisdiction in which such treatment is provided. For the purposes of section 1862(a)(4) and subject to the limitations and conditions provided in the previous sentence, such term includes a doctor of one of the arts, specified in such previous sentence, legally authorized to prac-

tice such art in the country in which the inpatient hospital services (referred to in such section 1862(a)(4)) are furnished.

Medical and Other Health Services

(s) The term "medical and other health services" means any of the following items or services:

(1) physicians' services;

(2)(A) services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills (or would have been so included but for the application of section 1847B);

(B) hospital services (including drugs and biologicals which are not usually self-administered by the patient) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services;

(C) diagnostic services which are—

(i) furnished to an individual as an outpatient by a hospital or by others under arrangements with them made by a hospital, and

(ii) ordinarily furnished by such hospital (or by others under such arrangements) to its outpatients for the purpose of diagnostic study;

(D) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services;

(E) rural health clinic services and Federally qualified health center services;

(F) home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies, and, for items and services furnished on or after January 1, 2011, renal dialysis services (as defined in section 1881(b)(14)(B));

(G) antigens (subject to quantity limitations prescribed in regulations by the Secretary) prepared by a physician, as defined in section 1861(r)(1), for a particular patient, including antigens so prepared which are forwarded to another qualified person (including a rural health clinic) for administration to such patient, from time to time, by or under the supervision of another such physician;

(H)(i) services furnished pursuant to a contract under section 1876 to a member of an eligible organization by a physician assistant or by a nurse practitioner (as defined in subsection (aa)(5)) and such services and supplies furnished as an incident to his service to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service; and

(ii) services furnished pursuant to a risk-sharing contract under section 1876(g) to a member of an eligible organization by a clinical psychologist (as defined by the Secretary) or by a clinical social worker (as defined in subsection (hh)(2)), and such services and supplies furnished as an incident to such clinical psychologist's services or clinical social worker's serv-

ices to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service;

(I) blood clotting factors, for hemophilia patients competent to use such factors to control bleeding without medical or other supervision, and items related to the administration of such factors, subject to utilization controls deemed necessary by the Secretary for the efficient use of such factors;

(J) prescription drugs used in immunosuppressive therapy furnished, to an individual who receives an organ transplant for which payment is made under this title;

(K)(i) services which would be physicians' services and services described in subsections (ww)(1) and (hhh) if furnished by a physician (as defined in subsection (r)(1)) and which are performed by a physician assistant (as defined in subsection (aa)(5)) under the supervision of a physician (as so defined) and which the physician assistant is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as incident to such services as would be covered under subparagraph (A) if furnished incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services,

(ii) services which would be physicians' services and services described in subsections (ww)(1) and (hhh) if furnished by a physician (as defined in subsection (r)(1)) and which are performed by a nurse practitioner or clinical nurse specialist (as defined in subsection (aa)(5)) working in collaboration (as defined in subsection (aa)(6)) with a physician (as defined in subsection (r)(1)) which the nurse practitioner or clinical nurse specialist is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as an incident to such services as would be covered under subparagraph (A) if furnished incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services;

(L) certified nurse-midwife services;

(M) qualified psychologist services;

(N) clinical social worker services (as defined in subsection (hh)(2));

(O) erythropoietin for dialysis patients competent to use such drug without medical or other supervision with respect to the administration of such drug, subject to methods and standards established by the Secretary by regulation for the safe and effective use of such drug, and items related to the administration of such drug;

(P) prostate cancer screening tests (as defined in subsection (oo));

(Q) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an anticancer chemotherapeutic agent for a given indication, and containing an active ingredient (or ingredients), which is the same indication and active ingredient (or ingredients) as a drug which the

carrier determines would be covered pursuant to subparagraph (A) or (B) if the drug could not be self-administered;

(R) colorectal cancer screening tests (as defined in subsection (pp));

(S) diabetes outpatient self-management training services (as defined in subsection (qq));

(T) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an acute anti-emetic used as part of an anticancer chemotherapeutic regimen if the drug is administered by a physician (or as prescribed by a physician)—

(i) for use immediately before, at, or within 48 hours after the time of the administration of the anticancer chemotherapeutic agent; and

(ii) as a full replacement for the anti-emetic therapy which would otherwise be administered intravenously;

(U) screening for glaucoma (as defined in subsection (uu)) for individuals determined to be at high risk for glaucoma, individuals with a family history of glaucoma and individuals with diabetes;

(V) medical nutrition therapy services (as defined in subsection (vv)(1)) in the case of a beneficiary with diabetes or a renal disease who—

(i) has not received diabetes outpatient self-management training services within a time period determined by the Secretary;

(ii) is not receiving maintenance dialysis for which payment is made under section 1881; and

(iii) meets such other criteria determined by the Secretary after consideration of protocols established by dietitian or nutrition professional organizations;

(W) an initial preventive physical examination (as defined in subsection (ww));

(X) cardiovascular screening blood tests (as defined in subsection (xx)(1));

(Y) diabetes screening tests (as defined in subsection (yy));

(Z) intravenous immune globulin for the treatment of primary immune deficiency diseases in the home (as defined in subsection (zz));

(AA) ultrasound screening for abdominal aortic aneurysm (as defined in subsection (bbb)) for an individual—

(i) who receives a referral for such an ultrasound screening as a result of an initial preventive physical examination (as defined in section 1861(ww)(1));

(ii) who has not been previously furnished such an ultrasound screening under this title; and

(iii) who—

(I) has a family history of abdominal aortic aneurysm; or

(II) manifests risk factors included in a beneficiary category recommended for screening by the United States Preventive Services Task Force regarding abdominal aortic aneurysms;

(BB) additional preventive services (described in subsection (ddd)(1));

(CC) items and services furnished under a cardiac rehabilitation program (as defined in subsection (eee)(1)) or under a pulmonary rehabilitation program (as defined in subsection (fff)(1));

(DD) items and services furnished under an intensive cardiac rehabilitation program (as defined in subsection (eee)(4));

(EE) kidney disease education services (as defined in subsection (ggg)); and

(FF) personalized prevention plan services (as defined in subsection (hhh));

(3) diagnostic X-ray tests (including tests under the supervision of a physician, furnished in a place of residence used as the patient's home, if the performance of such tests meets such conditions relating to health and safety as the Secretary may find necessary and including diagnostic mammography if conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act), diagnostic laboratory tests, and other diagnostic tests;

(4) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians;

(5) surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations;

(6) durable medical equipment;

(7) ambulance service where the use of other methods of transportation is contraindicated by the individual's condition, but, subject to section 1834(l)(14), only to the extent provided in regulations;

(8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens;

(9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition;

(10)(A) pneumococcal vaccine and its administration and, subject to section 4071(b) of the Omnibus Budget Reconciliation Act of 1987, influenza vaccine and its administration; and

(B) hepatitis B vaccine and its administration, furnished to an individual who is at high or intermediate risk of contracting hepatitis B (as determined by the Secretary under regulations);

(11) services of a certified registered nurse anesthetist (as defined in subsection (bb));

(12) subject to section 4072(e) of the Omnibus Budget Reconciliation Act of 1987, extra-depth shoes with inserts or custom molded shoes with inserts for an individual with diabetes, if—

(A) the physician who is managing the individual's diabetic condition (i) documents that the individual has peripheral neuropathy with evidence of callus formation, a history of pre-ulcerative calluses, a history of previous ulceration, foot deformity, or previous amputation, or poor

circulation, and (ii) certifies that the individual needs such shoes under a comprehensive plan of care related to the individual's diabetic condition;

(B) the particular type of shoes are prescribed by a podiatrist or other qualified physician (as established by the Secretary); and

(C) the shoes are fitted and furnished by a podiatrist or other qualified individual (such as a pedorthist or orthotist, as established by the Secretary) who is not the physician described in subparagraph (A) (unless the Secretary finds that the physician is the only such qualified individual in the area);

(13) screening mammography (as defined in subsection (jj));

(14) screening pap smear and screening pelvic exam; and

(15) bone mass measurement (as defined in subsection (rr)).

No diagnostic tests performed in any laboratory, including a laboratory that is part of a rural health clinic, or a hospital (which, for purposes of this sentence, means an institution considered a hospital for purposes of section 1814(d)) shall be included within paragraph (3) unless such laboratory—

(16) if situated in any State in which State or applicable local law provides for licensing of establishments of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing establishments of this nature, as meeting the standards established for such licensing; and

(17)(A) meets the certification requirements under section 353 of the Public Health Service Act; and

(B) meets such other conditions relating to the health and safety of individuals with respect to whom such tests are performed as the Secretary may find necessary.

There shall be excluded from the diagnostic services specified in paragraph (2)(C) any item or service (except services referred to in paragraph (1)) which would not be included under subsection (b) if it were furnished to an inpatient of a hospital. None of the items and services referred to in the preceding paragraphs (other than paragraphs (1) and (2)(A)) of this subsection which are furnished to a patient of an institution which meets the definition of a hospital for purposes of section 1814(d) shall be included unless such other conditions are met as the Secretary may find necessary relating to health and safety of individuals with respect to whom such items and services are furnished.

Drugs and Biologicals

(t)(1) The term "drugs" and the term "biologicals", except for purposes of subsection (m)(5) and paragraph (2), include only such drugs (including contrast agents) and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.

(2)(A) For purposes of paragraph (1), the term "drugs" also includes any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication (as described in subparagraph (B)).

(B) In subparagraph (A), the term "medically accepted indication", with respect to the use of a drug, includes any use which has been approved by the Food and Drug Administration for the drug, and includes another use of the drug if—

(i) the drug has been approved by the Food and Drug Administration; and

(ii)(I) such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, the United States Pharmacopoeia-Drug Information (or its successor publications), and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia, or

(II) the carrier involved determines, based upon guidance provided by the Secretary to carriers for determining accepted uses of drugs, that such use is medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in publications which have been identified for purposes of this subclause by the Secretary.

The Secretary may revise the list of compendia in clause (ii)(I) as is appropriate for identifying medically accepted indications for drugs. On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.

Provider of Services

(u) The term "provider of services" means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or, for purposes of section 1814(g) and section 1835(e), a fund.

Reasonable Cost

(v)(1)(A) The reasonable cost of any services shall be the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services, and shall be determined in accordance with regulations establishing the method or methods to be used, and the items to be included, in determining such costs for various types or classes of institutions, agencies, and services; except that in any case to which paragraph (2) or (3) applies, the amount of the payment determined under such paragraph with respect to the services involved shall be considered the reasonable cost of such services. In prescribing the regulations referred to in the preceding sentence, the Secretary shall consider, among other things, the principles generally applied by national organizations or established prepayment organizations (which have developed such principles) in com-

puting the amount of payment, to be made by persons other than the recipients of services, to providers of services on account of services furnished to such recipients by such providers. Such regulations may provide for determination of the costs of services on a per diem, per unit, per capita, or other basis, may provide for using different methods in different circumstances, may provide for the use of estimates of costs of particular items or services, may provide for the establishment of limits on the direct or indirect overall incurred costs or incurred costs of specific items or services or groups of items or services to be recognized as reasonable based on estimates of the costs necessary in the efficient delivery of needed health services to individuals covered by the insurance programs established under this title, and may provide for the use of charges or a percentage of charges where this method reasonably reflects the costs. Such regulations shall (i) take into account both direct and indirect costs of providers of services (excluding therefrom any such costs, including standby costs, which are determined in accordance with regulations to be unnecessary in the efficient delivery of services covered by the insurance programs established under this title) in order that, under the methods of determining costs, the necessary costs of efficiently delivering covered services to individuals covered by the insurance programs established by this title will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by such insurance programs, and (ii) provide for the making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the aggregate reimbursement produced by the methods of determining costs proves to be either inadequate or excessive.

(B) In the case of extended care services, the regulations under subparagraph (A) shall not include provision for specific recognition of a return on equity capital.

(C) Where a hospital has an arrangement with a medical school under which the faculty of such school provides services at such hospital, an amount not in excess of the reasonable cost of such services to the medical school shall be included in determining the reasonable cost to the hospital of furnishing services—

(i) for which payment may be made under part A, but only if—

(I) payment for such services as furnished under such arrangement would be made under part A to the hospital had such services been furnished by the hospital, and

(II) such hospital pays to the medical school at least the reasonable cost of such services to the medical school, or

(ii) for which payment may be made under part B, but only if such hospital pays to the medical school at least the reasonable cost of such services to the medical school.

(D) Where (i) physicians furnish services which are either inpatient hospital services (including services in conjunction with the teaching programs of such hospital) by reason of paragraph (7) of subsection (b) or for which entitlement exists by reason of clause (II) of section 1832(a)(2)(B)(i), and (ii) such hospital (or medical school under arrangement with such hospital) incurs no actual cost in the furnishing of such services, the reasonable cost of such services shall (under regulations of the Secretary) be deemed to be the

cost such hospital or medical school would have incurred had it paid a salary to such physicians rendering such services approximately equivalent to the average salary paid to all physicians employed by such hospital (or if such employment does not exist, or is minimal in such hospital, by similar hospitals in a geographic area of sufficient size to assure reasonable inclusion of sufficient physicians in development of such average salary).

(E) Such regulations may, in the case of skilled nursing facilities in any State, provide for the use of rates, developed by the State in which such facilities are located, for the payment of the cost of skilled nursing facility services furnished under the State's plan approved under title XIX (and such rates may be increased by the Secretary on a class or size of institution or on a geographical basis by a percentage factor not in excess of 10 percent to take into account determinable items or services or other requirements under this title not otherwise included in the computation of such State rates), if the Secretary finds that such rates are reasonably related to (but not necessarily limited to) analyses undertaken by such State of costs of care in comparable facilities in such State. Notwithstanding the previous sentence, such regulations with respect to skilled nursing facilities shall take into account (in a manner consistent with subparagraph (A) and based on patient-days of services furnished) the costs (including the costs of services required to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident eligible for benefits under this title) of such facilities complying with the requirements of subsections (b), (c), and (d) of section 1819 (including the costs of conducting nurse aide training and competency evaluation programs and competency evaluation programs).

(F) Such regulations shall require each provider of services (other than a fund) to make reports to the Secretary of information described in section 1121(a) in accordance with the uniform reporting system (established under such section) for that type of provider.

(G)(i) In any case in which a hospital provides inpatient services to an individual that would constitute post-hospital extended care services if provided by a skilled nursing facility and a quality improvement organization (or, in the absence of such a qualified organization, the Secretary or such agent as the Secretary may designate) determines that inpatient hospital services for the individual are not medically necessary but post-hospital extended care services for the individual are medically necessary and such extended care services are not otherwise available to the individual (as determined in accordance with criteria established by the Secretary) at the time of such determination, payment for such services provided to the individual shall continue to be made under this title at the payment rate described in clause (ii) during the period in which—

(I) such post-hospital extended care services for the individual are medically necessary and not otherwise available to the individual (as so determined),

(II) inpatient hospital services for the individual are not medically necessary, and

(III) the individual is entitled to have payment made for post-hospital extended care services under this title,

except that if the Secretary determines that there is not an excess of hospital beds in such hospital and (subject to clause (iv)) there is not an excess of hospital beds in the area of such hospital, such payment shall be made (during such period) on the basis of the amount otherwise payable under part A with respect to inpatient hospital services.

(ii)(I) Except as provided in subclause (II), the payment rate referred to in clause (i) is a rate equal to the estimated adjusted State-wide average rate per patient-day paid for services provided in skilled nursing facilities under the State plan approved under title XIX for the State in which such hospital is located, or, if the State in which the hospital is located does not have a State plan approved under title XIX, the estimated adjusted State-wide average allowable costs per patient-day for extended care services under this title in that State.

(II) If a hospital has a unit which is a skilled nursing facility, the payment rate referred to in clause (i) for the hospital is a rate equal to the lesser of the rate described in subclause (I) or the allowable costs in effect under this title for extended care services provided to patients of such unit.

(iii) Any day on which an individual receives inpatient services for which payment is made under this subparagraph shall, for purposes of this Act (other than this subparagraph), be deemed to be a day on which the individual received inpatient hospital services.

(iv) In determining under clause (i), in the case of a public hospital, whether or not there is an excess of hospital beds in the area of such hospital, such determination shall be made on the basis of only the public hospitals (including the hospital) which are in the area of the hospital and which are under common ownership with that hospital.

(H) In determining such reasonable cost with respect to home health agencies, the Secretary may not include—

(i) any costs incurred in connection with bonding or establishing an escrow account by any such agency as a result of the surety bond requirement described in subsection (o)(7) and the financial security requirement described in subsection (o)(8);

(ii) in the case of home health agencies to which the surety bond requirement described in subsection (o)(7) and the financial security requirement described in subsection (o)(8) apply, any costs attributed to interest charged such an agency in connection with amounts borrowed by the agency to repay overpayments made under this title to the agency, except that such costs may be included in reasonable cost if the Secretary determines that the agency was acting in good faith in borrowing the amounts;

(iii) in the case of contracts entered into by a home health agency after the date of the enactment of this subparagraph for the purpose of having services furnished for or on behalf of such agency, any cost incurred by such agency pursuant to any such contract which is entered into for a period exceeding five years; and

(iv) in the case of contracts entered into by a home health agency before the date of the enactment of this subparagraph for the purpose of having services furnished for or on behalf of such agency, any cost incurred by such agency pursuant to any

such contract, which determines the amount payable by the home health agency on the basis of a percentage of the agency's reimbursement or claim for reimbursement for services furnished by the agency, to the extent that such cost exceeds the reasonable value of the services furnished on behalf of such agency.

(I) In determining such reasonable cost, the Secretary may not include any costs incurred by a provider with respect to any services furnished in connection with matters for which payment may be made under this title and furnished pursuant to a contract between the provider and any of its subcontractors which is entered into after the date of the enactment of this subparagraph and the value or cost of which is $10,000 or more over a twelve-month period unless the contract contains a clause to the effect that—

(i) until the expiration of four years after the furnishing of such services pursuant to such contract, the subcontractor shall make available, upon written request by the Secretary, or upon request by the Comptroller General, or any of their duly authorized representatives, the contract, and books, documents and records of such subcontractor that are necessary to certify the nature and extent of such costs, and

(ii) if the subcontractor carries out any of the duties of the contract through a subcontract, with a value or cost of $10,000 or more over a twelve-month period, with a related organization, such subcontract shall contain a clause to the effect that until the expiration of four years after the furnishing of such services pursuant to such subcontract, the related organization shall make available, upon written request by the Secretary, or upon request by the Comptroller General, or any of their duly authorized representatives, the subcontract, and books, documents and records of such organization that are necessary to verify the nature and extent of such costs.

The Secretary shall prescribe in regulation criteria and procedures which the Secretary shall use in obtaining access to books, documents, and records under clauses required in contracts and subcontracts under this subparagraph.

(J) Such regulations may not provide for any inpatient routine salary cost differential as a reimbursable cost for hospitals and skilled nursing facilities.

(K)(i) The Secretary shall issue regulations that provide, to the extent feasible, for the establishment of limitations on the amount of any costs or charges that shall be considered reasonable with respect to services provided on an outpatient basis by hospitals (other than bona fide emergency services as defined in clause (ii)) or clinics (other than rural health clinics), which are reimbursed on a cost basis or on the basis of cost related charges, and by physicians utilizing such outpatient facilities. Such limitations shall be reasonably related to the charges in the same area for similar services provided in physicians' offices. Such regulations shall provide for exceptions to such limitations in cases where similar services are not generally available in physicians' offices in the area to individuals entitled to benefits under this title.

(ii) For purposes of clause (i), the term "bona fide emergency services" means services provided in a hospital emergency room after the sudden onset of a medical condition manifesting itself by

acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—

(I) placing the patient's health in serious jeopardy;

(II) serious impairment to bodily functions; or

(III) serious dysfunction of any bodily organ or part.

(L)(i) The Secretary, in determining the amount of the payments that may be made under this title with respect to services furnished by home health agencies, may not recognize as reasonable (in the efficient delivery of such services) costs for the provision of such services by an agency to the extent these costs exceed (on the aggregate for the agency) for cost reporting periods beginning on or after—

(I) July 1, 1985, and before July 1, 1986, 120 percent of the mean of the labor-related and nonlabor per visit costs for freestanding home health agencies,

(II) July 1, 1986, and before July 1, 1987, 115 percent of such mean,

(III) July 1, 1987, and before October 1, 1997, 112 percent of such mean,

(IV) October 1, 1997, and before October 1, 1998, 105 percent of the median of the labor-related and nonlabor per visit costs for freestanding home health agencies, or

(V) October 1, 1998, 106 percent of such median.

(ii) Effective for cost reporting periods beginning on or after July 1, 1986, such limitations shall be applied on an aggregate basis for the agency, rather than on a discipline specific basis. The Secretary may provide for such exemptions and exceptions to such limitation as he deems appropriate.

(iii) Not later than July 1, 1991, and annually thereafter (but not for cost reporting periods beginning on or after July 1, 1994, and before July 1, 1996, or on or after July 1, 1997, and before October 1, 1997), the Secretary shall establish limits under this subparagraph for cost reporting periods beginning on or after such date by utilizing the area wage index applicable under section 1886(d)(3)(E) and determined using the survey of the most recent available wages and wage-related costs of hospitals located in the geographic area in which the home health service is furnished (determined without regard to whether such hospitals have been reclassified to a new geographic area pursuant to section 1886(d)(8)(B), a decision of the Medicare Geographic Classification Review Board under section 1886(d)(10), or a decision of the Secretary).

(iv) In establishing limits under this subparagraph for cost reporting periods beginning after September 30, 1997, the Secretary shall not take into account any changes in the home health market basket, as determined by the Secretary, with respect to cost reporting periods which began on or after July 1, 1994, and before July 1, 1996.

(v) For services furnished by home health agencies for cost reporting periods beginning on or after October 1, 1997, subject to clause (viii)(I), the Secretary shall provide for an interim system of limits. Payment shall not exceed the costs determined under the preceding provisions of this subparagraph or, if lower, the product of—

(I) an agency-specific per beneficiary annual limitation calculated based 75 percent on 98 percent of the reasonable costs (including nonroutine medical supplies) for the agency's 12-month cost reporting period ending during fiscal year 1994, and based 25 percent on 98 percent of the standardized regional average of such costs for the agency's census division, as applied to such agency, for cost reporting periods ending during fiscal year 1994, such costs updated by the home health market basket index; and

(II) the agency's unduplicated census count of patients (entitled to benefits under this title) for the cost reporting period subject to the limitation.

(vi) For services furnished by home health agencies for cost reporting periods beginning on or after October 1, 1997, the following rules apply:

(I) For new providers and those providers without a 12-month cost reporting period ending in fiscal year 1994 subject to clauses (viii)(II) and (viii)(III), the per beneficiary limitation shall be equal to the median of these limits (or the Secretary's best estimates thereof) applied to other home health agencies as determined by the Secretary. A home health agency that has altered its corporate structure or name shall not be considered a new provider for this purpose.

(II) For beneficiaries who use services furnished by more than one home health agency, the per beneficiary limitations shall be prorated among the agencies.

(vii)(I) Not later than January 1, 1998, the Secretary shall establish per visit limits applicable for fiscal year 1998, and not later than April 1, 1998, the Secretary shall establish per beneficiary limits under clause (v)(I) for fiscal year 1998.

(II) Not later than August 1 of each year (beginning in 1998) the Secretary shall establish the limits applicable under this subparagraph for services furnished during the fiscal year beginning October 1 of the year.

(viii)(I) In the case of a provider with a 12-month cost reporting period ending in fiscal year 1994, if the limit imposed under clause (v) (determined without regard to this subclause) for a cost reporting period beginning during or after fiscal year 1999 is less than the median described in clause (vi)(I) (but determined as if any reference in clause (v) to "98 percent" were a reference to "100 percent"), the limit otherwise imposed under clause (v) for such provider and period shall be increased by ⅓ of such difference.

(II) Subject to subclause (IV), for new providers and those providers without a 12-month cost reporting period ending in fiscal year 1994, but for which the first cost reporting period begins before fiscal year 1999, for cost reporting periods beginning during or after fiscal year 1999, the per beneficiary limitation described in clause (vi)(I) shall be equal to the median described in such clause (determined as if any reference in clause (v) to "98 percent" were a reference to "100 percent").

(III) Subject to subclause (IV), in the case of a new provider for which the first cost reporting period begins during or after fiscal year 1999, the limitation applied under clause (vi)(I) (but only with respect to such provider) shall be equal to 75 percent of the median described in clause (vi)(I).

(IV) In the case of a new provider or a provider without a 12-month cost reporting period ending in fiscal year 1994, subclause (II) shall apply, instead of subclause (III), to a home health agency which filed an application for home health agency provider status under this title before September 15, 1998, or which was approved as a branch of its parent agency before such date and becomes a subunit of the parent agency or a separate agency on or after such date.

(V) Each of the amounts specified in subclauses (I) through (III) are such amounts as adjusted under clause (iii) to reflect variations in wages among different areas.

(ix) Notwithstanding the per beneficiary limit under clause (viii), if the limit imposed under clause (v) (determined without regard to this clause) for a cost reporting period beginning during or after fiscal year 2000 is less than the median described in clause (vi)(I) (but determined as if any reference in clause (v) to "98 percent" were a reference to "100 percent"), the limit otherwise imposed under clause (v) for such provider and period shall be increased by 2 percent.

(x) Notwithstanding any other provision of this subparagraph, in updating any limit under this subparagraph by a home health market basket index for cost reporting periods beginning during each of fiscal years 2000, 2002, and 2003, the update otherwise provided shall be reduced by 1.1 percentage points. With respect to cost reporting periods beginning during fiscal year 2001, the update to any limit under this subparagraph shall be the home health market basket index.

(M) Such regulations shall provide that costs respecting care provided by a provider of services, pursuant to an assurance under title VI or XVI of the Public Health Service Act that the provider will make available a reasonable volume of services to persons unable to pay therefor, shall not be allowable as reasonable costs.

(N) In determining such reasonable costs, costs incurred for activities directly related to influencing employees respecting unionization may not be included.

(O)(i) In establishing an appropriate allowance for depreciation and for interest on capital indebtedness with respect to an asset of a provider of services which has undergone a change of ownership, such regulations shall provide, except as provided in clause (iii), that the valuation of the asset after such change of ownership shall be the historical cost of the asset, as recognized under this title, less depreciation allowed, to the owner of record as of the date of enactment of the Balanced Budget Act of 1997 (or, in the case of an asset not in existence as of that date, the first owner of record of the asset after that date).

(ii) Such regulations shall not recognize, as reasonable in the provision of health care services, costs (including legal fees, accounting and administrative costs, travel costs, and the costs of feasibility studies) attributable to the negotiation or settlement of the sale or purchase of any capital asset (by acquisition or merger) for which any payment has previously been made under this title.

(iii) In the case of the transfer of a hospital from ownership by a State to ownership by a nonprofit corporation without monetary consideration, the basis for capital allowances to the new owner

shall be the book value of the hospital to the State at the time of the transfer.

(P) If such regulations provide for the payment for a return on equity capital (other than with respect to costs of inpatient hospital services), the rate of return to be recognized, for determining the reasonable cost of services furnished in a cost reporting period, shall be equal to the average of the rates of interest, for each of the months any part of which is included in the period, on obligations issued for purchase by the Federal Hospital Insurance Trust Fund.

(Q) Except as otherwise explicitly authorized, the Secretary is not authorized to limit the rate of increase on allowable costs of approved medical educational activities.

(R) In determining such reasonable cost, costs incurred by a provider of services representing a beneficiary in an unsuccessful appeal of a determination described in section 1869(b) shall not be allowable as reasonable costs.

(S)(i) Such regulations shall not include provision for specific recognition of any return on equity capital with respect to hospital outpatient departments.

(ii)(I) Such regulations shall provide that, in determining the amount of the payments that may be made under this title with respect to all the capital-related costs of outpatient hospital services, the Secretary shall reduce the amounts of such payments otherwise established under this title by 15 percent for payments attributable to portions of cost reporting periods occurring during fiscal year 1990, by 15 percent for payments attributable to portions of cost reporting periods occurring during fiscal year 1991, and by 10 percent for payments attributable to portions of cost reporting periods occurring during fiscal years 1992 through 1999 and until the first date that the prospective payment system under section 1833(t) is implemented.

(II) The Secretary shall reduce the reasonable cost of outpatient hospital services (other than the capital-related costs of such services) otherwise determined pursuant to section 1833(a)(2)(B)(i)(I) by 5.8 percent for payments attributable to portions of cost reporting periods occurring during fiscal years 1991 through 1999 and until the first date that the prospective payment system under section 1833(t) is implemented.

(III) Subclauses (I) and (II) shall not apply to payments with respect to the costs of hospital outpatient services provided by any hospital that is a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) or a critical access hospital (as defined in section 1861(mm)(1)).

(IV) In applying subclauses (I) and (II) to services for which payment is made on the basis of a blend amount under section 1833(i)(3)(A)(ii) or 1833(n)(1)(A)(ii), the costs reflected in the amounts described in sections 1833(i)(3)(B)(i)(I) and 1833(n)(1)(B)(i)(I), respectively, shall be reduced in accordance with such subclause.

(T) In determining such reasonable costs for hospitals, no reduction in copayments under section 1833(t)(8)(B) shall be treated as a bad debt and the amount of bad debts otherwise treated as allowable costs which are attributable to the deductibles and coinsurance amounts under this title shall be reduced—

(i) for cost reporting periods beginning during fiscal year 1998, by 25 percent of such amount otherwise allowable,

(ii) for cost reporting periods beginning during fiscal year 1999, by 40 percent of such amount otherwise allowable,

(iii) for cost reporting periods beginning during fiscal year 2000, by 45 percent of such amount otherwise allowable,

(iv) for cost reporting periods beginning during fiscal years 2001 through 2012, by 30 percent of such amount otherwise allowable, and

(v) for cost reporting periods beginning during fiscal year 2013 or a subsequent fiscal year, by 35 percent of such amount otherwise allowable.

(U) In determining the reasonable cost of ambulance services (as described in subsection (s)(7)) provided during fiscal year 1998, during fiscal year 1999, and during so much of fiscal year 2000 as precedes January 1, 2000, the Secretary shall not recognize the costs per trip in excess of costs recognized as reasonable for ambulance services provided on a per trip basis during the previous fiscal year (after application of this subparagraph), increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the fiscal year involved reduced by 1.0 percentage point. For ambulance services provided after June 30, 1998, the Secretary may provide that claims for such services must include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(V) In determining such reasonable costs for skilled nursing facilities and (beginning with respect to cost reporting periods beginning during fiscal year 2013) for covered skilled nursing services described in section 1888(e)(2)(A) furnished by hospital providers of extended care services (as described in section 1883), the amount of bad debts otherwise treated as allowed costs which are attributable to the coinsurance amounts under this title for individuals who are entitled to benefits under part A and—

(i) are not described in section 1935(c)(6)(A)(ii) shall be reduced by—

(I) for cost reporting periods beginning on or after October 1, 2005, but before fiscal year 2013, 30 percent of such amount otherwise allowable; and

(II) for cost reporting periods beginning during fiscal year 2013 or a subsequent fiscal year, by 35 percent of such amount otherwise allowable.

(ii) are described in such section—

(I) for cost reporting periods beginning on or after October 1, 2005, but before fiscal year 2013, shall not be reduced;

(II) for cost reporting periods beginning during fiscal year 2013, shall be reduced by 12 percent of such amount otherwise allowable;

(III) for cost reporting periods beginning during fiscal year 2014, shall be reduced by 24 percent of such amount otherwise allowable; and

(IV) for cost reporting periods beginning during a subsequent fiscal year, shall be reduced by 35 percent of such amount otherwise allowable.

(W)(i) In determining such reasonable costs for providers described in clause (ii), the amount of bad debts otherwise treated as allowable costs which are attributable to deductibles and coinsurance amounts under this title shall be reduced—

(I) for cost reporting periods beginning during fiscal year 2013, by 12 percent of such amount otherwise allowable;

(II) for cost reporting periods beginning during fiscal year 2014, by 24 percent of such amount otherwise allowable; and

(III) for cost reporting periods beginning during a subsequent fiscal year, by 35 percent of such amount otherwise allowable.

(ii) A provider described in this clause is a provider of services not described in subparagraph (T) or (V), a supplier, or any other type of entity that receives payment for bad debts under the authority under subparagraph (A).

(2)(A) If the bed and board furnished as part of inpatient hospital services (including inpatient tuberculosis hospital services and inpatient psychiatric hospital services) or post-hospital extended care services is in accommodations more expensive than semi-private accommodations, the amount taken into account for purposes of payment under this title with respect to such services may not exceed the amount that would be taken into account with respect to such services if furnished in such semi-private accommodations unless the more expensive accommodations were required for medical reasons.

(B) Where a provider of services which has an agreement in effect under this title furnishes to an individual items or services which are in excess of or more expensive than the items or services with respect to which payment may be made under part A or part B, as the case may be, the Secretary shall take into account for purposes of payment to such provider of services only the items or services with respect to which such payment may be made.

(3) If the bed and board furnished as part of inpatient hospital services (including inpatient tuberculosis hospital services and inpatient psychiatric hospital services) or post-hospital extended care services is in accommodations other than, but not more expensive than, semi-private accommodations and the use of such other accommodations rather than semi-private accommodations was neither at the request of the patient nor for a reason which the Secretary determines is consistent with the purposes of this title, the amount of the payment with respect to such bed and board under part A shall be the amount otherwise payable under this title for such bed and board furnished in semi-private accommodations minus the difference between the charge customarily made by the hospital or skilled nursing facility for bed and board in semi-private accommodations and the charge customarily made by it for bed and board in the accommodations furnished.

(4) If a provider of services furnishes items or services to an individual which are in excess of or more expensive than the items or services determined to be necessary in the efficient delivery of needed health services and charges are imposed for such more expensive items or services under the authority granted in section 1866(a)(2)(B)(ii), the amount of payment with respect to such items or services otherwise due such provider in any fiscal period shall be reduced to the extent that such payment plus such charges ex-

ceed the cost actually incurred for such items or services in the fiscal period in which such charges are imposed.

(5)(A) Where physical therapy services, occupational therapy services, speech therapy services, or other therapy services or services of other health-related personnel (other than physicians) are furnished under an arrangement with a provider of services or other organization, specified in the first sentence of subsection (p) (including through the operation of subsection (g)) the amount included in any payment to such provider or other organization under this title as the reasonable cost of such services (as furnished under such arrangements) shall not exceed an amount equal to the salary which would reasonably have been paid for such services (together with any additional costs that would have been incurred by the provider or other organization) to the person performing them if they had been performed in an employment relationship with such provider or other organization (rather than under such arrangement) plus the cost of such other expenses (including a reasonable allowance for traveltime and other reasonable types of expense related to any differences in acceptable methods of organization for the provision of such therapy) incurred by such person, as the Secretary may in regulations determine to be appropriate.

(B) Notwithstanding the provisions of subparagraph (A), if a provider of services or other organization specified in the first sentence of section 1861(p) requires the services of a therapist on a limited part-time basis, or only to perform intermittent services, the Secretary may make payment on the basis of a reasonable rate per unit of service, even though such rate is greater per unit of time than salary related amounts, where he finds that such greater payment is, in the aggregate, less than the amount that would have been paid if such organization had employed a therapist on a full- or part-time salary basis.

(6) For purposes of this subsection, the term "semi-private accommodations" means two-bed, three-bed, or four-bed accommodations.

(7)(A) For limitation on Federal participation for capital expenditures which are out of conformity with a comprehensive plan of a State or areawide planning agency, see section 1122.

(B) For further limitations on reasonable cost and determination of payment amounts for operating costs of inpatient hospital services and waivers for certain States, see section 1886.

(C) For provisions restricting payment for provider-based physicians' services and for payments under certain percentage arrangements, see section 1887.

(D) For further limitations on reasonable cost and determination of payment amounts for routine service costs of skilled nursing facilities, see subsections (a) through (c) of section 1888.

(8) ITEMS UNRELATED TO PATIENT CARE.—Reasonable costs do not include costs for the following—

(i) entertainment, including tickets to sporting and other entertainment events;

(ii) gifts or donations;

(iii) personal use of motor vehicles;

(iv) costs for fines and penalties resulting from violations of Federal, State, or local laws; and

(v) education expenses for spouses or other dependents of providers of services, their employees or contractors.

Arrangements for Certain Services

(w)(1) The term "arrangements" is limited to arrangements under which receipt of payment by the hospital, critical access hospital, skilled nursing facility, home health agency, or hospice program (whether in its own right or as agent), with respect to services for which an individual is entitled to have payment made under this title, discharges the liability of such individual or any other person to pay for the services.

(2) Utilization review activities conducted, in accordance with the requirements of the program established under part B of title XI of the Social Security Act with respect to services furnished by a hospital or critical access hospital to patients insured under part A of this title or entitled to have payment made for such services under part B of this title or under a State plan approved under title XIX, by a quality improvement organization designated for the area in which such hospital or critical access hospital is located shall be deemed to have been conducted pursuant to arrangements between such hospital or critical access hospital and such organization under which such hospital or critical access hospital is obligated to pay to such organization, as a condition of receiving payment for hospital or critical access hospital services so furnished under this part or under such a State plan, such amount as is reasonably incurred and requested (as determined under regulations of the Secretary) by such organization in conducting such review activities with respect to services furnished by such hospital or critical access hospital to such patients.

State and United States

(x) The terms "State" and "United States" have the meaning given to them by subsections (h) and (i), respectively, of section 210.

Extended Care in Religious Nonmedical Health Care Institutions

(y)(1) The term "skilled nursing facility" also includes a religious nonmedical health care institution (as defined in subsection (ss)(1)), but only (except for purposes of subsection (a)(2)) with respect to items and services ordinarily furnished by such an institution to inpatients, and payment may be made with respect to services provided by or in such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise applicable) as may be provided in regulations consistent with section 1821.

(2) Notwithstanding any other provision of this title, payment under part A may not be made for services furnished an individual in a skilled nursing facility to which paragraph (1) applies unless such individual elects, in accordance with regulations, for a spell of illness to have such services treated as post-hospital extended care services for purposes of such part; and payment under part A may not be made for post-hospital extended care services—

(A) furnished an individual during such spell of illness in a skilled nursing facility to which paragraph (1) applies after—

(i) such services have been furnished to him in such a facility for 30 days during such spell, or

(ii) such services have been furnished to him during such spell in a skilled nursing facility to which such paragraph does not apply; or

(B) furnished an individual during such spell of illness in a skilled nursing facility to which paragraph (1) does not apply after such services have been furnished to him during such spell in a skilled nursing facility to which such paragraph applies.

(3) The amount payable under part A for post-hospital extended care services furnished an individual during any spell of illness in a skilled nursing facility to which paragraph (1) applies shall be reduced by a coinsurance amount equal to one-eighth of the inpatient hospital deductible for each day before the 31st day on which he is furnished such services in such a facility during such spell (and the reduction under this paragraph shall be in lieu of any reduction under section 1813(a)(3)).

(4) For purposes of subsection (i), the determination of whether services furnished by or in an institution described in paragraph (1) constitute post-hospital extended care services shall be made in accordance with and subject to such conditions, limitations, and requirements as may be provided in regulations.

Institutional Planning

(z) An overall plan and budget of a hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, or home health agency shall be considered sufficient if it—

(1) provides for an annual operating budget which includes all anticipated income and expenses related to items which would, under generally accepted accounting principles, be considered income and expense items (except that nothing in this paragraph shall require that there be prepared, in connection with any budget, an item-by-item identification of the components of each type of anticipated expenditure or income);

(2)(A) provides for a capital expenditures plan for at least a 3-year period (including the year to which the operating budget described in paragraph (1) is applicable) which includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditure in excess of $600,000 (or such lesser amount as may be established by the State under section 1122(g)(1) in which the hospital is located) related to the acquisition of land, the improvement of land, buildings, and equipment, and the replacement, modernization, and expansion of the buildings and equipment which would, under generally accepted accounting principles, be considered capital items;

(B) provides that such plan is submitted to the agency designated under section 1122(b), or if no such agency is designated, to the appropriate health planning agency in the State (but this subparagraph shall not apply in the case of a facility exempt from review under section 1122 by reason of section 1122(j));

(3) provides for review and updating at least annually; and

(4) is prepared, under the direction of the governing body of the institution or agency, by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the institution or agency.

Rural Health Clinic Services and Federally Qualified Health Center Services

(aa)(1) The term "rural health clinic services" means —

(A) physicians' services and such services and supplies as are covered under section 1861(s)(2)(A) if furnished as an incident to a physician's professional service and items and services described in section 1861(s)(10),

(B) such services furnished by a physician assistant or a nurse practitioner (as defined in paragraph (5)), by a clinical psychologist (as defined by the Secretary) or by a clinical social worker (as defined in subsection (hh)(1)), and such services and supplies furnished as an incident to his service as would otherwise be covered if furnished by a physician or as an incident to a physician's service, and

(C) in the case of a rural health clinic located in an area in which there exists a shortage of home health agencies, part-time or intermittent nursing care and related medical supplies (other than drugs and biologicals) furnished by a registered professional nurse or licensed practical nurse to a homebound individual under a written plan of treatment (i) established and periodically reviewed by a physician described in paragraph (2)(B), or (ii) established by a nurse practitioner or physician assistant and periodically reviewed and approved by a physician described in paragraph (2)(B),

when furnished to an individual as an outpatient of a rural health clinic.

(2) The term "rural health clinic" means a facility which —

(A) is primarily engaged in furnishing to outpatients services described in subparagraphs (A) and (B) of paragraph (1);

(B) in the case of a facility which is not a physician-directed clinic, has an arrangement (consistent with the provisions of State and local law relative to the practice, performance, and delivery of health services) with one or more physicians (as defined in subsection (r)(1)) under which provision is made for the periodic review by such physicians of covered services furnished by physician assistants and nurse practitioners, the supervision and guidance by such physicians of physician assistants and nurse practitioners, the preparation by such physicians of such medical orders for care and treatment of clinic patients as may be necessary, and the availability of such physicians for such referral of and consultation for patients as is necessary and for advice and assistance in the management of medical emergencies; and, in the case of a physician-directed clinic, has one or more of its staff physicians perform the activities accomplished through such an arrangement;

(C) maintains clinical records on all patients;

(D) has arrangements with one or more hospitals, having agreements in effect under section 1866, for the referral and admission of patients requiring inpatient services or such diag-

nostic or other specialized services as are not available at the clinic;

(E) has written policies, which are developed with the advice of (and with provision for review of such policies from time to time by) a group of professional personnel, including one or more physicians and one or more physician assistants or nurse practitioners, to govern those services described in paragraph (1) which it furnishes;

(F) has a physician, physician assistant, or nurse practitioner responsible for the execution of policies described in subparagraph (E) and relating to the provision of the clinic's services;

(G) directly provides routine diagnostic services, including clinical laboratory services, as prescribed in regulations by the Secretary, and has prompt access to additional diagnostic services from facilities meeting requirements under this title;

(H) in compliance with State and Federal law, has available for administering to patients of the clinic at least such drugs and biologicals as are determined by the Secretary to be necessary for the treatment of emergency cases (as defined in regulations) and has appropriate procedures or arrangements for storing, administering, and dispensing any drugs and biologicals;

(I) has a quality assessment and performance improvement program, and appropriate procedures for review of utilization of clinic services, as the Secretary may specify;

(J) has a nurse practitioner, a physician assistant, or a certified nurse-midwife (as defined in subsection (gg)) available to furnish patient care services not less than 50 percent of the time the clinic operates; and

(K) meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are furnished services by the clinic.

For the purposes of this title, such term includes only a facility which (i) is located in an area that is not an urbanized area (as defined by the Bureau of the Census) and in which there are insufficient numbers of needed health care practitioners (as determined by the Secretary), and that, within the previous 4-year period, has been designated by the chief executive officer of the State and certified by the Secretary as an area with a shortage of personal health services or designated by the Secretary either (I) as an area with a shortage of personal health services under section 330(b)(3) or 1302(7) of the Public Health Service Act, (II) as a health professional shortage area described in section 332(a)(1)(A) of that Act because of its shortage of primary medical care manpower, (III) as a high impact area described in section 329(a)(5) of that Act, of (IV) as an area which includes a population group which the Secretary determines has a health manpower shortage under section 332(a)(1)(B) of that Act, (ii) has filed an agreement with the Secretary by which it agrees not to charge any individual or other person for items or services for which such individual is entitled to have payment made under this title, except for the amount of any deductible or coinsurance amount imposed with respect to such items or services (not in excess of the amount customarily charged for such items and services by such clinic), pursuant to subsections

(a) and (b) of section 1833, (iii) employs a physician assistant or nurse practitioner, and (iv) is not a rehabilitation agency or a facility which is primarily for the care and treatment of mental diseases. A facility that is in operation and qualifies as a rural health clinic under this title or title XIX and that subsequently fails to satisfy the requirement of clause (i) shall be considered, for purposes of this title and title XIX, as still satisfying the requirement of such clause if it is determined, in accordance with criteria established by the Secretary in regulations, to be essential to the delivery of primary care services that would otherwise be unavailable in the geographic area served by the clinic. If a State agency has determined under section 1864(a) that a facility is a rural health clinic and the facility has applied to the Secretary for approval as such a clinic, the Secretary shall notify the facility of the Secretary's approval or disapproval not later than 60 days after the date of the State agency determination or the application (whichever is later).

(3) The term "Federally qualified health center services" means—

(A) services of the type described in subparagraphs (A) through (C) of paragraph (1) and preventive services (as defined in section 1861(ddd)(3)); and

(B) preventive primary health services that a center is required to provide under section 330 of the Public Health Service Act,

when furnished to an individual as an outpatient of a Federally qualified health center by the center or by a health care professional under contract with the center and, for this purpose, any reference to a rural health clinic or a physician described in paragraph (2)(B) is deemed a reference to a Federally qualified health center or a physician at the center, respectively.

(4) The term "Federally qualified health center" means an entity which—

(A)(i) is receiving a grant under section 330 of the Public Health Service Act, or

(ii)(I) is receiving funding from such a grant under a contract with the recipient of such a grant, and (II) meets the requirements to receive a grant under section 330 of such Act;

(B) based on the recommendation of the Health Resources and Services Administration within the Public Health Service, is determined by the Secretary to meet the requirements for receiving such a grant;

(C) was treated by the Secretary, for purposes of part B, as a comprehensive Federally funded health center as of January 1, 1990; or

(D) is an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

(5)(A) The term "physician assistant" and the term "nurse practitioner" mean, for purposes of this title, a physician assistant or nurse practitioner who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such

training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.

(B) The term "clinical nurse specialist" means, for purposes of this title, an individual who—

(i) is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed; and

(ii) holds a master's degree in a defined clinical area of nursing from an accredited educational institution.

(6) The term "collaboration" means a process in which a nurse practitioner works with a physician to deliver health care services within the scope of the practitioner's professional expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms as defined by the law of the State in which the services are performed.

(7)(A) The Secretary shall waive for a 1-year period the requirements of paragraph (2) that a rural health clinic employ a physician assistant, nurse practitioner or certified nurse midwife or that such clinic require such providers to furnish services at least 50 percent of the time that the clinic operates for any facility that requests such waiver if the facility demonstrates that the facility has been unable, despite reasonable efforts, to hire a physician assistant, nurse practitioner, or certified nurse-midwife in the previous 90-day period.

(B) The Secretary may not grant such a waiver under subparagraph (A) to a facility if the request for the waiver is made less than 6 months after the date of the expiration of any previous such waiver for the facility, or if the facility has not yet been determined to meet the requirements (including subparagraph (J) of the first sentence of paragraph (2)) of a rural health clinic.

(C) A waiver which is requested under this paragraph shall be deemed granted unless such request is denied by the Secretary within 60 days after the date such request is received.

Services of a Certified Registered Nurse Anesthetist

(bb)(1) The term "services of a certified registered nurse anesthetist" means anesthesia services and related care furnished by a certified registered nurse anesthetist (as defined in paragraph (2)) which the nurse anesthetist is legally authorized to perform as such by the State in which the services are furnished.

(2) The term "certified registered nurse anesthetist" means a certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the Secretary may use the same requirements as those established by a national organization for the certification of nurse anesthetists. Such term also includes, as prescribed by the Secretary, an anesthesiologist assistant.

Comprehensive Outpatient Rehabilitation Facility Services

(cc)(1) The term "comprehensive outpatient rehabilitation facility services" means the following items and services furnished by a physician or other qualified professional personnel (as defined in regulations by the Secretary) to an individual who is an outpatient

of a comprehensive outpatient rehabilitation facility under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician—

(A) physicians' services;

(B) physical therapy, occupational therapy, speech-language pathology services, and respiratory therapy;

(C) prosthetic and orthotic devices, including testing, fitting, or training in the use of prosthetic and orthotic devices;

(D) social and psychological services;

(E) nursing care provided by or under the supervision of a registered professional nurse;

(F) drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered;

(G) supplies and durable medical equipment; and

(H) such other items and services as are medically necessary for the rehabilitation of the patient and are ordinarily furnished by comprehensive outpatient rehabilitation facilities,

excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital. In the case of physical therapy, occupational therapy, and speech pathology services, there shall be no requirement that the item or service be furnished at any single fixed location if the item or service is furnished pursuant to such plan and payments are not otherwise made for the item or service under this title.

(2) The term "comprehensive outpatient rehabilitation facility" means a facility which—

(A) is primarily engaged in providing (by or under the supervision of physicians) diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons;

(B) provides at least the following comprehensive outpatient rehabilitation services: (i) physicians' services (rendered by physicians, as defined in section 1861(r)(1), who are available at the facility on a full- or part-time basis); (ii) physical therapy; and (iii) social or psychological services;

(C) maintains clinical records on all patients;

(D) has policies established by a group of professional personnel (associated with the facility), including one or more physicians defined in subsection (r)(1) to govern the comprehensive outpatient rehabilitation services it furnishes, and provides for the carrying out of such policies by a full- or part-time physician referred to in subparagraph (B)(i);

(E) has a requirement that every patient must be under the care of a physician;

(F) in the case of a facility in any State in which State or applicable local law provides for the licensing of facilities of this nature (i) is licensed pursuant to such law, or (ii) is approved by the agency of such State or locality, responsible for licensing facilities of this nature, as meeting the standards established for such licensing;

(G) has in effect a utilization review plan in accordance with regulations prescribed by the Secretary;

(H) has in effect an overall plan and budget that meets the requirements of subsection (z);

(I) provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000; and

(J) meets such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such facility, including conditions concerning qualifications of personnel in these facilities.

The Secretary may waive the requirement of a surety bond under subparagraph (I) in the case of a facility that provides a comparable surety bond under State law.

Hospice Care; Hospice Program

(dd)(1) The term "hospice care" means the following items and services provided to a terminally ill individual by, or by others under arrangements made by, a hospice program under a written plan (for providing such care to such individual) established and periodically reviewed by the individual's attending physician and by the medical director (and by the interdisciplinary group described in paragraph (2)(B)) of the program—

(A) nursing care provided by or under the supervision of a registered professional nurse,

(B) physical or occupational therapy, or speech-language pathology services,

(C) medical social services under the direction of a physician,

(D)(i) services of a home health aide who has successfully completed a training program approved by the Secretary and (ii) homemaker services,

(E) medical supplies (including drugs and biologicals) and the use of medical appliances, while under such a plan,

(F) physicians' services,

(G) short-term inpatient care (including both respite care and procedures necessary for pain control and acute and chronic symptom management) in an inpatient facility meeting such conditions as the Secretary determines to be appropriate to provide such care, but such respite care may be provided only on an intermittent, nonroutine, and occasional basis and may not be provided consecutively over longer than five days,

(H) counseling (including dietary counseling) with respect to care of the terminally ill individual and adjustment to his death, and

(I) any other item or service which is specified in the plan and for which payment may otherwise be made under this title.

The care and services described in subparagraphs (A) and (D) may be provided on a 24-hour, continuous basis only during periods of crisis (meeting criteria established by the Secretary) and only as necessary to maintain the terminally ill individual at home.

(2) The term "hospice program" means a public agency or private organization (or a subdivision thereof) which—

(A)(i) is primarily engaged in providing the care and services described in paragraph (1) and makes such services available (as needed) on a 24-hour basis and which also provides bereavement counseling for the immediate family of terminally ill individuals and services described in section 1812(a)(5),

(ii) provides for such care and services in individuals' homes, on an outpatient basis, and on a short-term inpatient basis, directly or under arrangements made by the agency or organization, except that—

(I) the agency or organization must routinely provide directly substantially all of each of the services described in subparagraphs (A), (C), and (H) of paragraph (1), except as otherwise provided in paragraph (5), and

(II) in the case of other services described in paragraph (1) which are not provided directly by the agency or organization, the agency or organization must maintain professional management responsibility for all such services furnished to an individual, regardless of the location or facility in which such services are furnished; and

(iii) provides assurances satisfactory to the Secretary that the aggregate number of days of inpatient care described in paragraph (1)(G) provided in any 12-month period to individuals who have an election in effect under section 1812(d) with respect to that agency or organization does not exceed 20 percent of the aggregate number of days during that period on which such elections for such individuals are in effect;

(B) has an interdisciplinary group of personnel which—

(i) includes at least—

(I) one physician (as defined in subsection (r)(1)),

(II) one registered professional nurse, and

(III) one social worker,

employed by or, in the case of a physician described in subclause (I), under contract with the agency or organization, and also includes at least one pastoral or other counselor,

(ii) provides (or supervises the provision of) the care and services described in paragraph (1), and

(iii) establishes the policies governing the provision of such care and services;

(C) maintains central clinical records on all patients;

(D) does not discontinue the hospice care it provides with respect to a patient because of the inability of the patient to pay for such care;

(E)(i) utilizes volunteers in its provision of care and services in accordance with standards set by the Secretary, which standards shall ensure a continuing level of effort to utilize such volunteers, and (ii) maintains records on the use of these volunteers and the cost savings and expansion of care and services achieved through the use of these volunteers;

(F) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, is licensed pursuant to such law; and

(G) meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are provided care and services by such agency or organization.

(3)(A) An individual is considered to be "terminally ill" if the individual has a medical prognosis that the individual's life expectancy is 6 months or less.

(B) The term "attending physician" means, with respect to an individual, the physician (as defined in subsection (r)(1)) or nurse practitioner (as defined in subsection (aa)(5)), who may be employed by a hospice program, whom the individual identifies as having the most significant role in the determination and delivery of medical care to the individual at the time the individual makes an election to receive hospice care.

(4)(A) An entity which is certified as a provider of services other than a hospice program shall be considered, for purposes of certification as a hospice program, to have met any requirements under paragraph (2) which are also the same requirements for certification as such other type of provider. The Secretary shall coordinate surveys for determining certification under this title so as to provide, to the extent feasible, for simultaneous surveys of an entity which seeks to be certified as a hospice program and as a provider of services of another type.

(B) Any entity which is certified as a hospice program and as a provider of another type shall have separate provider agreements under section 1866 and shall file separate cost reports with respect to costs incurred in providing hospice care and in providing other services and items under this title.

(C) Any entity that is certified as a hospice program shall be subject to a standard survey by an appropriate State or local survey agency, or an approved accreditation agency, as determined by the Secretary, not less frequently than once every 36 months beginning 6 months after the date of the enactment of this subparagraph and ending September 30, 2025.

(5)(A) The Secretary may waive the requirements of paragraph (2)(A)(ii)(I) for an agency or organization with respect to all or part of the nursing care described in paragraph (1)(A) if such agency or organization—

(i) is located in an area which is not an urbanized area (as defined by the Bureau of the Census);

(ii) was in operation on or before January 1, 1983; and

(iii) has demonstrated a good faith effort (as determined by the Secretary) to hire a sufficient number of nurses to provide such nursing care directly.

(B) Any waiver, which is in such form and containing such information as the Secretary may require and which is requested by an agency or organization under subparagraph (A) or (C), shall be deemed to be granted unless such request is denied by the Secretary within 60 days after the date such request is received by the Secretary. The granting of a waiver under subparagraph (A) or (C) shall not preclude the granting of any subsequent waiver request should such a waiver again become necessary.

(C) The Secretary may waive the requirements of paragraph (2)(A)(i) and (2)(A)(ii) for an agency or organization with respect to the services described in paragraph (1)(B) and, with respect to dietary counseling, paragraph (1)(H), if such agency or organization—

(i) is located in an area which is not an urbanized area (as defined by the Bureau of Census), and

(ii) demonstrates to the satisfaction of the Secretary that the agency or organization has been unable, despite diligent efforts, to recruit appropriate personnel.

(D) In extraordinary, exigent, or other non-routine circumstances, such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program's service area, a hospice program may enter into arrangements with another hospice program for the provision by that other program of services described in paragraph (2)(A)(ii)(I). The provisions of paragraph (2)(A)(ii)(II) shall apply with respect to the services provided under such arrangements.

(E) A hospice program may provide services described in paragraph (1)(A) other than directly by the program if the services are highly specialized services of a registered professional nurse and are provided non-routinely and so infrequently so that the provision of such services directly would be impracticable and prohibitively expensive.

Discharge Planning Process

(ee)(1) A discharge planning process of a hospital shall be considered sufficient if it is applicable to services furnished by the hospital to individuals entitled to benefits under this title and if it meets the guidelines and standards established by the Secretary under paragraph (2).

(2) The Secretary shall develop guidelines and standards for the discharge planning process in order to ensure a timely and smooth transition to the most appropriate type of and setting for post-hospital or rehabilitative care. The guidelines and standards shall include the following:

(A) The hospital must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning.

(B) Hospitals must provide a discharge planning evaluation for patients identified under subparagraph (A) and for other patients upon the request of the patient, patient's representative, or patient's physician.

(C) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-hospital care will be made before discharge and to avoid unnecessary delays in discharge.

(D) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-hospital services, including hospice care and post-hospital extended care services, and the availability of those services, including the availability of home health services through individuals and entities that participate in the program under this title and that serve the area in which the patient resides and that request to be listed by the hospital as available and, in the case of individuals who are likely to need post-hospital extended care services, the availability of such services through facilities that participate in the program under this title and that serve the area in which the patient resides.

(E) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

(F) Upon the request of a patient's physician, the hospital must arrange for the development and initial implementation of a discharge plan for the patient.

(G) Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered professional nurse, social worker, or other appropriately qualified personnel.

(H) Consistent with section 1802, the discharge plan shall—

(i) not specify or otherwise limit the qualified provider which may provide post-hospital home health services, and

(ii) identify (in a form and manner specified by the Secretary) any entity to whom the individual is referred in which the hospital has a disclosable financial interest (as specified by the Secretary consistent with section 1866(a)(1)(S)) or which has such an interest in the hospital.

(3) With respect to a discharge plan for an individual who is enrolled with a Medicare+Choice organization under a Medicare+Choice plan and is furnished inpatient hospital services by a hospital under a contract with the organization—

(A) the discharge planning evaluation under paragraph (2)(D) is not required to include information on the availability of home health services through individuals and entities which do not have a contract with the organization; and

(B) notwithstanding subparagraph (H)(i), the plan may specify or limit the provider (or providers) of post-hospital home health services or other post-hospital services under the plan.

Partial Hospitalization Services

(ff)(1) The term "partial hospitalization services" means the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which plan sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan.

(2) The items and services described in this paragraph are—

(A) individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law),

(B) occupational therapy requiring the skills of a qualified occupational therapist,

(C) services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients,

(D) drugs and biologicals furnished for therapeutic purposes (which cannot, as determined in accordance with regulations, be self-administered),

(E) individualized activity therapies that are not primarily recreational or diversionary,

(F) family counseling (the primary purpose of which is treatment of the individual's condition),

(G) patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment),

(H) diagnostic services, and

(I) such other items and services as the Secretary may provide (but in no event to include meals and transportation);

that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization, and furnished pursuant to such guidelines relating to frequency and duration of services as the Secretary shall by regulation establish (taking into account accepted norms of medical practice and the reasonable expectation of patient improvement).

(3)(A) A program described in this paragraph is a program which is furnished by a hospital to its outpatients or by a community mental health center (as defined in subparagraph (B)), and which is a distinct and organized intensive ambulatory treatment service offering less than 24-hour-daily care other than in an individual's home or in an inpatient or residential setting.

(B) For purposes of subparagraph (A), the term "community mental health center" means an entity that—

(i)(I) provides the mental health services described in section 1913(c)(1) of the Public Health Service Act; or

(II) in the case of an entity operating in a State that by law precludes the entity from providing itself the service described in subparagraph (E) of such section, provides for such service by contract with an approved organization or entity (as determined by the Secretary);

(ii) meets applicable licensing or certification requirements for community mental health centers in the State in which it is located;

(iii) provides at least 40 percent of its services to individuals who are not eligible for benefits under this title; and

(iv) meets such additional conditions as the Secretary shall specify to ensure (I) the health and safety of individuals being furnished such services, (II) the effective and efficient furnishing of such services, and (III) the compliance of such entity with the criteria described in section 1931(c)(1) of the Public Health Service Act.

Certified Nurse-Midwife Services

(gg)(1) The term "certified nurse-midwife services" means such services furnished by a certified nurse-midwife (as defined in paragraph (2)) and such services and supplies furnished as an incident to the nurse-midwife's service which the certified nurse-midwife is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) as would otherwise be covered if furnished by a physician or as an incident to a physicians' service.

(2) The term "certified nurse-midwife" means a registered nurse who has successfully completed a program of study and clinical experience meeting guidelines prescribed by the Secretary, or has been certified by an organization recognized by the Secretary.

Clinical Social Worker; Clinical Social Worker Services

(hh)(1) The term "clinical social worker" means an individual who—

(A) possesses a master's or doctor's degree in social work;

(B) after obtaining such degree has performed at least 2 years of supervised clinical social work; and

(C)(i) is licensed or certified as a clinical social worker by the State in which the services are performed, or

(ii) in the case of an individual in a State which does not provide for licensure or certification—

(I) has completed at least 2 years or 3,000 hours of post-master's degree supervised clinical social work practice under the supervision of a master's level social worker in an appropriate setting (as determined by the Secretary), and

(II) meets such other criteria as the Secretary establishes.

(2) The term "clinical social worker services" means services performed by a clinical social worker (as defined in paragraph (1)) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital and other than services furnished to an inpatient of a skilled nursing facility which the facility is required to provide as a requirement for participation) which the clinical social worker is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed as would otherwise be covered if furnished by a physician or as an incident to a physician's professional service.

Qualified Psychologist Services

(ii) The term "qualified psychologist services" means such services and such services and supplies furnished as an incident to his service furnished by a clinical psychologist (as defined by the Secretary) which the psychologist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) as would otherwise be covered if furnished by a physician or as an incident to a physician's service.

Screening Mammography

(jj) The term "screening mammography" means a radiologic procedure provided to a woman for the purpose of early detection of breast cancer and includes a physician's interpretation of the results of the procedure.

Covered Osteoporosis Drug

(kk) The term "covered osteoporosis drug" means an injectable drug approved for the treatment of post-menopausal osteoporosis provided to an individual by a home health agency if, in accordance with regulations promulgated by the Secretary—

(1) the individual's attending physician certifies that the individual has suffered a bone fracture related to post-menopausal osteoporosis and that the individual is unable to learn the skills needed to self-administer such drug or is otherwise

physically or mentally incapable of self-administering such drug; and

(2) the individual is confined to the individual's home (except when receiving items and services referred to in subsection (m)(7)).

Speech-Language Pathology Services; Audiology Services

(ll)(1) The term "speech-language pathology services" means such speech, language, and related function assessment and rehabilitation services furnished by a qualified speech-language pathologist as the speech-language pathologist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) as would otherwise be covered if furnished by a physician.

(2) The term "outpatient speech-language pathology services" has the meaning given the term "outpatient physical therapy services" in subsection (p), except that in applying such subsection—

(A) "speech-language pathology" shall be substituted for "physical therapy" each place it appears; and

(B) "speech-language pathologist" shall be substituted for "physical therapist" each place it appears.

(3) The term "audiology services" means such hearing and balance assessment services furnished by a qualified audiologist as the audiologist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law), as would otherwise be covered if furnished by a physician.

(4) In this subsection:

(A) The term "qualified speech-language pathologist" means an individual with a master's or doctoral degree in speech-language pathology who—

(i) is licensed as a speech-language pathologist by the State in which the individual furnishes such services, or

(ii) in the case of an individual who furnishes services in a State which does not license speech-language pathologists, has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience), performed not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field, and successfully completed a national examination in speech-language pathology approved by the Secretary.

(B) The term "qualified audiologist" means an individual with a master's or doctoral degree in audiology who—

(i) is licensed as an audiologist by the State in which the individual furnishes such services, or

(ii) in the case of an individual who furnishes services in a State which does not license audiologists, has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience), performed not less than 9 months of supervised full-time audiology services after obtaining a master's or doctoral degree in audiology or a related field, and successfully completed a national examination in audiology approved by the Secretary.

Critical Access Hospital; Critical Access Hospital Services

(mm)(1) The term "critical access hospital" means a facility certified by the Secretary as a critical access hospital under section 1820(e).

(2) The term "inpatient critical access hospital services" means items and services, furnished to an inpatient of a critical access hospital by such facility, that would be inpatient hospital services if furnished to an inpatient of a hospital by a hospital.

(3) The term "outpatient critical access hospital services" means medical and other health services furnished by a critical access hospital on an outpatient basis.

Screening Pap Smear; Screening Pelvic Exam

(nn)(1) The term "screening pap smear" means a diagnostic laboratory test consisting of a routine exfoliative cytology test (Papanicolaou test) provided to a woman for the purpose of early detection of cervical or vaginal cancer and includes a physician's interpretation of the results of the test, if the individual involved has not had such a test during the preceding 2 years, or during the preceding year in the case of a woman described in paragraph (3).

(2) The term "screening pelvic exam" means a pelvic examination provided to a woman if the woman involved has not had such an examination during the preceding 2 years, or during the preceding year in the case of a woman described in paragraph (3), and includes a clinical breast examination.

(3) A woman described in this paragraph is a woman who—

(A) is of childbearing age and has had a test described in this subsection during any of the preceding 3 years that indicated the presence of cervical or vaginal cancer or other abnormality; or

(B) is at high risk of developing cervical or vaginal cancer (as determined pursuant to factors identified by the Secretary).

Prostate Cancer Screening Tests

(oo)(1) The term "prostate cancer screening test" means a test that consists of any (or all) of the procedures described in paragraph (2) provided for the purpose of early detection of prostate cancer to a man over 50 years of age who has not had such a test during the preceding year.

(2) The procedures described in this paragraph are as follows:

(A) A digital rectal examination.

(B) A prostate-specific antigen blood test.

(C) For years beginning after 2002, such other procedures as the Secretary finds appropriate for the purpose of early detection of prostate cancer, taking into account changes in technology and standards of medical practice, availability, effectiveness, costs, and such other factors as the Secretary considers appropriate.

Colorectal Cancer Screening Tests

(pp)(1) The term "colorectal cancer screening test" means any of the following procedures furnished to an individual for the purpose of early detection of colorectal cancer:

(A) Screening fecal-occult blood test.

(B) Screening flexible sigmoidoscopy.

(C) Screening colonoscopy.

(D) Such other tests or procedures, and modifications to tests and procedures under this subsection, with such frequency and payment limits, as the Secretary determines appropriate, in consultation with appropriate organizations.

(2) An "individual at high risk for colorectal cancer" is an individual who, because of family history, prior experience of cancer or precursor neoplastic polyps, a history of chronic digestive disease condition (including inflammatory bowel disease, Crohn's Disease, or ulcerative colitis), the presence of any appropriate recognized gene markers for colorectal cancer, or other predisposing factors, faces a high risk for colorectal cancer.

Diabetes Outpatient Self-Management Training Services

(qq)(1) The term "diabetes outpatient self-management training services" means educational and training services furnished (at such times as the Secretary determines appropriate) to an individual with diabetes by a certified provider (as described in paragraph (2)(A)) in an outpatient setting by an individual or entity who meets the quality standards described in paragraph (2)(B), but only if the physician who is managing the individual's diabetic condition certifies that such services are needed under a comprehensive plan of care related to the individual's diabetic condition to ensure therapy compliance or to provide the individual with necessary skills and knowledge (including skills related to the self-administration of injectable drugs) to participate in the management of the individual's condition.

(2) In paragraph (1)—

(A) a "certified provider" is a physician, or other individual or entity designated by the Secretary, that, in addition to providing diabetes outpatient self-management training services, provides other items or services for which payment may be made under this title; and

(B) a physician, or such other individual or entity, meets the quality standards described in this paragraph if the physician, or individual or entity, meets quality standards established by the Secretary, except that the physician or other individual or entity shall be deemed to have met such standards if the physician or other individual or entity meets applicable standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who participated in the establishment of standards by such Board, or is recognized by an organization that represents individuals (including individuals under this title) with diabetes as meeting standards for furnishing the services.

Bone Mass Measurement

(rr)(1) The term "bone mass measurement" means a radiologic or radioisotopic procedure or other procedure approved by the Food and Drug Administration performed on a qualified individual (as defined in paragraph (2)) for the purpose of identifying bone mass

or detecting bone loss or determining bone quality, and includes a physician's interpretation of the results of the procedure.

(2) For purposes of this subsection, the term "qualified individual" means an individual who is (in accordance with regulations prescribed by the Secretary)—

(A) an estrogen-deficient woman at clinical risk for osteoporosis;

(B) an individual with vertebral abnormalities;

(C) an individual receiving long-term glucocorticoid steroid therapy;

(D) an individual with primary hyperparathyroidism; or

(E) an individual being monitored to assess the response to or efficacy of an approved osteoporosis drug therapy.

(3) The Secretary shall establish such standards regarding the frequency with which a qualified individual shall be eligible to be provided benefits for bone mass measurement under this title.

Religious Nonmedical Health Care Institution

(ss)(1) The term "religious nonmedical health care institution" means an institution that—

(A) is described in subsection (c)(3) of section 501 of the Internal Revenue Code of 1986 and is exempt from taxes under subsection (a) of such section;

(B) is lawfully operated under all applicable Federal, State, and local laws and regulations;

(C) provides only nonmedical nursing items and services exclusively to patients who choose to rely solely upon a religious method of healing and for whom the acceptance of medical health services would be inconsistent with their religious beliefs;

(D) provides such nonmedical items and services exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of such patients;

(E) provides such nonmedical items and services to inpatients on a 24-hour basis;

(F) on the basis of its religious beliefs, does not provide through its personnel or otherwise medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients;

(G)(i) is not owned by, under common ownership with, or has an ownership interest in, a provider of medical treatment or services;

(ii) is not affiliated with—

(I) a provider of medical treatment or services, or

(II) an individual who has an ownership interest in a provider of medical treatment or services;

(H) has in effect a utilization review plan which—

(i) provides for the review of admissions to the institution, of the duration of stays therein, of cases of continuous extended duration, and of the items and services furnished by the institution,

(ii) requires that such reviews be made by an appropriate committee of the institution that includes the

individuals responsible for overall administration and for supervision of nursing personnel at the institution,

(iii) provides that records be maintained of the meetings, decisions, and actions of such committee, and

(iv) meets such other requirements as the Secretary finds necessary to establish an effective utilization review plan;

(I) provides the Secretary with such information as the Secretary may require to implement section 1821, including information relating to quality of care and coverage determinations; and

(J) meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.

(2) To the extent that the Secretary finds that the accreditation of an institution by a State, regional, or national agency or association provides reasonable assurances that any or all of the requirements of paragraph (1) are met or exceeded, the Secretary may treat such institution as meeting the condition or conditions with respect to which the Secretary made such finding.

(3)(A)(i) In administering this subsection and section 1821, the Secretary shall not require any patient of a religious nonmedical health care institution to undergo medical screening, examination, diagnosis, prognosis, or treatment or to accept any other medical health care service, if such patient (or legal representative of the patient) objects thereto on religious grounds.

(ii) Clause (i) shall not be construed as preventing the Secretary from requiring under section 1821(a)(2) the provision of sufficient information regarding an individual's condition as a condition for receipt of benefits under part A for services provided in such an institution.

(B)(i) In administering this subsection and section 1821, the Secretary shall not subject a religious nonmedical health care institution or its personnel to any medical supervision, regulation, or control, insofar as such supervision, regulation, or control would be contrary to the religious beliefs observed by the institution or such personnel.

(ii) Clause (i) shall not be construed as preventing the Secretary from reviewing items and services billed by the institution to the extent the Secretary determines such review to be necessary to determine whether such items and services were not covered under part A, are excessive, or are fraudulent.

(4)(A) For purposes of paragraph (1)(G)(i), an ownership interest of less than 5 percent shall not be taken into account.

(B) For purposes of paragraph (1)(G)(ii), none of the following shall be considered to create an affiliation:

(i) An individual serving as an uncompensated director, trustee, officer, or other member of the governing body of a religious nonmedical health care institution.

(ii) An individual who is a director, trustee, officer, employee, or staff member of a religious nonmedical health care institution having a family relationship with an individual who is affiliated with (or has an ownership interest in) a provider of medical treatment or services.

(iii) An individual or entity furnishing goods or services as a vendor to both providers of medical treatment or services and religious nonmedical health care institutions.

Post-Institutional Home Health Services; Home Health Spell of Illness

(tt)(1) The term "post-institutional home health services" means home health services furnished to an individual—

(A) after discharge from a hospital or critical access hospital in which the individual was an inpatient for not less than 3 consecutive days before such discharge if such home health services were initiated within 14 days after the date of such discharge; or

(B) after discharge from a skilled nursing facility in which the individual was provided post-hospital extended care services if such home health services were initiated within 14 days after the date of such discharge.

(2) The term "home health spell of illness" with respect to any individual means a period of consecutive days—

(A) beginning with the first day (not included in a previous home health spell of illness) (i) on which such individual is furnished post-institutional home health services, and (ii) which occurs in a month for which the individual is entitled to benefits under part A, and

(B) ending with the close of the first period of 60 consecutive days thereafter on each of which the individual is neither an inpatient of a hospital or critical access hospital nor an inpatient of a facility described in section 1819(a)(1) or subsection (y)(1) nor provided home health services.

Screening for Glaucoma

(uu) The term "screening for glaucoma" means a dilated eye examination with an intraocular pressure measurement, and a direct ophthalmoscopy or a slit-lamp biomicroscopic examination for the early detection of glaucoma which is furnished by or under the direct supervision of an optometrist or ophthalmologist who is legally authorized to furnish such services under State law (or the State regulatory mechanism provided by State law) of the State in which the services are furnished, as would otherwise be covered if furnished by a physician or as an incident to a physician's professional service, if the individual involved has not had such an examination in the preceding year.

Medical Nutrition Therapy Services; Registered Dietitian or Nutrition Professional

(vv)(1) The term "medical nutrition therapy services" means nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional (as defined in paragraph (2)) pursuant to a referral by a physician (as defined in subsection (r)(1)).

(2) Subject to paragraph (3), the term "registered dietitian or nutrition professional" means an individual who—

(A) holds a baccalaureate or higher degree granted by a regionally accredited college or university in the United States

(or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics, as accredited by an appropriate national accreditation organization recognized by the Secretary for this purpose;

(B) has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional; and

(C)(i) is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed; or

(ii) in the case of an individual in a State that does not provide for such licensure or certification, meets such other criteria as the Secretary establishes.

(3) Subparagraphs (A) and (B) of paragraph (2) shall not apply in the case of an individual who, as of the date of the enactment of this subsection, is licensed or certified as a dietitian or nutrition professional by the State in which medical nutrition therapy services are performed.

Initial Preventive Physical Examination

(ww)(1) The term "initial preventive physical examination" means physicians' services consisting of a physical examination (including measurement of height, weight body mass index,, and blood pressure) with the goal of health promotion and disease detection and includes education, counseling, and referral with respect to screening and other preventive services described in paragraph (2) and end-of-life planning (as defined in paragraph (3)) upon the agreement with the individual, but does not include clinical laboratory tests.

(2) The screening and other preventive services described in this paragraph include the following:

(A) Pneumococcal, influenza, and hepatitis B vaccine and administration under subsection (s)(10).

(B) Screening mammography as defined in subsection (jj).

(C) Screening pap smear and screening pelvic exam as defined in subsection (nn).

(D) Prostate cancer screening tests as defined in subsection (oo).

(E) Colorectal cancer screening tests as defined in subsection (pp).

(F) Diabetes outpatient self-management training services as defined in subsection (qq)(1).

(G) Bone mass measurement as defined in subsection (rr).

(H) Screening for glaucoma as defined in subsection (uu).

(I) Medical nutrition therapy services as defined in subsection (vv).

(J) Cardiovascular screening blood tests as defined in subsection (xx)(1).

(K) Diabetes screening tests as defined in subsection (yy).

(L) Ultrasound screening for abdominal aortic aneurysm as defined in section 1861(bbb).

(M) An electrocardiogram.

(N) Additional preventive services (as defined in subsection (ddd)(1)).

(3) For purposes of paragraph (1), the term "end-of-life planning" means verbal or written information regarding—

(A) an individual's ability to prepare an advance directive in the case that an injury or illness causes the individual to be unable to make health care decisions; and

(B) whether or not the physician is willing to follow the individual's wishes as expressed in an advance directive.

Cardiovascular Screening Blood Test

(xx)(1) The term "cardiovascular screening blood test" means a blood test for the early detection of cardiovascular disease (or abnormalities associated with an elevated risk of cardiovascular disease) that tests for the following:

(A) Cholesterol levels and other lipid or triglyceride levels.

(B) Such other indications associated with the presence of, or an elevated risk for, cardiovascular disease as the Secretary may approve for all individuals (or for some individuals determined by the Secretary to be at risk for cardiovascular disease), including indications measured by noninvasive testing.

The Secretary may not approve an indication under subparagraph (B) for any individual unless a blood test for such is recommended by the United States Preventive Services Task Force.

(2) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency for each type of cardiovascular screening blood tests, except that such frequency may not be more often than once every 2 years.

Diabetes Screening Tests

(yy)(1) The term "diabetes screening tests" means testing furnished to an individual at risk for diabetes (as defined in paragraph (2)) for the purpose of early detection of diabetes, including—

(A) a fasting plasma glucose test; and

(B) such other tests, and modifications to tests, as the Secretary determines appropriate, in consultation with appropriate organizations.

(2) For purposes of paragraph (1), the term "individual at risk for diabetes" means an individual who has any of the following risk factors for diabetes:

(A) Hypertension.

(B) Dyslipidemia.

(C) Obesity, defined as a body mass index greater than or equal to 30 kg/m^2.

(D) Previous identification of an elevated impaired fasting glucose.

(E) Previous identification of impaired glucose tolerance.

(F) A risk factor consisting of at least 2 of the following characteristics:

(i) Overweight, defined as a body mass index greater than 25, but less than 30, kg/m^2.

(ii) A family history of diabetes.

(iii) A history of gestational diabetes mellitus or delivery of a baby weighing greater than 9 pounds.

(iv) 65 years of age or older.

(3) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency of diabetes screening tests, except that such frequency may not be more often

than twice within the 12-month period following the date of the most recent diabetes screening test of that individual.

Intravenous Immune Globulin

(zz) The term "intravenous immune globulin" means an approved pooled plasma derivative for the treatment in the patient's home of a patient with a diagnosed primary immune deficiency disease, but not including items or services related to the administration of the derivative, if a physician determines administration of the derivative in the patient's home is medically appropriate.

Extended Care in Religious Nonmedical Health Care Institutions

(aaa)(1) The term "home health agency" also includes a religious nonmedical health care institution (as defined in subsection (ss)(1)), but only with respect to items and services ordinarily furnished by such an institution to individuals in their homes, and that are comparable to items and services furnished to individuals by a home health agency that is not religious nonmedical health care institution.

(2)(A) Subject to subparagraphs (B), payment may be made with respect to services provided by such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise applicable) as may be provided in regulations consistent with section 1821.

(B) Notwithstanding any other provision of this title, payment may not be made under subparagraph (A)—

(i) in a year insofar as such payments exceed $700,000; and

(ii) after December 31, 2006.

Ultrasound Screening for Abdominal Aortic Aneurysm

(bbb) The term "ultrasound screening for abdominal aortic aneurysm" means—

(1) a procedure using sound waves (or such other procedures using alternative technologies, of commensurate accuracy and cost, that the Secretary may specify) provided for the early detection of abdominal aortic aneurysm; and

(2) includes a physician's interpretation of the results of the procedure.

Long-Term Care Hospital

(ccc) The term "long-term care hospital" means a hospital which—

(1) is primarily engaged in providing inpatient services, by or under the supervision of a physician, to Medicare beneficiaries whose medically complex conditions require a long hospital stay and programs of care provided by a long-term care hospital;

(2) has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days, or meets the requirements of clause (II) of section 1886(d)(1)(B)(iv);

(3) satisfies the requirements of subsection (e); and

(4) meets the following facility criteria:

(A) the institution has a patient review process, documented in the patient medical record, that screens patients prior to admission for appropriateness of admission to a long-term care hospital, validates within 48 hours of admission that patients meet admission criteria for long-term care hospitals, regularly evaluates patients throughout their stay for continuation of care in a long-term care hospital, and assesses the available discharge options when patients no longer meet such continued stay criteria;

(B) the institution has active physician involvement with patients during their treatment through an organized medical staff, physician-directed treatment with physician on-site availability on a daily basis to review patient progress, and consulting physicians on call and capable of being at the patient's side within a moderate period of time, as determined by the Secretary; and

(C) the institution has interdisciplinary team treatment for patients, requiring interdisciplinary teams of health care professionals, including physicians, to prepare and carry out an individualized treatment plan for each patient.

Additional Preventive Services; Preventive Services

(ddd)(1) The term "additional preventive services" means services not described in subparagraph (A) or (C) of paragraph (3) that identify medical conditions or risk factors and that the Secretary determines are—

(A) reasonable and necessary for the prevention or early detection of an illness or disability;

(B) recommended with a grade of A or B by the United States Preventive Services Task Force; and

(C) appropriate for individuals entitled to benefits under part A or enrolled under part B.

(2) In making determinations under paragraph (1) regarding the coverage of a new service, the Secretary shall use the process for making national coverage determinations (as defined in section 1869(f)(1)(B)) under this title. As part of the use of such process, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such service and may take into account the results of such assessment in making such determination.

(3) The term "preventive services" means the following:

(A) The screening and preventive services described in subsection (ww)(2) (other than the service described in subparagraph (M) of such subsection).

(B) An initial preventive physical examination (as defined in subsection (ww)).

(C) Personalized prevention plan services (as defined in subsection (hhh)(1)).

Cardiac Rehabilitation Program; Intensive Cardiac Rehabilitation Program

(eee)(1) The term "cardiac rehabilitation program" means a physician-supervised program (as described in paragraph (2)) that furnishes the items and services described in paragraph (3).

(2) A program described in this paragraph is a program under which—

(A) items and services under the program are delivered—

(i) in a physician's office;

(ii) in a hospital on an outpatient basis; or

(iii) in other settings determined appropriate by the Secretary.

(B) a physician is immediately available and accessible for medical consultation and medical emergencies at all times items and services are being furnished under the program, except that, in the case of items and services furnished under such a program in a hospital, such availability shall be presumed; and

(C) individualized treatment is furnished under a written plan established, reviewed, and signed by a physician every 30 days that describes—

(i) the individual's diagnosis;

(ii) the type, amount, frequency, and duration of the items and services furnished under the plan; and

(iii) the goals set for the individual under the plan.

(3) The items and services described in this paragraph are—

(A) physician-prescribed exercise;

(B) cardiac risk factor modification, including education, counseling, and behavioral intervention (to the extent such education, counseling, and behavioral intervention is closely related to the individual's care and treatment and is tailored to the individual's needs);

(C) psychosocial assessment;

(D) outcomes assessment; and

(E) such other items and services as the Secretary may determine, but only if such items and services are—

(i) reasonable and necessary for the diagnosis or active treatment of the individual's condition;

(ii) reasonably expected to improve or maintain the individual's condition and functional level; and

(iii) furnished under such guidelines relating to the frequency and duration of such items and services as the Secretary shall establish, taking into account accepted norms of medical practice and the reasonable expectation of improvement of the individual.

(4)(A) The term "intensive cardiac rehabilitation program" means a physician-supervised program (as described in paragraph (2)) that furnishes the items and services described in paragraph (3) and has shown, in peer-reviewed published research, that it accomplished—

(i) one or more of the following:

(I) positively affected the progression of coronary heart disease; or

(II) reduced the need for coronary bypass surgery; or

(III) reduced the need for percutaneous coronary interventions; and

(ii) a statistically significant reduction in 5 or more of the following measures from their level before receipt of cardiac rehabilitation services to their level after receipt of such services:

(I) low density lipoprotein;

(II) triglycerides;

(III) body mass index;

(IV) systolic blood pressure;

(V) diastolic blood pressure; or

(VI) the need for cholesterol, blood pressure, and diabetes medications.

(B) To be eligible for an intensive cardiac rehabilitation program, an individual must have—

(i) had an acute myocardial infarction within the preceding 12 months;

(ii) had coronary bypass surgery;

(iii) stable angina pectoris;

(iv) had heart valve repair or replacement;

(v) had percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; or

(vi) had a heart or heart-lung transplant.

(C) An intensive cardiac rehabilitation program may be provided in a series of 72 one-hour sessions (as defined in section 1848(b)(5)), up to 6 sessions per day, over a period of up to 18 weeks.

(5) The Secretary shall establish standards to ensure that a physician with expertise in the management of individuals with cardiac pathophysiology who is licensed to practice medicine in the State in which a cardiac rehabilitation program (or the intensive cardiac rehabilitation program, as the case may be) is offered—

(A) is responsible for such program; and

(B) in consultation with appropriate staff, is involved substantially in directing the progress of individual in the program.

Pulmonary Rehabilitation Program

(fff)(1) The term "pulmonary rehabilitation program" means a physician-supervised program (as described in subsection (eee)(2) with respect to a program under this subsection) that furnishes the items and services described in paragraph (2).

(2) The items and services described in this paragraph are—

(A) physician-prescribed exercise;

(B) education or training (to the extent the education or training is closely and clearly related to the individual's care and treatment and is tailored to such individual's needs);

(C) psychosocial assessment;

(D) outcomes assessment; and

(E) such other items and services as the Secretary may determine, but only if such items and services are—

(i) reasonable and necessary for the diagnosis or active treatment of the individual's condition;

(ii) reasonably expected to improve or maintain the individual's condition and functional level; and

(iii) furnished under such guidelines relating to the frequency and duration of such items and services as the Secretary shall establish, taking into account accepted norms of medical practice and the reasonable expectation of improvement of the individual.

(3) The Secretary shall establish standards to ensure that a physician with expertise in the management of individuals with respiratory pathophysiology who is licensed to practice medicine in the State in which a pulmonary rehabilitation program is offered—

(A) is responsible for such program; and

(B) in consultation with appropriate staff, is involved substantially in directing the progress of individual in the program.

Kidney Disease Education Services

(ggg)(1) The term "kidney disease education services" means educational services that are—

(A) furnished to an individual with stage IV chronic kidney disease who, according to accepted clinical guidelines identified by the Secretary, will require dialysis or a kidney transplant;

(B) furnished, upon the referral of the physician managing the individual's kidney condition, by a qualified person (as defined in paragraph (2)); and

(C) designed—

(i) to provide comprehensive information (consistent with the standards set under paragraph (3)) regarding—

(I) the management of comorbidities, including for purposes of delaying the need for dialysis;

(II) the prevention of uremic complications; and

(III) each option for renal replacement therapy (including hemodialysis and peritoneal dialysis at home and in-center as well as vascular access options and transplantation);

(ii) to ensure that the individual has the opportunity to actively participate in the choice of therapy; and

(iii) to be tailored to meet the needs of the individual involved.

(2)(A) The term "qualified person" means—

(i) a physician (as defined in section 1861(r)(1)) or a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5)), who furnishes services for which payment may be made under the fee schedule established under section 1848; and

(ii) a provider of services located in a rural area (as defined in section 1886(d)(2)(D)).

(B) Such term does not include a provider of services (other than a provider of services described in subparagraph (A)(ii)) or a renal dialysis facility.

(3) The Secretary shall set standards for the content of such information to be provided under paragraph (1)(C)(i) after consulting with physicians, other health professionals, health educators, professional organizations, accrediting organizations, kidney patient organizations, dialysis facilities, transplant centers, network organizations described in section 1881(c)(2), and other knowledgeable persons. To the extent possible the Secretary shall consult with

persons or entities described in the previous sentence, other than a dialysis facility, that has not received industry funding from a drug or biological manufacturer or dialysis facility.

(4) No individual shall be furnished more than 6 sessions of kidney disease education services under this title.

Annual Wellness Visit

(hhh)(1) The term "personalized prevention plan services" means the creation of a plan for an individual—

(A) that includes a health risk assessment (that meets the guidelines established by the Secretary under paragraph (4)(A)) of the individual that is completed prior to or as part of the same visit with a health professional described in paragraph (3); and

(B) that—

(i) takes into account the results of the health risk assessment; and

(ii) may contain the elements described in paragraph (2).

(2) Subject to paragraph (4)(H), the elements described in this paragraph are the following:

(A) The establishment of, or an update to, the individual's medical and family history.

(B) A list of current providers and suppliers that are regularly involved in providing medical care to the individual (including a list of all prescribed medications).

(C) A measurement of height, weight, body mass index (or waist circumference, if appropriate), blood pressure, and other routine measurements.

(D) Detection of any cognitive impairment.

(E) The establishment of, or an update to, the following:

(i) A screening schedule for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force and the Advisory Committee on Immunization Practices, and the individual's health status, screening history, and age-appropriate preventive services covered under this title.

(ii) A list of risk factors and conditions for which primary, secondary, or tertiary prevention interventions are recommended or are underway, including any mental health conditions or any such risk factors or conditions that have been identified through an initial preventive physical examination (as described under subsection (ww)(1)), and a list of treatment options and their associated risks and benefits.

(F) The furnishing of personalized health advice and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self-management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition.

(G) Any other element determined appropriate by the Secretary.

(3) A health professional described in this paragraph is—

(A) a physician;

(B) a practitioner described in clause (i) of section 1842(b)(18)(C); or

(C) a medical professional (including a health educator, registered dietitian, or nutrition professional) or a team of medical professionals, as determined appropriate by the Secretary, under the supervision of a physician.

(4)(A) For purposes of paragraph (1)(A), the Secretary, not later than 1 year after the date of enactment of this subsection, shall establish publicly available guidelines for health risk assessments. Such guidelines shall be developed in consultation with relevant groups and entities and shall provide that a health risk assessment—

(i) identify chronic diseases, injury risks, modifiable risk factors, and urgent health needs of the individual; and

(ii) may be furnished—

(I) through an interactive telephonic or web-based program that meets the standards established under subparagraph (B);

(II) during an encounter with a health care professional;

(III) through community-based prevention programs; or

(IV) through any other means the Secretary determines appropriate to maximize accessibility and ease of use by beneficiaries, while ensuring the privacy of such beneficiaries.

(B) Not later than 1 year after the date of enactment of this subsection, the Secretary shall establish standards for interactive telephonic or web-based programs used to furnish health risk assessments under subparagraph (A)(ii)(I). The Secretary may utilize any health risk assessment developed under section 4004(f) of the Patient Protection and Affordable Care Act as part of the requirement to develop a personalized prevention plan to comply with this subparagraph.

(C)(i) Not later than 18 months after the date of enactment of this subsection, the Secretary shall develop and make available to the public a health risk assessment model. Such model shall meet the guidelines under subparagraph (A) and may be used to meet the requirement under paragraph (1)(A).

(ii) Any health risk assessment that meets the guidelines under subparagraph (A) and is approved by the Secretary may be used to meet the requirement under paragraph (1)(A).

(D) The Secretary may coordinate with community-based entities (including State Health Insurance Programs, Area Agencies on Aging, Aging and Disability Resource Centers, and the Administration on Aging) to—

(i) ensure that health risk assessments are accessible to beneficiaries; and

(ii) provide appropriate support for the completion of health risk assessments by beneficiaries.

(E) The Secretary shall establish procedures to make beneficiaries and providers aware of the requirement that a beneficiary complete a health risk assessment prior to or at the same time as receiving personalized prevention plan services.

(F) To the extent practicable, the Secretary shall encourage the use of, integration with, and coordination of health information technology (including use of technology that is compatible with

electronic medical records and personal health records) and may experiment with the use of personalized technology to aid in the development of self-management skills and management of and adherence to provider recommendations in order to improve the health status of beneficiaries.

(G) A beneficiary shall be eligible to receive only an initial preventive physical examination (as defined under subsection (ww)(1)) during the 12-month period after the date that the beneficiary's coverage begins under part B and shall be eligible to receive personalized prevention plan services under this subsection each year thereafter provided that the beneficiary has not received either an initial preventive physical examination or personalized prevention plan services within the preceding 12-month period.

(H) The Secretary shall issue guidance that—

(i) identifies elements under paragraph (2) that are required to be provided to a beneficiary as part of their first visit for personalized prevention plan services; and

(ii) establishes a yearly schedule for appropriate provision of such elements thereafter.

EXCLUSIONS FROM COVERAGE AND MEDICARE AS SECONDARY PAYER

SEC. 1862. (a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(1)(A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1861(ddd)(1)), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

(B) in the case of items and services described in section 1861(s)(10), which are not reasonable and necessary for the prevention of illness,

(C) in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal illness,

(D) in the case of clinical care items and services provided with the concurrence of the Secretary and with respect to research and experimentation conducted by, or under contract with, the Medicare Payment Advisory Commission or the Secretary, which are not reasonable and necessary to carry out the purposes of section 1886(e)(6),

(E) in the case of research conducted pursuant to section 1142, which is not reasonable and necessary to carry out the purposes of that section,

(F) in the case of screening mammography, which is performed more frequently than is covered under section 1834(c)(2) or which is not conducted by a facility described in section 1834(c)(1)(B), in the case of screening pap smear and screening pelvic exam, which is performed more frequently than is provided under section 1861(nn), and, in the case of screening for glaucoma, which is performed more frequently than is provided under section 1861(uu),

(G) in the case of prostate cancer screening tests (as defined in section 1861(oo)), which are performed more frequently than is covered under such section,

(H) in the case of colorectal cancer screening tests, which are performed more frequently than is covered under section 1834(d),

(I) the frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation,

(J) in the case of a drug or biological specified in section 1847A(c)(6)(C) for which payment is made under part B that is furnished in a competitive area under section 1847B, that is not furnished by an entity under a contract under such section,

(K) in the case of an initial preventive physical examination, which is performed more than 1 year after the date the individual's first coverage period begins under part B,

(L) in the case of cardiovascular screening blood tests (as defined in section 1861(xx)(1)), which are performed more frequently than is covered under section 1861(xx)(2),

(M) in the case of a diabetes screening test (as defined in section 1861(yy)(1)), which is performed more frequently than is covered under section 1861(yy)(3),

(N) in the case of ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under section 1861(s)(2)(AA),

(O) in the case of kidney disease education services (as defined in paragraph (1) of section 1861(ggg)), which are furnished in excess of the number of sessions covered under paragraph (4) of such section, and

(P) in the case of personalized prevention plan services (as defined in section 1861(hhh)(1)), which are performed more frequently than is covered under such section;

(2) for which the individual furnished such items or services has no legal obligation to pay, and which no other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for, except in the case of Federally qualified health center services;

(3) which are paid for directly or indirectly by a governmental entity (other than under this Act and other than under a health benefits or insurance plan established for employees of such an entity), except in the case of rural health clinic services, as defined in section 1861(aa)(1), in the case of Federally qualified health center services, as defined in section 1861(aa)(3), in the case of services for which payment may be made under section 1880(e), and in such other cases as the Secretary may specify;

(4) which are not provided within the United States (except for inpatient hospital services furnished outside the United States under the conditions described in section 1814(f) and, subject to such conditions, limitations, and requirements as are provided under or pursuant to this title, physicians' services and ambulance services furnished an individual in conjunction with such inpatient hospital services but only for the period during which such inpatient hospital services were furnished);

(5) which are required as a result of war, or of an act of war, occurring after the effective date of such individual's current coverage under such part;

(6) which constitute personal comfort items (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(7) where such expenses are for routine physical checkups, eyeglasses (other than eyewear described in section 1861(s)(8)) or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes, hearing aids or examinations therefor, or immunizations (except as otherwise allowed under section 1861(s)(10) and subparagraph (B), (F), (G), (H), (K), or (P) of paragraph (1));

(8) where such expenses are for orthopedic shoes or other supportive devices for the feet, other than shoes furnished pursuant to section 1861(s)(12);

(9) where such expenses are for custodial care (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(10) where such expenses are for cosmetic surgery or are incurred in connection therewith, except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member;

(11) where such expenses constitute charges imposed by immediate relatives of such individual or members of his household;

(12) where such expenses are for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, except that payment may be made under part A in the case of inpatient hospital services in connection with the provision of such dental services if the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services;

(13) where such expenses are for—

(A) the treatment of flat foot conditions and the prescription of supportive devices therefor,

(B) the treatment of subluxations of the foot, or

(C) routine foot care (including the cutting or removal of corns or calluses, the trimming of nails, and other routine hygienic care);

(14) which are other than physicians' services (as defined in regulations promulgated specifically for purposes of this paragraph), services described by section 1861(s)(2)(K), certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist, and which are furnished to an individual who is a patient of a hospital or critical access hospital by an entity other than the hospital or critical access hospital, unless the services are furnished under arrangements (as defined in section 1861(w)(1)) with the entity made by the hospital or critical access hospital;

(15)(A) which are for services of an assistant at surgery in a cataract operation (including subsequent insertion of an intraocular lens) unless, before the surgery is performed, the appropriate quality improvement organization (under part B of title XI) or a carrier under section 1842 has approved of the

use of such an assistant in the surgical procedure based on the existence of a complicating medical condition, or

(B) which are for services of an assistant at surgery to which section 1848(i)(2)(B) applies;

(16) in the case in which funds may not be used for such items and services under the Assisted Suicide Funding Restriction Act of 1997;

(17) where the expenses are for an item or service furnished in a competitive acquisition area (as established by the Secretary under section 1847(a)) by an entity other than an entity with which the Secretary has entered into a contract under section 1847(b) for the furnishing of such an item or service in that area, unless the Secretary finds that the expenses were incurred in a case of urgent need, or in other circumstances specified by the Secretary;

(18) which are covered skilled nursing facility services described in section 1888(e)(2)(A)(i) and which are furnished to an individual who is a resident of a skilled nursing facility during a period in which the resident is provided covered post-hospital extended care services (or, for services described in section 1861(s)(2)(D), which are furnished to such an individual without regard to such period), by an entity other than the skilled nursing facility, unless the services are furnished under arrangements (as defined in section 1861(w)(1)) with the entity made by the skilled nursing facility;

(19) which are for items or services which are furnished pursuant to a private contract described in section 1802(b);

(20) in the case of outpatient physical therapy services, outpatient speech-language pathology services, or outpatient occupational therapy services furnished as an incident to a physician's professional services (as described in section 1861(s)(2)(A)), that do not meet the standards and conditions (other than any licensing requirement specified by the Secretary) under the second sentence of section 1861(p) (or under such sentence through the operation of subsection (g) or (ll)(2) of section 1861) as such standards and conditions would apply to such therapy services if furnished by a therapist;

(21) where such expenses are for home health services (including medical supplies described in section 1861(m)(5), but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who is under a plan of care of the home health agency if the claim for payment for such services is not submitted by the agency;

(22) subject to subsection (h), for which a claim is submitted other than in an electronic form specified by the Secretary;

(23) which are the technical component of advanced diagnostic imaging services described in section 1834(e)(1)(B) for which payment is made under the fee schedule established under section 1848(b) and that are furnished by a supplier (as defined in section 1861(d)), if such supplier is not accredited by an accreditation organization designated by the Secretary under section 1834(e)(2)(B);

(24) where such expenses are for renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14)) for which payment is made under such section unless such payment is

made under such section to a provider of services or a renal dialysis facility for such services; or

(25) not later than January 1, 2014, for which the payment is other than by electronic funds transfer (EFT) or an electronic remittance in a form as specified in ASC X12 835 Health Care Payment and Remittance Advice or subsequent standard.

Paragraph (7) shall not apply to Federally qualified health center services described in section 1861(aa)(3)(B). In making a national coverage determination (as defined in paragraph (1)(B) of section 1869(f)) the Secretary shall ensure consistent with subsection (l) that the public is afforded notice and opportunity to comment prior to implementation by the Secretary of the determination; meetings of advisory committees with respect to the determination are made on the record; in making the determination, the Secretary has considered applicable information (including clinical experience and medical, technical, and scientific evidence) with respect to the subject matter of the determination; and in the determination, provide a clear statement of the basis for the determination (including responses to comments received from the public), the assumptions underlying that basis, and make available to the public the data (other than proprietary data) considered in making the determination.

(b) MEDICARE AS SECONDARY PAYER.—

(1) REQUIREMENTS OF GROUP HEALTH PLANS.—

(A) WORKING AGED UNDER GROUP HEALTH PLANS.—

(i) IN GENERAL.—A group health plan—

(I) may not take into account that an individual (or the individual's spouse) who is covered under the plan by virtue of the individual's current employment status with an employer is entitled to benefits under this title under section 226(a), and

(II) shall provide that any individual age 65 or older (and the spouse age 65 or older of any individual) who has current employment status with an employer shall be entitled to the same benefits under the plan under the same conditions as any such individual (or spouse) under age 65.

(ii) EXCLUSION OF GROUP HEALTH PLAN OF A SMALL EMPLOYER.—Clause (i) shall not apply to a group health plan unless the plan is a plan of, or contributed to by, an employer that has 20 or more employees for each working day in each of 20 or more calendar weeks in the current calendar year or the preceding calendar year.

(iii) EXCEPTION FOR SMALL EMPLOYERS IN MULTIEMPLOYER OR MULTIPLE EMPLOYER GROUP HEALTH PLANS.—Clause (i) also shall not apply with respect to individuals enrolled in a multiemployer or multiple employer group health plan if the coverage of the individuals under the plan is by virtue of current employment status with an employer that does not have 20 or more individuals in current employment status for each working day in each of 20 or more calendar weeks in the current calendar year and the preceding calendar year; except that the exception provided in

this clause shall only apply if the plan elects treatment under this clause.

(iv) EXCEPTION FOR INDIVIDUALS WITH END STAGE RENAL DISEASE.—Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or (without regard to entitlement under section 226) would upon application be, entitled to benefits under section 226A.

(v) GROUP HEALTH PLAN DEFINED.—In this subparagraph, and subparagraph (C), the term "group health plan" has the meaning given such term in section 5000(b)(1) of the Internal Revenue Code of 1986, without regard to section 5000(d) of such Code

(B) DISABLED INDIVIDUALS IN LARGE GROUP HEALTH PLANS.—

(i) IN GENERAL.—A large group health plan (as defined in clause (iii)) may not take into account that an individual (or a member of the individual's family) who is covered under the plan by virtue of the individual's current employment status with an employer is entitled to benefits under this title under section 226(b).

(ii) EXCEPTION FOR INDIVIDUALS WITH END STAGE RENAL DISEASE.—Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or (without regard to entitlement under section 226) would upon application be, entitled to benefits under section 226A.

(iii) LARGE GROUP HEALTH PLAN DEFINED.—In this subparagraph, the term "large group health plan" has the meaning given such term in section 5000(b)(2) of the Internal Revenue Code of 1986, without regard to section 5000(d) of such Code.

(C) INDIVIDUALS WITH END STAGE RENAL DISEASE.—A group health plan (as defined in subparagraph (A)(v))—

(i) may not take into account that an individual is entitled to or eligible for benefits under this title under section 226A during the 12-month period which begins with the first month in which the individual becomes entitled to benefits under part A under the provisions of section 226A, or, if earlier, the first month in which the individual would have been entitled to benefits under such part under the provisions of section 226A if the individual had filed an application for such benefits; and

(ii) may not differentiate in the benefits it provides between individuals having end stage renal disease and other individuals covered by such plan on the basis of the existence of end stage renal disease, the need for renal dialysis, or in any other manner;

except that clause (ii) shall not prohibit a plan from paying benefits secondary to this title when an individual is entitled to or eligible for benefits under this title under section

226A after the end of the 12-month period described in clause (i). Effective for items and services furnished on or after February 1, 1991, and before the date of enactment of the Balanced Budget Act of 1997 (with respect to periods beginning on or after February 1, 1990), this subparagraph shall be applied by substituting "18- month" for "12-month" each place it appears. Effective for items and services furnished on or after the date of enactment of the Balanced Budget Act of 1997, (with respect to periods beginning on or after the date that is 18 months prior to such date), clauses (i) and (ii) shall be applied by substituting "30-month" for "12-month" each place it appears.

(D) TREATMENT OF CERTAIN MEMBERS OF RELIGIOUS ORDERS.—In this subsection, an individual shall not be considered to be employed, or an employee, with respect to the performance of services as a member of a religious order which are considered employment only by virtue of an election made by the religious order under section 3121(r) of the Internal Revenue Code of 1986.

(E) GENERAL PROVISIONS.—For purposes of this subsection:

(i) AGGREGATION RULES.—

(I) All employers treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as a single employer.

(II) All employees of the members of an affiliated service group (as defined in section 414(m) of such Code) shall be treated as employed by a single employer.

(III) Leased employees (as defined in section 414(n)(2) of such Code) shall be treated as employees of the person for whom they perform services to the extent they are so treated under section 414(n) of such Code.

In applying sections of the Internal Revenue Code of 1986 under this clause, the Secretary shall rely upon regulations and decisions of the Secretary of the Treasury respecting such sections.

(ii) CURRENT EMPLOYMENT STATUS DEFINED.—An individual has "current employment status" with an employer if the individual is an employee, is the employer, or is associated with the employer in a business relationship.

(iii) TREATMENT OF SELF-EMPLOYED PERSONS AS EMPLOYERS.—The term "employer" includes a self-employed person.

(F) LIMITATION ON BENEFICIARY LIABILITY.—An individual who is entitled to benefits under this title and is furnished an item or service for which such benefits are incorrectly paid is not liable for repayment of such benefits under this paragraph unless payment of such benefits was made to the individual.

(2) MEDICARE SECONDARY PAYER.—

(A) IN GENERAL.—Payment under this title may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that—

(i) payment has been made, or can reasonably be expected to be made, with respect to the item or service as required under paragraph (1), or

(ii) payment has been made or can reasonably be expected to be made under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance.

In the subsection, the term "primary plan" means a group health plan or large group health plan, to the extent that clause (i) applies, and a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance, to the extent that clause (ii) applies. An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.

(B) CONDITIONAL PAYMENT.—

(i) AUTHORITY TO MAKE CONDITIONAL PAYMENT.—The Secretary may make payment under this title with respect to an item or service if a primary plan described in subparagraph (A)(ii) has not made or cannot reasonably be expected to make payment with respect to such item or service promptly (as determined in accordance with regulations). Any such payment by the Secretary shall be conditioned on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.

(ii) REPAYMENT REQUIRED.—Subject to paragraph (9), a primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this title with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means. If reimbursement is not made to the appropriate Trust Fund before the expiration of the 60-day period that begins on the date notice of, or information related to, a primary plan's responsibility for such payment or other information is received, the Secretary may charge interest (beginning with the date on which the notice or other information is received) on the amount of the reimbursement until reimburse-

ment is made (at a rate determined by the Secretary in accordance with regulations of the Secretary of the Treasury applicable to charges for late payments).

(iii) ACTION BY UNITED STATES.—In order to recover payment made under this title for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity. The United States may not recover from a third-party administrator under this clause in cases where the third-party administrator would not be able to recover the amount at issue from the employer or group health plan and is not employed by or under contract with the employer or group health plan at the time the action for recovery is initiated by the United States or for whom it provides administrative services due to the insolvency or bankruptcy of the employer or plan. An action may not be brought by the United States under this clause with respect to payment owed unless the complaint is filed not later than 3 years after the date of the receipt of notice of a settlement, judgment, award, or other payment made pursuant to paragraph (8) relating to such payment owed.

(iv) SUBROGATION RIGHTS.—The United States shall be subrogated (to the extent of payment made under this title for such an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan.

(v) WAIVER OF RIGHTS.—The Secretary may waive (in whole or in part) the provisions of this subparagraph in the case of an individual claim if the Secretary determines that the waiver is in the best interests of the program established under this title.

(vi) CLAIMS-FILING PERIOD.—Notwithstanding any other time limits that may exist for filing a claim under an employer group health plan, the United States may seek to recover conditional payments in accordance with this subparagraph where the request for payment is submitted to the entity required or responsible under this subsection to pay with respect to the item or service (or any portion thereof) under a primary plan within the 3-year period beginning on the date on which the item or service was furnished.

(vii) USE OF WEBSITE TO DETERMINE FINAL CONDITIONAL REIMBURSEMENT AMOUNT.—

(I) NOTICE TO SECRETARY OF EXPECTED DATE OF A SETTLEMENT, JUDGMENT, ETC.—In the case of a payment made by the Secretary pursuant to clause (i) for items and services provided to the claimant, the claimant or applicable plan (as defined in paragraph (8)(F)) may at any time beginning 120 days before the reasonably expected date of a settlement, judgment, award, or other payment, notify the Secretary that a payment is reasonably expected and the expected date of such payment.

(II) SECRETARIAL PROVIDING ACCESS TO CLAIMS INFORMATION THROUGH A WEBSITE.—The Secretary shall maintain and make available to individuals to whom items and services are furnished under this title (and to authorized family or other representatives recognized under regulations and to an applicable plan which has obtained the consent of the individual) access to information on the claims for such items and services (including payment amounts for such claims), including those claims that relate to a potential settlement, judgment, award, or other payment. Such access shall be provided to an individual, representative, or plan through a website that requires a password to gain access to the information. The Secretary shall update the information on claims and payments on such website in as timely a manner as possible but not later than 15 days after the date that payment is made. Information related to claims and payments subject to the notice under subclause (I) shall be maintained and made available consistent with the following:

(aa) The information shall be as complete as possible and shall include provider or supplier name, diagnosis codes (if any), dates of service, and conditional payment amounts.

(bb) The information accurately identifies those claims and payments that are related to a potential settlement, judgment, award, or other payment to which the provisions of this subsection apply.

(cc) The website provides a method for the receipt of secure electronic communications with the individual, representative, or plan involved.

(dd) The website provides that information is transmitted from the website in a form that includes an official time and date that the information is transmitted.

(ee) The website shall permit the individual, representative, or plan to download a statement of reimbursement amounts (in this

clause referred to as a "statement of reimbursement amount") on payments for claims under this title relating to a potential settlement, judgment, award, or other payment.

(III) USE OF TIMELY WEB DOWNLOAD AS BASIS FOR FINAL CONDITIONAL AMOUNT.—If an individual (or other claimant or applicable plan with the consent of the individual) obtains a statement of reimbursement amount from the website during the protected period as defined in subclause (V) and the related settlement, judgment, award or other payment is made during such period, then the last statement of reimbursement amount that is downloaded during such period and within 3 business days before the date of the settlement, judgment, award, or other payment shall constitute the final conditional amount subject to recovery under clause (ii) related to such settlement, judgment, award, or other payment.

(IV) RESOLUTION OF DISCREPANCIES.—If the individual (or authorized representative) believes there is a discrepancy with the statement of reimbursement amount, the Secretary shall provide a timely process to resolve the discrepancy. Under such process the individual (or representative) must provide documentation explaining the discrepancy and a proposal to resolve such discrepancy. Within 11 business days after the date of receipt of such documentation, the Secretary shall determine whether there is a reasonable basis to include or remove claims on the statement of reimbursement. If the Secretary does not make such determination within the 11 business-day period, then the proposal to resolve the discrepancy shall be accepted. If the Secretary determines within such period that there is not a reasonable basis to include or remove claims on the statement of reimbursement, the proposal shall be rejected. If the Secretary determines within such period that there is a reasonable basis to conclude there is a discrepancy, the Secretary must respond in a timely manner by agreeing to the proposal to resolve the discrepancy or by providing documentation showing with good cause why the Secretary is not agreeing to such proposal and establishing an alternate discrepancy resolution. In no case shall the process under this subclause be treated as an appeals process or as establishing a right of appeal for a statement of reimbursement amount and there shall be no administrative or judicial review of the Secretary's determinations under this subclause.

(V) PROTECTED PERIOD.—In subclause (III), the term "protected period" means, with respect to a settlement, judgment, award or other payment re-

lating to an injury or incident, the portion (if any) of the period beginning on the date of notice under subclause (I) with respect to such settlement, judgment, award, or other payment that is after the end of a Secretarial response period beginning on the date of such notice to the Secretary. Such Secretarial response period shall be a period of 65 days, except that such period may be extended by the Secretary for a period of an additional 30 days if the Secretary determines that additional time is required to address claims for which payment has been made. Such Secretarial response period shall be extended and shall not include any days for any part of which the Secretary determines (in accordance with regulations) that there was a failure in the claims and payment posting system and the failure was justified due to exceptional circumstances (as defined in such regulations). Such regulations shall define exceptional circumstances in a manner so that not more than 1 percent of the repayment obligations under this subclause would qualify as exceptional circumstances.

(VI) EFFECTIVE DATE.—The Secretary shall promulgate final regulations to carry out this clause not later than 9 months after the date of the enactment of this clause.

(VII) WEBSITE INCLUDING SUCCESSOR TECHNOLOGY.—In this clause, the term "website" includes any successor technology.

(viii) RIGHT OF APPEAL FOR SECONDARY PAYER DETERMINATIONS RELATING TO LIABILITY INSURANCE (INCLUDING SELF-INSURANCE), NO FAULT INSURANCE, AND WORKERS' COMPENSATION LAWS AND PLANS.—The Secretary shall promulgate regulations establishing a right of appeal and appeals process, with respect to any determination under this subsection for a payment made under this title for an item or service for which the Secretary is seeking to recover conditional payments from an applicable plan (as defined in paragraph (8)(F)) that is a primary plan under subsection (A)(ii), under which the applicable plan involved, or an attorney, agent, or third party administrator on behalf of such plan, may appeal such determination. The individual furnished such an item or service shall be notified of the plan's intent to appeal such determination

(C) TREATMENT OF QUESTIONNAIRES.—The Secretary may not fail to make payment under subparagraph (A) solely on the ground that an individual failed to complete a questionnaire concerning the existence of a primary plan.

(3) ENFORCEMENT.—

(A) PRIVATE CAUSE OF ACTION.—There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary pay-

ment (or appropriate reimbursement) in accordance with paragraphs (1) and (2)(A).

(B) REFERENCE TO EXCISE TAX WITH RESPECT TO NONCONFORMING GROUP HEALTH PLANS.—For provision imposing an excise tax with respect to nonconforming group health plans, see section 5000 of the Internal Revenue Code of 1986.

(C) PROHIBITION OF FINANCIAL INCENTIVES NOT TO ENROLL IN A GROUP HEALTH PLAN OR A LARGE GROUP HEALTH PLAN.—It is unlawful for an employer or other entity to offer any financial or other incentive for an individual entitled to benefits under this title not to enroll (or to terminate enrollment) under a group health plan or a large group health plan which would (in the case of such enrollment) be a primary plan (as defined in paragraph (2)(A)). Any entity that violates the previous sentence is subject to a civil money penalty of not to exceed $5,000 for each such violation. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(4) COORDINATION OF BENEFITS.—Where payment for an item or service by a primary plan is less than the amount of the charge for such item or service and is not payment in full, payment may be made under this title (without regard to deductibles and coinsurance under this title) for the remainder of such charge, but—

(A) payment under this title may not exceed an amount which would be payable under this title for such item or service if paragraph (2)(A) did not apply; and

(B) payment under this title, when combined with the amount payable under the primary plan, may not exceed—

(i) in the case of an item or service payment for which is determined under this title on the basis of reasonable cost (or other cost-related basis) or under section 1886, the amount which would be payable under this title on such basis, and

(ii) in the case of an item or service for which payment is authorized under this title on another basis—

(I) the amount which would be payable under the primary plan (without regard to deductibles and coinsurance under such plan), or

(II) the reasonable charge or other amount which would be payable under this title (without regard to deductibles and coinsurance under this title),

whichever is greater.

(5) IDENTIFICATION OF SECONDARY PAYER SITUATIONS.—

(A) REQUESTING MATCHING INFORMATION.—

(i) COMMISSIONER OF SOCIAL SECURITY.—The Commissioner of Social Security shall, not less often that annually, transmit to the Secretary of the Treasury a list of the names and TINs of medicare beneficiaries (as defined in section 6103(l)(12) of the Internal Rev-

enue Code of 1986) and request that the Secretary disclose to the Commissioner the information described in subparagraph (A) of such section.

(ii) ADMINISTRATOR.—The Administrator of the Centers for Medicare & Medicaid Services shall request, not less often than annually, the Commissioner of the Social Security Administration to disclose to the Administrator the information described in subparagraph (B) of section 6103(l)(12) of the Internal Revenue Code of 1986.

(B) DISCLOSURE TO FISCAL INTERMEDIARIES AND CARRIERS.—In addition to any other information provided under this title to fiscal intermediaries and carriers, the Administrator shall disclose to such intermediaries and carriers (or to such a single intermediary or carrier as the Secretary may designate) the information received under subparagraph (A) for purposes of carrying out this subsection.

(C) CONTACTING EMPLOYERS.—

(i) IN GENERAL.—With respect to each individual (in this subparagraph referred to as an "employee") who was furnished a written statement under section 6051 of the Internal Revenue Code of 1986 by a qualified employer (as defined in section 6103(l)(12)(E)(iii) of such Code), as disclosed under subparagraph (B), the appropriate fiscal intermediary or carrier shall contact the employer in order to determine during what period the employee or employee's spouse may be (or have been) covered under a group health plan of the employer and the nature of the coverage that is or was provided under the plan (including the name, address, and identifying number of the plan).

(ii) EMPLOYER RESPONSE.—Within 30 days of the date of receipt of the inquiry, the employer shall notify the intermediary or carrier making the inquiry as to the determinations described in clause (i). An employer (other than a Federal or other governmental entity) who willfully or repeatedly fails to provide timely and accurate notice in accordance with the previous sentence shall be subject to a civil money penalty of not to exceed $1,000 for each individual with respect to which such an inquiry is made. The provision of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(D) OBTAINING INFORMATION FROM BENEFICIARIES.—Before an individual applies for benefits under part A or enrolls under part B, the Administrator shall mail the individual a questionnaire to obtain information on whether the individual is covered under a primary plan and the nature of the coverage provided under the plan, including the name, address, and identifying number of the plan.

(E) END DATE.—The provisions of this paragraph shall not apply to information required to be provided on or after July 1, 2016.

(6) SCREENING REQUIREMENTS FOR PROVIDERS AND SUPPLIERS.—

(A) IN GENERAL.—Notwithstanding any other provision of this title, no payment may be made for any item or service furnished under part B unless the entity furnishing such item or service completes (to the best of its knowledge and on the basis of information obtained from the individual to whom the item or service is furnished) the portion of the claim form relating to the availability of other health benefit plans.

(B) PENALTIES.—An entity that knowingly, willfully, and repeatedly fails to complete a claim form in accordance with subparagraph (A) or provides inaccurate information relating to the availability of other health benefit plans on a claim form under such subparagraph shall be subject to a civil money penalty of not to exceed $2,000 for each such incident. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(7) REQUIRED SUBMISSION OF INFORMATION BY GROUP HEALTH PLANS.—

(A) REQUIREMENT.—On and after the first day of the first calendar quarter beginning after the date that is 1 year after the date of the enactment of this paragraph, an entity serving as an insurer or third party administrator for a group health plan, as defined in paragraph (1)(A)(v), and, in the case of a group health plan that is self-insured and self-administered, a plan administrator or fiduciary, shall—

(i) secure from the plan sponsor and plan participants such information as the Secretary shall specify for the purpose of identifying situations where the group health plan is or has been a primary plan to the program under this title; and

(ii) submit such information to the Secretary in a form and manner (including frequency) specified by the Secretary.

(B) ENFORCEMENT.—

(i) IN GENERAL.—An entity, a plan administrator, or a fiduciary described in subparagraph (A) that fails to comply with the requirements under such subparagraph shall be subject to a civil money penalty of $1,000 for each day of noncompliance for each individual for which the information under such subparagraph should have been submitted. The provisions of subsections (e) and (k) of section 1128A shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). A civil money penalty under this clause shall be in addition

to any other penalties prescribed by law and in addition to any Medicare secondary payer claim under this title with respect to an individual.

(ii) DEPOSIT OF AMOUNTS COLLECTED.—Any amounts collected pursuant to clause (i) shall be deposited in the Federal Hospital Insurance Trust Fund under section 1817.

(C) SHARING OF INFORMATION.—Notwithstanding any other provision of law, under terms and conditions established by the Secretary, the Secretary—

(i) shall share information on entitlement under Part A and enrollment under Part B under this title with entities, plan administrators, and fiduciaries described in subparagraph (A);

(ii) may share the entitlement and enrollment information described in clause (i) with entities and persons not described in such clause; and

(iii) may share information collected under this paragraph as necessary for purposes of the proper coordination of benefits.

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

(8) REQUIRED SUBMISSION OF INFORMATION BY OR ON BEHALF OF LIABILITY INSURANCE (INCLUDING SELF-INSURANCE), NO FAULT INSURANCE, AND WORKERS' COMPENSATION LAWS AND PLANS.—

(A) REQUIREMENT.—On and after the first day of the first calendar quarter beginning after the date that is 18 months after the date of the enactment of this paragraph, an applicable plan shall—

(i) determine whether a claimant (including an individual whose claim is unresolved) is entitled to benefits under the program under this title on any basis; and

(ii) if the claimant is determined to be so entitled, submit the information described in subparagraph (B) with respect to the claimant to the Secretary in a form and manner (including frequency) specified by the Secretary.

(B) REQUIRED INFORMATION.—The information described in this subparagraph is—

(i) the identity of the claimant for which the determination under subparagraph (A) was made; and

(ii) such other information as the Secretary shall specify in order to enable the Secretary to make an appropriate determination concerning coordination of benefits, including any applicable recovery claim.

Not later than 18 months after the date of enactment of this sentence, the Secretary shall modify the reporting requirements under this paragraph so that an applicable plan in complying with such requirements is permitted but not required to access or report to the Secretary beneficiary social security account numbers or health identification claim numbers, except that the deadline for such

modification shall be extended by one or more periods (specified by the Secretary) of up to 1 year each if the Secretary notifies the committees of jurisdiction of the House of Representatives and of the Senate that the prior deadline for such modification, without such extension, threatens patient privacy or the integrity of the secondary payer program under this subsection. Any such deadline extension notice shall include information on the progress being made in implementing such modification and the anticipated implementation date for such modification.

(C) TIMING.—Information shall be submitted under subparagraph (A)(ii) within a time specified by the Secretary after the claim is resolved through a settlement, judgment, award, or other payment (regardless of whether or not there is a determination or admission of liability).

(D) CLAIMANT.—For purposes of subparagraph (A), the term "claimant" includes—

(i) an individual filing a claim directly against the applicable plan; and

(ii) an individual filing a claim against an individual or entity insured or covered by the applicable plan.

(E) ENFORCEMENT.—

(i) IN GENERAL.—An applicable plan that fails to comply with the requirements under subparagraph (A) with respect to any claimant may be subject to a civil money penalty of up to $1,000 for each day of noncompliance with respect to each claimant. The provisions of subsections (e) and (k) of section 1128A shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). A civil money penalty under this clause shall be in addition to any other penalties prescribed by law and in addition to any Medicare secondary payer claim under this title with respect to an individual.

(ii) DEPOSIT OF AMOUNTS COLLECTED.—Any amounts collected pursuant to clause (i) shall be deposited in the Federal Hospital Insurance Trust Fund.

(F) APPLICABLE PLAN.—In this paragraph, the term "applicable plan" means the following laws, plans, or other arrangements, including the fiduciary or administrator for such law, plan, or arrangement:

(i) Liability insurance (including self-insurance).

(ii) No fault insurance.

(iii) Workers' compensation laws or plans.

(G) SHARING OF INFORMATION.—The Secretary may share information collected under this paragraph as necessary for purposes of the proper coordination of benefits.

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

(I) REGULATIONS.—Not later than 60 days after the date of the enactment of this subparagraph, the Secretary shall publish a notice in the Federal Register soliciting proposals, which will be accepted during a 60-day period, for

the specification of practices for which sanctions will and will not be imposed under subparagraph (E), including not imposing sanctions for good faith efforts to identify a beneficiary pursuant to this paragraph under an applicable entity responsible for reporting information. After considering the proposals so submitted, the Secretary, in consultation with the Attorney General, shall publish in the Federal Register, including a 60-day period for comment, proposed specified practices for which such sanctions will and will not be imposed. After considering any public comments received during such period, the Secretary shall issue final rules specifying such practices.

(9) EXCEPTION.—

(A) IN GENERAL.—Clause (ii) of paragraph (2)(B) and any reporting required by paragraph (8) shall not apply with respect to any settlement, judgment, award, or other payment by an applicable plan arising from liability insurance (including self-insurance) and from alleged physical trauma-based incidents (excluding alleged ingestion, implantation, or exposure cases) constituting a total payment obligation to a claimant of not more than the single threshold amount calculated by the Secretary under subparagraph (B) for the year involved.

(B) ANNUAL COMPUTATION OF THRESHOLD.—

(i) IN GENERAL.—Not later than November 15 before each year, the Secretary shall calculate and publish a single threshold amount for settlements, judgments, awards, or other payments for obligations arising from liability insurance (including self-insurance) and for alleged physical trauma-based incidents (excluding alleged ingestion, implantation, or exposure cases) subject to this section for that year. The annual single threshold amount for a year shall be set such that the estimated average amount to be credited to the Medicare trust funds of collections of conditional payments from such settlements, judgments, awards, or other payments arising from liability insurance (including self-insurance) and for such alleged incidents subject to this section shall equal the estimated cost of collection incurred by the United States (including payments made to contractors) for a conditional payment arising from liability insurance (including self-insurance) and for such alleged incidents subject to this section for the year. At the time of calculating, but before publishing, the single threshold amount for 2014, the Secretary shall inform, and seek review of, the Comptroller General of the United States with regard to such amount.

(ii) PUBLICATION.—The Secretary shall include, as part of such publication for a year—

(I) the estimated cost of collection incurred by the United States (including payments made to contractors) for a conditional payment arising from liability insurance (including self-insurance) and for such alleged incidents; and

(II) a summary of the methodology and data used by the Secretary in computing such threshold amount and such cost of collection.

(C) EXCLUSION OF ONGOING EXPENSES.—For purposes of this paragraph and with respect to a settlement, judgment, award, or other payment not otherwise addressed in clause (ii) of paragraph (2)(B) that includes ongoing responsibility for medical payments (excluding settlements, judgments, awards, or other payments made by a workers' compensation law or plan or no fault insurance), the amount utilized for calculation of the threshold described in subparagraph (A) shall include only the cumulative value of the medical payments made under this title.

(D) REPORT TO CONGRESS.—Not later than November 15 before each year, the Secretary shall submit to the Congress a report on the single threshold amount for settlements, judgments, awards, or other payments for conditional payment obligations arising from liability insurance (including self-insurance) and alleged incidents described in subparagraph (A) for that year and on the establishment and application of similar thresholds for such payments for conditional payment obligations arising from worker compensation cases and from no fault insurance cases subject to this section for the year. For each such report, the Secretary shall—

(i) calculate the threshold amount by using the methodology applicable to certain liability claims described in subparagraph (B); and

(ii) include a summary of the methodology and data used in calculating each threshold amount and the amount of estimated savings under this title achieved by the Secretary implementing each such threshold.

(c) No payment may be made under part B for any expenses incurred for—

(1) a drug product—

(A) which is described in section 107(c)(3) of the Drug Amendments of 1962,

(B) which may be dispensed only upon prescription,

(C) for which the Secretary has issued a notice of an opportunity for a hearing under subsection (e) of section 505 of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug product under such section because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling, and

(D) for which the Secretary has not determined there is a compelling justification for its medical need; and

(2) any other drug product—

(A) which is identical, related, or similar (as determined in accordance with section 310.6 of title 21 of the Code of Federal Regulations) to a drug product described in paragraph (1), and

(B) for which the Secretary has not determined there is a compelling justification for its medical need,

until such time as the Secretary withdraws such proposed order.

(d) For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1867 to an individual who is entitled to benefits under this title, determinations as to whether the item or service is reasonable and necessary shall be made on the basis of the information available to the treating physician or practitioner (including the patient's presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not on the patient's principal diagnosis). When making such determinations with respect to such an item or service, the Secretary shall not consider the frequency with which the item or service was provided to the patient before or after the time of the admission or visit.

(e)(1) No payment may be made under this title with respect to any item or service (other than an emergency item or service, not including items or services furnished in an emergency room of a hospital) furnished—

(A) by an individual or entity during the period when such individual or entity is excluded pursuant to section 1128, 1128A, 1156 or 1842(j)(2) from participation in the program under this title; or

(B) at the medical direction or on the prescription of a physician during the period when he is excluded pursuant to section 1128, 1128A, 1156 or 1842(j)(2) from participation in the program under this title and when the person furnishing such item or service knew or had reason to know of the exclusion (after a reasonable time period after reasonable notice has been furnished to the person).

(2) Where an individual eligible for benefits under this title submits a claim for payment for items or services furnished by an individual or entity excluded from participation in the programs under this title, pursuant to section 1128, 1128A, 1156, 1160 (as in effect on September 2, 1982), 1842(j)(2), 1862(d) (as in effect on the date of the enactment of the Medicare and Medicaid Patient and Program Protection Act of 1987), or l866, and such beneficiary did not know or have reason to know that such individual or entity was so excluded, then, to the extent permitted by this title, and notwithstanding such exclusion, payment shall be made for such items or services. In each such case the Secretary shall notify the beneficiary of the exclusion of the individual or entity furnishing the items or services. Payment shall not be made for items or services furnished by an excluded individual or entity to a beneficiary after a reasonable time (as determined by the Secretary in regulations) after the Secretary has notified the beneficiary of the exclusion of that individual or entity.

(f) The Secretary shall establish utilization guidelines for the determination of whether or not payment may be made, consistent with paragraph (1)(A) of subsection (a), under part A or part B for expenses incurred with respect to the provision of home health services, and shall provide for the implementation of such guidelines through a process of selective postpayment coverage review by intermediaries or otherwise.

(g) The Secretary shall, in making the determinations under paragraphs (1) and (9) of subsection (a), and for the purposes of

promoting the effective, efficient, and economical delivery of health care services, and of promoting the quality of services of the type for which payment may be made under this title, enter into contracts with quality improvement organizations pursuant to part B of title XI of this Act.

(h)(1) The Secretary—

(A) shall waive the application of subsection (a)(22) in cases in which—

(i) there is no method available for the submission of claims in an electronic form; or

(ii) the entity submitting the claim is a small provider of services or supplier; and

(B) may waive the application of such subsection in such unusual cases as the Secretary finds appropriate.

(2) For purposes of this subsection, the term "small provider of services or supplier" means—

(A) a provider of services with fewer than 25 full-time equivalent employees; or

(B) a physician, practitioner, facility, or supplier (other than provider of services) with fewer than 10 full-time equivalent employees.

(i) In order to supplement the activities of the Medicare Payment Advisory Commission under section 1886(e) in assessing the safety, efficacy, and cost-effectiveness of new and existing medical procedures, the Secretary may carry out, or award grants or contracts for, original research and experimentation of the type described in clause (ii) of section 1886(e)(6)(E) with respect to such a procedure if the Secretary finds that—

(1) such procedure is not of sufficient commercial value to justify research and experimentation by a commercial organization;

(2) research and experimentation with respect to such procedure is not of a type that may appropriately be carried out by an institute, division, or bureau of the National Institutes of Health; and

(3) such procedure has the potential to be more cost-effective in the treatment of a condition than procedures currently in use with respect to such condition.

(j)(1) Any advisory committee appointed to advise the Secretary on matters relating to the interpretation, application, or implementation of subsection (a)(1) shall assure the full participation of a nonvoting member in the deliberations of the advisory committee, and shall provide such nonvoting member access to all information and data made available to voting members of the advisory committee, other than information that—

(A) is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section (relating to trade secrets); or

(B) the Secretary determines would present a conflict of interest relating to such nonvoting member.

(2) If an advisory committee described in paragraph (1) organizes into panels of experts according to types of items or services considered by the advisory committee, any such panel of experts may report any recommendation with respect to such items or services di-

rectly to the Secretary without the prior approval of the advisory committee or an executive committee thereof.

(k)(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)) providing supplemental or secondary coverage to individuals also entitled to services under this title shall not require a medicare claims determination under this title for dental benefits specifically excluded under subsection (a)(12) as a condition of making a claims determination for such benefits under the group health plan.

(2) A group health plan may require a claims determination under this title in cases involving or appearing to involve inpatient dental hospital services or dental services expressly covered under this title pursuant to actions taken by the Secretary.

(l) NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS.—

(1) FACTORS AND EVIDENCE USED IN MAKING NATIONAL COVERAGE DETERMINATIONS.—The Secretary shall make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary shall develop guidance documents to carry out this paragraph in a manner similar to the development of guidance documents under section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)).

(2) TIMEFRAME FOR DECISIONS ON REQUESTS FOR NATIONAL COVERAGE DETERMINATIONS.—In the case of a request for a national coverage determination that—

(A) does not require a technology assessment from an outside entity or deliberation from the Medicare Coverage Advisory Committee, the decision on the request shall be made not later than 6 months after the date of the request; or

(B) requires such an assessment or deliberation and in which a clinical trial is not requested, the decision on the request shall be made not later than 9 months after the date of the request.

(3) PROCESS FOR PUBLIC COMMENT IN NATIONAL COVERAGE DETERMINATIONS.—

(A) PERIOD FOR PROPOSED DECISION.—Not later than the end of the 6-month period (or 9-month period for requests described in paragraph (2)(B)) that begins on the date a request for a national coverage determination is made, the Secretary shall make a draft of proposed decision on the request available to the public through the Internet website of the Centers for Medicare & Medicaid Services or other appropriate means.

(B) 30-DAY PERIOD FOR PUBLIC COMMENT.—Beginning on the date the Secretary makes a draft of the proposed decision available under subparagraph (A), the Secretary shall provide a 30-day period for public comment on such draft.

(C) 60-DAY PERIOD FOR FINAL DECISION.—Not later than 60 days after the conclusion of the 30-day period referred to under subparagraph (B), the Secretary shall—

(i) make a final decision on the request;

(ii) include in such final decision summaries of the public comments received and responses to such comments;

(iii) make available to the public the clinical evidence and other data used in making such a decision when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and

(iv) in the case of a final decision under clause (i) to grant the request for the national coverage determination, the Secretary shall assign a temporary or permanent code (whether existing or unclassified) and implement the coding change.

(4) CONSULTATION WITH OUTSIDE EXPERTS IN CERTAIN NATIONAL COVERAGE DETERMINATIONS.—With respect to a request for a national coverage determination for which there is not a review by the Medicare Coverage Advisory Committee, the Secretary shall consult with appropriate outside clinical experts.

(5) LOCAL COVERAGE DETERMINATION PROCESS.—

(A) PLAN TO PROMOTE CONSISTENCY OF COVERAGE DETERMINATIONS.—The Secretary shall develop a plan to evaluate new local coverage determinations to determine which determinations should be adopted nationally and to what extent greater consistency can be achieved among local coverage determinations.

(B) CONSULTATION.—The Secretary shall require the fiscal intermediaries or carriers providing services within the same area to consult on all new local coverage determinations within the area.

(C) DISSEMINATION OF INFORMATION.—The Secretary should serve as a center to disseminate information on local coverage determinations among fiscal intermediaries and carriers to reduce duplication of effort.

(D) LOCAL COVERAGE DETERMINATIONS.—The Secretary shall require each medicare administrative contractor that develops a local coverage determination to make available on the website of such contractor and in the coverage database on the Medicare website, at least 45 days before the effective date of such determination, the following information:

(i) Such determination in its entirety.

(ii) Where and when the proposed determination was first made public.

(iii) Hyperlinks to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.

(iv) A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence.

(v) An explanation of the rationale that supports such determination.

(6) NATIONAL AND LOCAL COVERAGE DETERMINATION DEFINED.—For purposes of this subsection—

(A) NATIONAL COVERAGE DETERMINATION.—The term "national coverage determination" means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title.

(B) LOCAL COVERAGE DETERMINATION.—The term "local coverage determination" has the meaning given that in section 1869(f)(2)(B).

(m) COVERAGE OF ROUTINE COSTS ASSOCIATED WITH CERTAIN CLINICAL TRIALS OF CATEGORY A DEVICES.—

(1) IN GENERAL.—In the case of an individual entitled to benefits under part A, or enrolled under part B, or both who participates in a category A clinical trial, the Secretary shall not exclude under subsection (a)(1) payment for coverage of routine costs of care (as defined by the Secretary) furnished to such individual in the trial.

(2) CATEGORY A CLINICAL TRIAL.—For purposes of paragraph (1), a "category A clinical trial" means a trial of a medical device if—

(A) the trial is of an experimental/investigational (category A) medical device (as defined in regulations under section 405.201(b) of title 42, Code of Federal Regulations (as in effect as of September 1, 2003));

(B) the trial meets criteria established by the Secretary to ensure that the trial conforms to appropriate scientific and ethical standards; and

(C) in the case of a trial initiated before January 1, 2010, the device involved in the trial has been determined by the Secretary to be intended for use in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition.

(n) REQUIREMENT OF A SURETY BOND FOR CERTAIN PROVIDERS OF SERVICES AND SUPPLIERS.—

(1) IN GENERAL.—The Secretary may require a provider of services or supplier described in paragraph (2) to provide the Secretary on a continuing basis with a surety bond in a form specified by the Secretary in an amount (not less than $50,000) that the Secretary determines is commensurate with the volume of the billing of the provider of services or supplier. The Secretary may waive the requirement of a bond under the preceding sentence in the case of a provider of services or supplier that provides a comparable surety bond under State law.

(2) PROVIDER OF SERVICES OR SUPPLIER DESCRIBED.—A provider of services or supplier described in this paragraph is a provider of services or supplier the Secretary determines appropriate based on the level of risk involved with respect to the provider of services or supplier, and consistent with the surety bond requirements under sections 1834(a)(16)(B) and 1861(o)(7)(C).

(o) SUSPENSION OF PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD.—

(1) IN GENERAL.—The Secretary may suspend payments to a provider of services or supplier under this title pending an investigation of a credible allegation of fraud against the provider of services or supplier, unless the Secretary determines there is good cause not to suspend such payments.

(2) CONSULTATION.—The Secretary shall consult with the Inspector General of the Department of Health and Human Services in determining whether there is a credible allegation of fraud against a provider of services or supplier.

(3) PROMULGATION OF REGULATIONS.—The Secretary shall promulgate regulations to carry out this subsection and section 1903(i)(2)(C).

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PAYMENT TO HOSPITALS FOR INPATIENT HOSPITAL SERVICES

SEC. 1886. (a)(1)(A)(i) The Secretary, in determining the amount of the payments that may be made under this title with respect to operating costs of inpatient hospital services (as defined in paragraph (4)) shall not recognize as reasonable (in the efficient delivery of health services) costs for the provision of such services by a hospital for a cost reporting period to the extent such costs exceed the applicable percentage (as determined under clause (ii)) of the average of such costs for all hospitals in the same grouping as such hospital for comparable time periods.

(ii) For purposes of clause (i), the applicable percentage for hospital cost reporting periods beginning—

(I) on or after October 1, 1982, and before October 1, 1983, is 120 percent;

(II) on or after October 1, 1983, and before October 1, 1984, is 115 percent; and

(III) on or after October 1, 1984, is 110 percent.

(B)(i) For purposes of subparagraph (A) the Secretary shall establish case mix indexes for all short- term hospitals, and shall set limits for each hospital based upon the general mix of types of medical cases with respect to which such hospital provides services for which payment may be made under this title.

(ii) The Secretary shall set such limits for a cost reporting period of a hospital—

(I) by updating available data for a previous period to the immediate preceding cost reporting period by the estimated average rate of change of hospital costs industry-wide, and

(II) by projecting for the cost reporting period by the applicable percentage increase (as defined in subsection (b)(3)(B)).

(C) The limitation established under subparagraph (A) for any hospital shall in no event be lower than the allowable operating costs of inpatient hospital services (as defined in paragraph (4)) recognized under this title for such hospital for such hospital's last cost reporting period prior to the hospital's first cost reporting period for which this section is in effect.

(D) Subparagraph (A) shall not apply to cost reporting periods beginning on or after October 1, 1983.

(2) The Secretary shall provide for such exemptions from, and exceptions and adjustments to, the limitation established under paragraph (1)(A) as he deems appropriate, including those which he deems necessary to take into account—

(A) the special needs of sole community hospitals, of new hospitals, of risk based health maintenance organizations, and of hospitals which provide atypical services or essential community services, and to take into account extraordinary circumstances beyond the hospital's control, medical and paramedical education costs, significantly fluctuating population in the service area of the hospital, and unusual labor costs,

(B) the special needs of psychiatric hospitals and of public or other hospitals that serve a significantly disproportionate number of patients who have low income or are entitled to benefits under part A of this title, and

(C) a decrease in the inpatient hospital services that a hospital provides and that are customarily provided directly by similar hospitals which results in a significant distortion in the operating costs of inpatient hospital services.

(3) The limitation established under paragraph (1)(A) shall not apply with respect to any hospital which—

(A) is located outside of a standard metropolitan statistical area, and

(B)(i) has less than 50 beds, and

(ii) was in operation and had less than 50 beds on the date of the enactment of this section.

(4) For purposes of this section, the term "operating costs of inpatient hospital services" includes all routine operating costs, ancillary service operating costs, and special care unit operating costs with respect to inpatient hospital services as such costs are determined on an average per admission or per discharge basis (as determined by the Secretary), and includes the costs of all services for which payment may be made under this title that are provided by the hospital (or by an entity wholly owned or operated by the hospital) to the patient during the 3 days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1 day) immediately preceding the date of the patient's admission if such services are diagnostic services (including clinical diagnostic laboratory tests) or are other services related to the admission (as defined by the Secretary). Such term does not include costs of approved educational activities, a return on equity capital, or, other capital-related costs (as defined by the Secretary for periods before October 1, 1987). In applying the first sentence of this paragraph, the term "other services related to the admission" includes all services that are not diagnostic services (other than ambulance and maintenance renal dialysis services) for which payment may be made under this title that are provided by a hospital (or an entity wholly owned or operated by the hospital) to a patient—

(A) on the date of the patient's inpatient admission; or

(B) during the 3 days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1 day) immediately preceding the date of such admission unless the hospital demonstrates (in a form and manner, and at a time, specified by the Secretary) that such services are not related (as determined by the Secretary) to such admission.

(b)(1) Notwithstanding section 1814(b) but subject to the provisions of section 1813, if the operating costs of inpatient hospital services (as defined in subsection (a)(4)) of a hospital (other than a subsection (d) hospital, as defined in subsection (d)(1)(B) and other than a rehabilitation facility described in subsection (j)(1)) for a cost reporting period subject to this paragraph—

(A) are less than or equal to the target amount (as defined in paragraph (3)) for that hospital for that period, the amount of the payment with respect to such operating costs payable under part A on a per discharge or per admission basis (as the

case may be) shall be equal to the amount of such operating costs, plus—

(i) 15 percent of the amount by which the target amount exceeds the amount of the operating costs, or

(ii) 2 percent of the target amount,

whichever is less;

(B) are greater than the target amount but do not exceed 110 percent of the target amount, the amount of the payment with respect to those operating costs payable under part A on a per discharge basis shall equal the target amount; or

(C) are greater than 110 percent of the target amount, the amount of the payment with respect to such operating costs payable under part A on a per discharge or per admission basis (as the case may be) shall be equal to (i) the target amount, plus (ii) in the case of cost reporting periods beginning on or after October 1, 1991, an additional amount equal to 50 percent of the amount by which the operating costs exceed 110 percent of the target amount (except that such additional amount may not exceed 10 percent of the target amount) after any exceptions or adjustments are made to such target amount for the cost reporting period;

plus the amount, if any, provided under paragraph (2), except that in no case may the amount payable under this title (other than on the basis of a DRG prospective payment rate determined under subsection (d)) with respect to operating costs of inpatient hospital services exceed the maximum amount payable with respect to such costs pursuant to subsection (a).

(2)(A) Except as provided in subparagraph (E), in addition to the payment computed under paragraph (1), in the case of an eligible hospital (described in subparagraph (B)) for a cost reporting period beginning on or after October 1, 1997, the amount of payment on a per discharge basis under paragraph (1) shall be increased by the lesser of—

(i) 50 percent of the amount by which the operating costs are less than the expected costs (as defined in subparagraph (D)) for the period; or

(ii) 1 percent of the target amount for the period.

(B) For purposes of this paragraph, an "eligible hospital" means with respect to a cost reporting period, a hospital—

(i) that has received payments under this subsection for at least 3 full cost reporting periods before that cost reporting period, and

(ii) whose operating costs for the period are less than the least of its target amount, its trended costs (as defined in subparagraph (C)), or its expected costs (as defined in subparagraph (D)) for the period.

(C) For purposes of subparagraph (B)(ii), the term "trended costs" means for a hospital cost reporting period ending in a fiscal year—

(i) in the case of a hospital for which its cost reporting period ending in fiscal year 1996 was its third or subsequent full cost reporting period for which it receives payments under this subsection, the lesser of the operating costs or target amount for that hospital for its cost reporting period ending in fiscal year 1996, or

(ii) in the case of any other hospital, the operating costs for that hospital for its third full cost reporting period for which it receives payments under this subsection,

increased (in a compounded manner) for each succeeding fiscal year (through the fiscal year involved) by the market basket percentage increase for the fiscal year.

(D) For purposes of this paragraph, the term "expected costs", with respect to the cost reporting period ending in a fiscal year, means the lesser of the operating costs of inpatient hospital services or target amount per discharge for the previous cost reporting period updated by the market basket percentage increase (as defined in paragraph (3)(B)(iii)) for the fiscal year.

(E)(i) In the case of an eligible hospital that is a hospital or unit that is within a class of hospital described in clause (ii) with a 12-month cost reporting period beginning before the enactment of this subparagraph, in determining the amount of the increase under subparagraph (A), the Secretary shall substitute for the percentage of the target amount applicable under subparagraph (A)(ii)—

(I) for a cost reporting period beginning on or after October 1, 2000, and before September 30, 2001, 1.5 percent; and

(II) for a cost reporting period beginning on or after October 1, 2001, and before September 30, 2002, 2 percent.

(ii) For purposes of clause (i), each of the following shall be treated as a separate class of hospital:

(I) Hospitals described in clause (i) of subsection (d)(1)(B) and psychiatric units described in the matter following clause (v) of such subsection.

(II) Hospitals described in clause (iv) of such subsection.

(3)(A) Except as provided in subparagraph (C) and succeeding subparagraphs and in paragraph (7)(A)(ii), for purposes of this subsection, the term "target amount" means, with respect to a hospital for a particular 12-month cost reporting period—

(i) in the case of the first such reporting period for which this subsection is in effect, the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under this title for such hospital for the preceding 12-month cost reporting period, and

(ii) in the case of a later reporting period, the target amount for the preceding 12-month cost reporting period,

increased by the applicable percentage increase under subparagraph (B) for that particular cost reporting period.

(B)(i) For purposes of subsection (d) and subsection (j) for discharges occurring during a fiscal year, the "applicable percentage increase" shall be—

(I) for fiscal year 1986, ½ percent,

(II) for fiscal year 1987, 1.15 percent,

(III) for fiscal year 1988, 3.0 percent for hospitals located in a rural area, 1.5 percent for hospitals located in a large urban area (as defined in subsection (d)(2)(D)), and 1.0 percent for hospitals located in other urban areas,

(IV) for fiscal year 1989, the market basket percentage increase minus 1.5 percentage points for hospitals located in a rural area, the market basket percentage increase minus 2.0 percentage points for hospitals located in a large urban area,

and the market basket percentage increase minus 2.5 percentage points for hospitals located in other urban areas,

(V) for fiscal year 1990, the market basket percentage increase plus 4.22 percentage points for hospitals located in a rural area, the market basket percentage increase plus 0.12 percentage points for hospitals located in a large urban area, and the market basket percentage increase minus 0.53 percentage points for hospitals located in other urban areas,

(VI) for fiscal year 1991, the market basket percentage increase minus 2.0 percentage points for hospitals in a large urban or other urban area, and the market basket percentage increase minus 0.7 percentage point for hospitals located in a rural area,

(VII) for fiscal year 1992, the market basket percentage increase minus 1.6 percentage points for hospitals in a large urban or other urban area, and the market basket percentage increase minus 0.6 percentage point for hospitals located in a rural area,

(VIII) for fiscal year 1993, the market basket percentage increase minus 1.55 percentage point for hospitals in a large urban or other urban area, and the market basket percentage increase minus 0.55 for hospitals located in a rural area,

(IX) for fiscal year 1994, the market basket percentage increase minus 2.5 percentage points for hospitals located in a large urban or other urban area, and the market basket percentage increase minus 1.0 percentage point for hospitals located in a rural area,

(X) for fiscal year 1995, the market basket percentage increase minus 2.5 percentage points for hospitals located in a large urban or other urban area, and such percentage increase for hospitals located in a rural area as will provide for the average standardized amount determined under subsection (d)(3)(A) for hospitals located in a rural area being equal to such average standardized amount for hospitals located in an urban area (other than a large urban area),

(XI) for fiscal year 1996, the market basket percentage increase minus 2.0 percentage points for hospitals in all areas,

(XII) for fiscal year 1997, the market basket percentage increase minus 0.5 percentage point for hospitals in all areas,

(XIII) for fiscal year 1998, 0 percent,

(XIV) for fiscal year 1999, the market basket percentage increase minus 1.9 percentage points for hospitals in all areas,

(XV) for fiscal year 2000, the market basket percentage increase minus 1.8 percentage points for hospitals in all areas,

(XVI) for fiscal year 2001, the market basket percentage increase for hospitals in all areas,

(XVII) for fiscal year 2002, the market basket percentage increase minus 0.55 percentage points for hospitals in all areas,

(XVIII) for fiscal year 2003, the market basket percentage increase minus 0.55 percentage points for hospitals in all areas,

(XIX) for each of fiscal years 2004 through 2006, subject to clause (vii), the market basket percentage increase for hospitals in all areas; and

(XX) for each subsequent fiscal year, subject to clauses (viii), (ix), (xi), and (xii), the market basket percentage increase for hospitals in all areas.

(ii) For purposes of subparagraphs (A) and (E), the "applicable percentage increase" for 12-month cost reporting periods beginning during—

(I) fiscal year 1986, is 0.5 percent,

(II) fiscal year 1987, is 1.15 percent,

(III) fiscal year 1988, is the market basket percentage increase minus 2.0 percentage points,

(IV) a subsequent fiscal year ending on or before September 30, 1993, is the market basket percentage increase,

(V) fiscal years 1994 through 1997, is the market basket percentage increase minus the applicable reduction (as defined in clause (v)(II)), or in the case of a hospital for a fiscal year for which the hospital's update adjustment percentage (as defined in clause (v)(I)) is at least 10 percent, the market basket percentage increase,

(VI) for fiscal year 1998, is 0 percent,

(VII) for fiscal years 1999 through 2002, is the applicable update factor specified under clause (vi) for the fiscal year, and

(VIII) subsequent fiscal years is the market basket percentage increase.

(iii) For purposes of this subparagraph, the term "market basket percentage increase" means, with respect to cost reporting periods and discharges occurring in a fiscal year, the percentage, estimated by the Secretary before the beginning of the period or fiscal year, by which the cost of the mix of goods and services (including personnel costs but excluding nonoperating costs) comprising routine, ancillary, and special care unit inpatient hospital services, based on an index of appropriately weighted indicators of changes in wages and prices which are representative of the mix of goods and services included in such inpatient hospital services, for the period or fiscal year will exceed the cost of such mix of goods and services for the preceding 12-month cost reporting period or fiscal year.

(iv) For purposes of subparagraphs (C) and (D), the "applicable percentage increase" is—

(I) for 12-month cost reporting periods beginning during fiscal years 1986 through 1993, the applicable percentage increase specified in clause (ii),

(II) for fiscal year 1994, the market basket percentage increase minus 2.3 percentage points (adjusted to exclude any portion of a cost reporting period beginning during fiscal year 1993 for which the applicable percentage increase is determined under subparagraph (I)),

(III) for fiscal year 1995, the market basket percentage increase minus 2.2 percentage points, and

(IV) for fiscal year 1996 and each subsequent fiscal year, the applicable percentage increase under clause (i).

(v) For purposes of clause (ii)(V)—

(I) a hospital's "update adjustment percentage" for a fiscal year is the percentage by which the hospital's allowable operating costs of inpatient hospital services recognized under this title for the cost reporting period beginning in fiscal year 1990 exceeds the hospital's target amount (as determined under sub-

paragraph (A)) for such cost reporting period, increased for each fiscal year (beginning with fiscal year 1994) by the sum of any of the hospital's applicable reductions under subclause (V) for previous fiscal years; and

(II) the "applicable reduction" with respect to a hospital for a fiscal year is the lesser of 1 percentage point or the percentage point difference between 10 percent and the hospital's update adjustment percentage for the fiscal year.

(vi) For purposes of clause (ii)(VII) for a fiscal year, if a hospital's allowable operating costs of inpatient hospital services recognized under this title for the most recent cost reporting period for which information is available—

(I) is equal to, or exceeds, 110 percent of the hospital's target amount (as determined under subparagraph (A)) for such cost reporting period, the applicable update factor specified under this clause is the market basket percentage;

(II) exceeds 100 percent, but is less than 110 percent, of such target amount for the hospital, the applicable update factor specified under this clause is 0 percent or, if greater, the market basket percentage minus 0.25 percentage points for each percentage point by which such allowable operating costs (expressed as a percentage of such target amount) is less than 110 percent of such target amount;

(III) is equal to, or less than 100 percent, but exceeds ⅔ of such target amount for the hospital, the applicable update factor specified under this clause is 0 percent or, if greater, the market basket percentage minus 2.5 percentage points; or

(IV) does not exceed ⅔ of such target amount for the hospital, the applicable update factor specified under this clause is 0 percent.

(vii)(I) For purposes of clause (i)(XIX) for fiscal years 2005 and 2006, in a case of a subsection (d) hospital that does not submit data to the Secretary in accordance with subclause (II) with respect to such a fiscal year, the applicable percentage increase under such clause for such fiscal year shall be reduced by 0.4 percentage points. Such reduction shall apply only with respect to the fiscal year involved, and the Secretary shall not take into account such reduction in computing the applicable percentage increase under clause (i)(XIX) for a subsequent fiscal year.

(II) For fiscal years 2005 and 2006, each subsection (d) hospital shall submit to the Secretary quality data (for a set of 10 indicators established by the Secretary as of November 1, 2003) that relate to the quality of care furnished by the hospital in inpatient settings in a form and manner, and at a time, specified by the Secretary for purposes of this clause, but with respect to fiscal year 2005, the Secretary shall provide for a 30-day grace period for the submission of data by a hospital.

(viii)(I) For purposes of clause (i) for fiscal year 2007 and each subsequent fiscal year, in the case of a subsection (d) hospital that does not submit, to the Secretary in accordance with this clause, data required to be submitted on measures selected under this clause with respect to such a fiscal year, the applicable percentage increase under clause (i) for such fiscal year shall be reduced by 2.0 percentage points (or, beginning with fiscal year 2015, by one-quarter of such applicable percentage increase (determined without re-

gard to clause (ix), (xi), or (xii))). Such reduction shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase under clause (i) for a subsequent fiscal year, and the Secretary and the Medicare Payment Advisory Commission shall carry out the requirements under section 5001(b) of the Deficit Reduction Act of 2005.

(II) Each subsection (d) hospital shall submit data on measures selected under this clause to the Secretary in a form and manner, and at a time, specified by the Secretary for purposes of this clause. The Secretary may require hospitals to submit data on measures that are not used for the determination of value-based incentive payments under subsection (o).

(III) The Secretary shall expand, beyond the measures specified under clause (vii)(II) and consistent with the succeeding subclauses, the set of measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in inpatient settings.

(IV) Effective for payments beginning with fiscal year 2007, in expanding the number of measures under subclause (III), the Secretary shall begin to adopt the baseline set of performance measures as set forth in the November 2005 report by the Institute of Medicine of the National Academy of Sciences under section 238(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(V) Effective for payments for fiscal years 2008 through 2012, the Secretary shall add other measures that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

(VI) For purposes of this clause and clause (vii), the Secretary may replace any measures or indicators in appropriate cases, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown not to represent the best clinical practice.

(VII) The Secretary shall establish procedures for making information regarding measures submitted under this clause available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in inpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(VIII) Effective for payments beginning with fiscal year 2013, with respect to quality measures for outcomes of care, the Secretary shall provide for such risk adjustment as the Secretary determines to be appropriate to maintain incentives for hospitals to treat patients with severe illnesses or conditions.

(IX)(aa) Subject to item (bb), effective for payments beginning with fiscal year 2013, each measure specified by the Secretary under this clause shall be endorsed by the entity with a contract under section 1890(a).

(bb) In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical

measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(X) To the extent practicable, the Secretary shall, with input from consensus organizations and other stakeholders, take steps to ensure that the measures specified by the Secretary under this clause are coordinated and aligned with quality measures applicable to—

(aa) physicians under section 1848(k); and

(bb) other providers of services and suppliers under this title.

(XI) The Secretary shall establish a process to validate measures specified under this clause as appropriate. Such process shall include the auditing of a number of randomly selected hospitals sufficient to ensure validity of the reporting program under this clause as a whole and shall provide a hospital with an opportunity to appeal the validation of measures reported by such hospital.

(ix)(I) For purposes of clause (i) for fiscal year 2015 and each subsequent fiscal year, in the case of an eligible hospital (as defined in subsection (n)(6)(A)) that is not a meaningful EHR user (as defined in subsection (n)(3)) for an EHR reporting period for such fiscal year, three-quarters of the applicable percentage increase otherwise applicable under clause (i) (determined without regard to clause (viii), (xi), or (xii)) for such fiscal year shall be reduced by 33⅓ percent for fiscal year 2015, 66⅔ percent for fiscal year 2016, and 100 percent for fiscal year 2017 and each subsequent fiscal year. Such reduction shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase under clause (i) for a subsequent fiscal year.

[(II) The Secretary may, on a case-by-case basis, exempt a subsection (d) hospital from the application of subclause (I) with respect to a fiscal year if the Secretary determines, subject to annual renewal, that requiring such hospital to be a meaningful EHR user during such fiscal year would result in a significant hardship, such as in the case of a hospital in a rural area without sufficient Internet access. In no case may a hospital be granted an exemption under this subclause for more than 5 years.**]**

(II)(aa) The Secretary may, on a case-by-case basis, exempt a subsection (d) hospital from the application of subclause (I) with respect to a fiscal year if the Secretary determines, subject to annual renewal, that requiring such hospital to be a meaningful EHR user during such fiscal year would result in a significant hardship, such as in the case of a hospital in a rural area without sufficient Internet access.

(bb) The Secretary may, on a case-by-case basis, exempt a subsection (d) hospital from the application of subclause (I) with respect to a fiscal year if the Secretary determines, subject to annual renewal, that such hospital was determined to not be a meaningful EHR user because the qualified electronic health record used by such hospital was decertified under section 3001(c)(5)(C) of the Public Health Service Act. An exemption under the previous sentence may be applied to a subsection (d) hospital only, subject to items (cc)

and (dd), during the first payment year with respect to the first EHR reporting period to which such decertification applies.

(cc) In no case shall an exemption by reason of item (bb) be for a period of less than 12 months.

(dd) An exemption under item (bb) may be extended for a period of an additional 12 months subject to the limitation described in item (ee).

(ee) Subject to item (cc), in no case may a hospital be granted an exemption under this subclause for more than 5 years.

(III) For fiscal year 2015 and each subsequent fiscal year, a State in which hospitals are paid for services under section 1814(b)(3) shall adjust the payments to each subsection (d) hospital in the State that is not a meaningful EHR user (as defined in subsection (n)(3)) in a manner that is designed to result in an aggregate reduction in payments to hospitals in the State that is equivalent to the aggregate reduction that would have occurred if payments had been reduced to each subsection (d) hospital in the State in a manner comparable to the reduction under the previous provisions of this clause. The State shall report to the Secretary the methodology it will use to make the payment adjustment under the previous sentence.

(IV) For purposes of this clause, the term "EHR reporting period" means, with respect to a fiscal year, any period (or periods) as specified by the Secretary.

(x)(I) The Secretary shall develop standard Internet website reports tailored to meet the needs of various stakeholders such as hospitals, patients, researchers, and policymakers. The Secretary shall seek input from such stakeholders in determining the type of information that is useful and the formats that best facilitate the use of the information.

(II) The Secretary shall modify the Hospital Compare Internet website to make the use and navigation of that website readily available to individuals accessing it.

(xi)(I) For 2012 and each subsequent fiscal year, after determining the applicable percentage increase described in clause (i) and after application of clauses (viii) and (ix), such percentage increase shall be reduced by the productivity adjustment described in subclause (II).

(II) The productivity adjustment described in this subclause, with respect to a percentage, factor, or update for a fiscal year, year, cost reporting period, or other annual period, is a productivity adjustment equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period).

(III) The application of subclause (I) may result in the applicable percentage increase described in clause (i) being less than 0.0 for a fiscal year, and may result in payment rates under this section for a fiscal year being less than such payment rates for the preceding fiscal year.

(xii) After determining the applicable percentage increase described in clause (i), and after application of clauses (viii), (ix), and (xi), the Secretary shall reduce such applicable percentage increase—

(I) for each of fiscal years 2010 and 2011, by 0.25 percentage point;

(II) for each of fiscal years 2012 and 2013, by 0.1 percentage point;

(III) for fiscal year 2014, by 0.3 percentage point;

(IV) for each of fiscal years 2015 and 2016, by 0.2 percentage point; and

(V) for each of fiscal years 2017, 2018, and 2019, by 0.75 percentage point.

The application of this clause may result in the applicable percentage increase described in clause (i) being less than 0.0 for a fiscal year, and may result in payment rates under this section for a fiscal year being less than such payment rates for the preceding fiscal year.

(C) In the case of a hospital that is a sole community hospital (as defined in subsection (d)(5)(D)(iii)), subject to subparagraphs (I) and (L), the term "target amount" means—

(i) with respect to the first 12-month cost reporting period in which this subparagraph is applied to the hospital—

(I) the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under this title for the hospital for the 12-month cost reporting period (in this subparagraph referred to as the "base cost reporting period") preceding the first cost reporting period for which this subsection was in effect with respect to such hospital, increased (in a compounded manner) by—

(II) the applicable percentage increases applied to such hospital under this paragraph for cost reporting periods after the base cost reporting period and up to and including such first 12-month cost reporting period,

(ii) with respect to a later cost reporting period beginning before fiscal year 1994, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(iv) for discharges occurring in the fiscal year in which that later cost reporting period begins,

(iii) with respect to discharges occurring in fiscal year 1994, the target amount for the cost reporting period beginning in fiscal year 1993 increased by the applicable percentage increase under subparagraph (B)(iv), or

(iv) with respect to discharges occurring in fiscal year 1995 and each subsequent fiscal year, the target amount for the preceding year increased by the applicable percentage increase under subparagraph (B)(iv).

There shall be substituted for the base cost reporting period described in clause (i) a hospital's cost reporting period (if any) beginning during fiscal year 1987 if such substitution results in an increase in the target amount for the hospital.

(D) For cost reporting periods ending on or before September 30, 1994, and for cost reporting periods occurring on or after October 1, 1997, and before October 1, 2017, in the case of a hospital that is a medicare-dependent, small rural hospital (as defined in subsection (d)(5)(G)), subject to subparagraph (K), the term "target amount" means—

(i) with respect to the first 12-month cost reporting period in which this subparagraph is applied to the hospital—

(I) the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under this title for the hospital for the 12-month cost reporting period (in this subparagraph referred to as the "base cost reporting period") preceding the first cost reporting period for which this subsection was in effect with respect to such hospital, increased (in a compounded manner) by—

(II) the applicable percentage increases applied to such hospital under this paragraph for cost reporting periods after the base cost reporting period and up to and including such first 12-month cost reporting period, or

(ii) with respect to a later cost reporting period beginning before fiscal year 1994, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(iv) for discharges occurring in the fiscal year in which that later cost reporting period begins,

(iii) with respect to discharges occurring in fiscal year 1994, the target amount for the cost reporting period beginning in fiscal year 1993 increased by the applicable percentage increase under subparagraph (B)(iv), and

(iv) with respect to discharges occurring during fiscal year 1998 through fiscal year 2017, the target amount for the preceding year increased by the applicable percentage increase under subparagraph (B)(iv).

There shall be substituted for the base cost reporting period described in clause (i) a hospital's cost reporting period (if any) beginning during fiscal year 1987 if such substitution results in an increase in the target amount for the hospital.

(E) In the case of a hospital described in clause (v) of subsection (d)(1)(B), the term "target amount" means—

(i) with respect to the first 12-month cost reporting period in which this subparagraph is applied to the hospital—

(I) the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under this title for the hospital for the 12-month cost reporting period (in this subparagraph referred to as the "base cost reporting period") preceding the first cost reporting period for which this subsection was in effect with respect to such hospital, increased (in a compounded manner) by—

(II) the sum of the applicable percentage increases applied to such hospital under this paragraph for cost reporting periods after the base cost reporting period and up to and including such first 12-month cost reporting period, or

(ii) with respect to a later cost reporting period, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(ii) for that later cost reporting period.

There shall be substituted for the base cost reporting period described in clause (i) a hospital's cost reporting period (if any) beginning during fiscal year 1987 if such substitution results in an increase in the target amount for the hospital.

(F)(i) In the case of a hospital (or unit described in the matter following clause (v) of subsection (d)(1)(B)) that received payment under this subsection for inpatient hospital services furnished during cost reporting periods beginning before October 1, 1990, that is within a class of hospital described in clause (iii), and that elects (in a form and manner determined by the Secretary) this subparagraph to apply to the hospital, the target amount for the hospital's 12-month cost reporting period beginning during fiscal year 1998 is equal to the average described in clause (ii).

(ii) The average described in this clause for a hospital or unit shall be determined by the Secretary as follows:

(I) The Secretary shall determine the allowable operating costs for inpatient hospital services for the hospital or unit for each of the 5 cost reporting periods for which the Secretary has the most recent settled cost reports as of the date of the enactment of this subparagraph.

(II) The Secretary shall increase the amount determined under subclause (I) for each cost reporting period by the applicable percentage increase under subparagraph (B)(ii) for each subsequent cost reporting period up to the cost reporting period described in clause (i).

(III) The Secretary shall identify among such 5 cost reporting periods the cost reporting periods for which the amount determined under subclause (II) is the highest, and the lowest.

(IV) The Secretary shall compute the averages of the amounts determined under subclause (II) for the 3 cost reporting periods not identified under subclause (III).

(iii) For purposes of this subparagraph, each of the following shall be treated as a separate class of hospital:

(I) Hospitals described in clause (i) of subsection (d)(1)(B) and psychiatric units described in the matter following clause (v) of such subsection.

(II) Hospitals described in clause (ii) of such subsection and rehabilitation units described in the matter following clause (v) of such subsection.

(III) Hospitals described in clause (iii) of such subsection.

(IV) Hospitals described in clause (iv) of such subsection.

(V) Hospitals described in clause (v) of such subsection.

(G)(i) In the case of a qualified long-term care hospital (as defined in clause (ii)) that elects (in a form and manner determined by the Secretary) this subparagraph to apply to the hospital, the target amount for the hospital's 12-month cost reporting period beginning during fiscal year 1998 is equal to the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under this title for the hospital for the 12-month cost reporting period beginning during fiscal year 1996, increased by the applicable percentage increase for the cost reporting period beginning during fiscal year 1997.

(ii) In clause (i), a "qualified long-term care hospital" means, with respect to a cost reporting period, a hospital described in clause (iv) of subsection (d)(1)(B) during each of the 2 cost reporting periods for which the Secretary has the most recent settled cost reports as of the date of the enactment of this subparagraph for each of which—

(I) the hospital's allowable operating costs of inpatient hospital services recognized under this title exceeded 115 percent of the hospital's target amount, and

(II) the hospital would have a disproportionate patient percentage of at least 70 percent (as determined by the Secretary under subsection (d)(5)(F)(vi)) if the hospital were a subsection (d) hospital.

(H)(i) In the case of a hospital or unit that is within a class of hospital described in clause (iv), for a cost reporting period beginning during fiscal years 1998 through 2002, the target amount for such a hospital or unit may not exceed the amount as updated up to or for such cost reporting period under clause (ii).

(ii)(I) In the case of a hospital or unit that is within a class of hospital described in clause (iv), the Secretary shall estimate the 75th percentile of the target amounts for such hospitals within such class for cost reporting periods ending during fiscal year 1996, as adjusted under clause (iii).

(II) The Secretary shall update the amount determined under subclause (I), for each cost reporting period after the cost reporting period described in such subclause and up to the first cost reporting period beginning on or after October 1, 1997, by a factor equal to the market basket percentage increase.

(III) For cost reporting periods beginning during each of fiscal years 1999 through 2002, subject to subparagraph (J), the Secretary shall update such amount by a factor equal to the market basket percentage increase.

(iii) In applying clause (ii)(I) in the case of a hospital or unit, the Secretary shall provide for an appropriate adjustment to the labor-related portion of the amount determined under such subparagraph to take into account differences between average wage-related costs in the area of the hospital and the national average of such costs within the same class of hospital.

(iv) For purposes of this subparagraph, each of the following shall be treated as a separate class of hospital:

(I) Hospitals described in clause (i) of subsection (d)(1)(B) and psychiatric units described in the matter following clause (v) of such subsection.

(II) Hospitals described in clause (ii) of such subsection and rehabilitation units described in the matter following clause (v) of such subsection.

(III) Hospitals described in clause (iv) of such subsection.

(I)(i) Subject to subparagraph (L), for cost reporting periods beginning on or after October 1, 2000, in the case of a sole community hospital there shall be substituted for the amount otherwise determined under subsection (d)(5)(D)(i), if such substitution results in a greater amount of payment under this section for the hospital—

(I) with respect to discharges occurring in fiscal year 2001, 75 percent of the amount otherwise applicable to the hospital under subsection (d)(5)(D)(i) (referred to in this clause as the "subsection (d)(5)(D)(i) amount") and 25 percent of the rebased target amount (as defined in clause (ii));

(II) with respect to discharges occurring in fiscal year 2002, 50 percent of the subsection (d)(5)(D)(i) amount and 50 percent of the rebased target amount;

(III) with respect to discharges occurring in fiscal year 2003, 25 percent of the subsection (d)(5)(D)(i) amount and 75 percent of the rebased target amount; and

(IV) with respect to discharges occurring after fiscal year 2003, 100 percent of the rebased target amount.

(ii) For purposes of this subparagraph, the "rebased target amount" has the meaning given the term "target amount" in subparagraph (C) except that—

(I) there shall be substituted for the base cost reporting period the 12-month cost reporting period beginning during fiscal year 1996;

(II) any reference in subparagraph (C)(i) to the "first cost reporting period" described in such subparagraph is deemed a reference to the first cost reporting period beginning on or after October 1, 2000; and

(III) applicable increase percentage shall only be applied under subparagraph (C)(iv) for discharges occurring in fiscal years beginning with fiscal year 2002.

(iii) In no case shall a hospital be denied treatment as a sole community hospital or payment (on the basis of a target rate as such as a hospital) because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances, so long as data for at least one applicable base cost reporting period is available.

(J) For cost reporting periods beginning during fiscal year 2001, for a hospital described in subsection (d)(1)(B)(iv)—

(i) the limiting or cap amount otherwise determined under subparagraph (H) shall be increased by 2 percent; and

(ii) the target amount otherwise determined under subparagraph (A) shall be increased by 25 percent (subject to the limiting or cap amount determined under subparagraph (H), as increased by clause (i)).

(K)(i) With respect to discharges occurring on or after October 1, 2006, in the case of a medicare-dependent, small rural hospital, for purposes of applying subparagraph (D)—

(I) there shall be substituted for the base cost reporting period described in subparagraph (D)(i) the 12-month cost reporting period beginning during fiscal year 2002; and

(II) any reference in such subparagraph to the "first cost reporting period" described in such subparagraph is deemed a reference to the first cost reporting period beginning on or after October 1, 2006.

(ii) This subparagraph shall only apply to a hospital if the substitution described in clause (i)(I) results in an increase in the target amount under subparagraph (D) for the hospital.

(L)(i) For cost reporting periods beginning on or after January 1, 2009, in the case of a sole community hospital there shall be substituted for the amount otherwise determined under subsection (d)(5)(D)(i) of this section, if such substitution results in a greater amount of payment under this section for the hospital, the subparagraph (L) rebased target amount.

(ii) For purposes of this subparagraph, the term "subparagraph (L) rebased target amount" has the meaning given the term "target amount" in subparagraph (C), except that—

(I) there shall be substituted for the base cost reporting period the 12-month cost reporting period beginning during fiscal year 2006;

(II) any reference in subparagraph (C)(i) to the "first cost reporting period" described in such subparagraph is deemed a reference to the first cost reporting period beginning on or after January 1, 2009; and

(III) the applicable percentage increase shall only be applied under subparagraph (C)(iv) for discharges occurring on or after January 1, 2009.

(4)(A)(i) The Secretary shall provide for an exception and adjustment to (and in the case of a hospital described in subsection (d)(1)(B)(iii), may provide an exemption from) the method under this subsection for determining the amount of payment to a hospital where events beyond the hospital's control or extraordinary circumstances, including changes in the case mix of such hospital, create a distortion in the increase in costs for a cost reporting period (including any distortion in the costs for the base period against which such increase is measured). The Secretary may provide for such other exemptions from, and exceptions and adjustments to, such method as the Secretary deems appropriate, including the assignment of a new base period which is more representative, as determined by the Secretary, of the reasonable and necessary cost of inpatient services and including those which he deems necessary to take into account a decrease in the inpatient hospital services that a hospital provides and that are customarily provided directly by similar hospitals which results in a significant distortion in the operating costs of inpatient hospital services. The Secretary shall announce a decision on any request for an exemption, exception, or adjustment under this paragraph not later than 180 days after receiving a completed application from the intermediary for such exemption, exception, or adjustment, and shall include in such decision a detailed explanation of the grounds on which such request was approved or denied.

(ii) The payment reductions under paragraph (3)(B)(ii)(V) shall not be considered by the Secretary in making adjustments pursuant to clause (i). In making such reductions, the Secretary shall treat the applicable update factor described in paragraph (3)(B)(vi) for a fiscal year as being equal to the market basket percentage for that year.

(B) In determining under subparagraph (A) whether to assign a new base period which is more representative of the reasonable and necessary cost to a hospital of providing inpatient services, the Secretary shall take into consideration—

(i) changes in applicable technologies and medical practices, or differences in the severity of illness among patients, that increase the hospital's costs;

(ii) whether increases in wages and wage-related costs for hospitals located in the geographic area in which the hospital is located exceed the average of the increases in such costs paid by hospitals in the United States; and

(iii) such other factors as the Secretary considers appropriate in determining increases in the hospital's costs of providing inpatient services.

(C) Paragraph (1) shall not apply to payment of hospitals which is otherwise determined under paragraph (3) of section 1814(b).

(5) In the case of any hospital having any cost reporting period of other than a 12-month period, the Secretary shall determine the 12-month period which shall be used for purposes of this section.

(6) In the case of any hospital which becomes subject to the taxes under section 3111 of the Internal Revenue Code of 1954, with respect to any or all of its employees, for part or all of a cost reporting period, and was not subject to such taxes with respect to any or all of its employees for all or part of the 12-month base cost reporting period referred to in subsection (b)(3)(A)(i), the Secretary shall provide for an adjustment by increasing the base period amount described in such subsection for such hospital by an amount equal to the amount of such taxes which would have been paid or accrued by such hospital for such base period if such hospital had been subject to such taxes for all of such base period with respect to all its employees, minus the amount of any such taxes actually paid or accrued for such base period.

(7)(A) Notwithstanding paragraph (1), in the case of a hospital or unit that is within a class of hospital described in subparagraph (B) which first receives payments under this section on or after October 1, 1997—

(i) for each of the first 2 cost reporting periods for which the hospital has a settled cost report, the amount of the payment with respect to operating costs described in paragraph (1) under part A on a per discharge or per admission basis (as the case may be) is equal to the lesser of—

(I) the amount of operating costs for such respective period, or

(II) 110 percent of the national median (as estimated by the Secretary) of the target amount for hospitals in the same class as the hospital for cost reporting periods ending during fiscal year 1996, updated by the hospital market basket increase percentage to the fiscal year in which the hospital first received payments under this section, as adjusted under subparagraph (C); and

(ii) for purposes of computing the target amount for the subsequent cost reporting period, the target amount for the preceding cost reporting period is equal to the amount determined under clause (i) for such preceding period.

(B) For purposes of this paragraph, each of the following shall be treated as a separate class of hospital:

(i) Hospitals described in clause (i) of subsection (d)(1)(B) and psychiatric units described in the matter following clause (v) of such subsection.

(ii) Hospitals described in clause (ii) of such subsection and rehabilitation units described in the matter following clause (v) of such subsection.

(iii) Hospitals described in clause (iv) of such subsection.

(C) In applying subparagraph (A)(i)(II) in the case of a hospital or unit, the Secretary shall provide for an appropriate adjustment to the labor-related portion of the amount determined under such subparagraph to take into account differences between average wage-related costs in the area of the hospital and the national average of such costs within the same class of hospital.

(c)(1) The Secretary may provide, in his discretion, that payment with respect to services provided by a hospital in a State may be made in accordance with a hospital reimbursement control system in a State, rather than in accordance with the other provisions of this title, if the chief executive officer of the State requests such treatment and if—

(A) the Secretary determines that the system, if approved under this subsection, will apply (i) to substantially all non-Federal acute care hospitals (as defined by the Secretary) in the State and (ii) to the review of at least 75 percent of all revenues or expenses in the State for inpatient hospital services and of revenues or expenses for inpatient hospital services provided under the State's plan approved under title XIX;

(B) the Secretary has been provided satisfactory assurances as to the equitable treatment under the system of all entities (including Federal and State programs) that pay hospitals for inpatient hospital services, of hospital employees, and of hospital patients;

(C) the Secretary has been provided satisfactory assurances that under the system, over 36-month periods (the first such period beginning with the first month in which this subsection applies to that system in the State), the amount of payments made under this title under such system will not exceed the amount of payments which would otherwise have been made under this title not using such system;

(D) the Secretary determines that the system will not preclude an eligible organization (as defined in section 1876(b)) from negotiating directly with hospitals with respect to the organization's rate of payment for inpatient hospital services; and

(E) the Secretary determines that the system requires hospitals to meet the requirement of section 1866(a)(1)(G) and the system provides for the exclusion of certain costs in accordance with section 1862(a)(14) (except for such waivers thereof as the Secretary provides by regulation).

The Secretary cannot deny the application of a State under this subsection on the ground that the State's hospital reimbursement control system is based on a payment methodology other than on the basis of a diagnosis-related group or on the ground that the amount of payments made under this title under such system must be less than the amount of payments which would otherwise have been made under this title not using such system. If the Secretary determines that the conditions described in subparagraph (C) are based on maintaining payment amounts at no more than a specified percentage increase above the payment amounts in a base period, the State has the option of applying such test (for inpatient hospital services under part A) on an aggregate payment basis or on the basis of the amount of payment per inpatient discharge or admission. If the Secretary determines that the conditions described in subparagraph (C) are based on maintaining aggregate payment amounts below a national average percentage increase in total payments under part A for inpatient hospital services, the Secretary cannot deny the application of a State under this subsection on the ground that the State's rate of increase in such pay-

ments for such services must be less than such national average rate of increase.

(2) In determining under paragraph (1)(C) the amount of payment which would otherwise have been made under this title for a State, the Secretary may provide for appropriate adjustment of such amount to take into account previous reductions effected in the amount of payments made under this title in the State due to the operation of the hospital reimbursement control system in the State if the system has resulted in an aggregate rate of increase in operating costs of inpatient hospital services (as defined in subsection (a)(4)) under this title for hospitals in the State which is less than the aggregate rate of increase in such costs under this title for hospitals in the United States.

(3) The Secretary shall discontinue payments under a system described in paragraph (1) if the Secretary—

(A) determines that the system no longer meets the requirements of subparagraphs (A), (D), and (E) of paragraph (1) and, if applicable, the requirements of paragraph (5), or

(B) has reason to believe that the assurances described in subparagraph (B) or (C) of paragraph (1) (or, if applicable, in paragraph (5)) are not being (or will not be) met.

(4) The Secretary shall approve the request of a State under paragraph (1) with respect to a hospital reimbursement control system if—

(A) the requirements of subparagraphs (A), (B), (C), (D), and (E) of paragraph (1) have been met with respect to the system, and

(B) with respect to that system a waiver of certain requirements of title XVIII of the Social Security Act has been approved on or before (and which is in effect as of) the date of the enactment of the Social Security Amendments of 1983, pursuant to section 402(a) of the Social Security Amendments of 1967 or section 222(a) of the Social Security Amendments of 1972.

With respect to a State system described in this paragraph, the Secretary shall judge the effectiveness of such system on the basis of its rate of increase or inflation in inpatient hospital payments for individuals under this title, as compared to the national rate of increase or inflation for such payments, with the State retaining the option to have the test applied on the basis of the aggregate payments under the State system as compared to aggregate payments which would have been made under the national system since October 1, 1984, to the most recent date for which annual data are available.

(5) The Secretary shall approve the request of a State under paragraph (1) with respect to a hospital reimbursement control system if—

(A) the requirements of subparagraphs (A), (B), (C), (D), and (E) of paragraph (1) have been met with respect to the system;

(B) the Secretary determines that the system—

(i) is operated directly by the State or by an entity designated pursuant to State law,

(ii) provides for payment of hospitals covered under the system under a methodology (which sets forth exceptions and adjustments, as well as any method for changes in the

methodology) by which rates or amounts to be paid for hospital services during a specified period are established under the system prior to the defined rate period, and

(iii) hospitals covered under the system will make such reports (in lieu of cost and other reports, identified by the Secretary, otherwise required under this title) as the Secretary may require in order to properly monitor assurances provided under this subsection;

(C) the State has provided the Secretary with satisfactory assurances that operation of the system will not result in any change in hospital admission practices which result in—

(i) a significant reduction in the proportion of patients (receiving hospital services covered under the system) who have no third-party coverage and who are unable to pay for hospital services,

(ii) a significant reduction in the proportion of individuals admitted to hospitals for inpatient hospital services for which payment is (or is likely to be) less than the anticipated charges for or costs of such services,

(iii) the refusal to admit patients who would be expected to require unusually costly or prolonged treatment for reasons other than those related to the appropriateness of the care available at the hospital, or

(iv) the refusal to provide emergency services to any person who is in need of emergency services if the hospital provides such services;

(D) any change by the State in the system which has the effect of materially reducing payments to hospitals can only take effect upon 60 days notice to the Secretary and to the hospitals the payment to which is likely to be materially affected by the change; and

(E) the State has provided the Secretary with satisfactory assurances that in the development of the system the State has consulted with local governmental officials concerning the impact of the system on public hospitals.

The Secretary shall respond to requests of States under this paragraph within 60 days of the date the request is submitted to the Secretary.

(6) If the Secretary determines that the assurances described in paragraph (1)(C) have not been met with respect to any 36-month period, the Secretary may reduce payments under this title to hospitals under the system in an amount equal to the amount by which the payment under this title under such system for such period exceeded the amount of payments which would otherwise have been made under this title not using such system.

(7) In the case of a State which made a request under paragraph (5) before December 31, 1984, for the approval of a State hospital reimbursement control system and which request was approved—

(A) in applying paragraphs (1)(C) and (6), a reference to a "36-month period" is deemed a reference to a "48-month period", and

(B) in order to allow the State the opportunity to provide the assurances described in paragraph (1)(C) for a 48-month period, the Secretary may not discontinue payments under the system, under the authority of paragraph (3)(A) because the

Secretary has reason to believe that such assurances are not being (or will not be) met, before July 1, 1986.

(d)(1)(A) Notwithstanding section 1814(b) but subject to the provisions of section 1813, the amount of the payment with respect to the operating costs of inpatient hospital services (as defined in subsection (a)(4)) of a subsection (d) hospital (as defined in subparagraph (B)) for inpatient hospital discharges in a cost reporting period or in a fiscal year—

(i) beginning on or after October 1, 1983, and before October 1, 1984, is equal to the sum of—

(I) the target percentage (as defined in subparagraph (C)) of the hospital's target amount for the cost reporting period (as defined in subsection (b)(3)(A), but determined without the application of subsection (a)), and

(II) the DRG percentage (as defined in subparagraph (C)) of the regional adjusted DRG prospective payment rate determined under paragraph (2) for such discharges;

(ii) beginning on or after October 1, 1984, and before October 1, 1987, is equal to the sum of—

(I) the target percentage (as defined in subparagraph (C)) of the hospital's target amount for the cost reporting period (as defined in subsection (b)(3)(A), but determined without the application of subsection (a)), and

(II) the DRG percentage (as defined in subparagraph (C)) of the applicable combined adjusted DRG prospective payment rate determined under subparagraph (D) for such discharges; or

(iii) beginning on or after April 1, 1988, is equal to

(I) the national adjusted DRG prospective payment rate determined under paragraph (3) for such discharges, or

(II) for discharges occurring during a fiscal year ending on or before September 30, 1996, the sum of 85 percent of the national adjusted DRG prospective payment rate determined under paragraph (3) for such discharges and 15 percent of the regional adjusted DRG prospective payment rate determined under such paragraph, but only if the average standardized amount (described in clause (i)(I) or clause (ii)(I) of paragraph (3)(D)) for hospitals within the region of, and in the same large urban or other area (or, for discharges occurring during a fiscal year ending on or before September 30, 1994, the same rural, large urban, or other urban area) as, the hospital is greater than the average standardized amount (described in the respective clause) for hospitals within the United States in that type of area for discharges occurring during such fiscal year.

(B) As used in this section, the term "subsection (d) hospital" means a hospital located in one of the fifty States or the District of Columbia other than—

(i) a psychiatric hospital (as defined in section 1861(f)),

(ii) a rehabilitation hospital (as defined by the Secretary),

(iii) a hospital whose inpatients are predominantly individuals under 18 years of age,

(iv)(I) a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days, or

(II) a hospital that first received payment under this subsection in 1986 which has an average inpatient length of stay (as determined by the Secretary) of greater than 20 days and that has 80 percent or more of its annual medicare inpatient discharges with a principal diagnosis that reflects a finding of neoplastic disease in the 12-month cost reporting period ending in fiscal year 1997, or

(v)(I) a hospital that the Secretary has classified, at any time on or before December 31, 1990, (or, in the case of a hospital that, as of the date of the enactment of this clause, is located in a State operating a demonstration project under section 1814(b), on or before December 31, 1991) for purposes of applying exceptions and adjustments to payment amounts under this subsection, as a hospital involved extensively in treatment for or research on cancer,

(II) a hospital that was recognized as a comprehensive cancer center or clinical cancer research center by the National Cancer Institute of the National Institutes of Health as of April 20, 1983, that is located in a State which, as of December 19, 1989, was not operating a demonstration project under section 1814(b), that applied and was denied, on or before December 31, 1990, for classification as a hospital involved extensively in treatment for or research on cancer under this clause (as in effect on the day before the date of the enactment of this subclause), that as of the date of the enactment of this subclause, is licensed for less than 50 acute care beds, and that demonstrates for the 4–year period ending on December 31, 1996, that at least 50 percent of its total discharges have a principal finding of neoplastic disease, as defined in subparagraph (E), or

(III) a hospital that was recognized as a clinical cancer research center by the National Cancer Institute of the National Institutes of Health as of February 18, 1998, that has never been reimbursed for inpatient hospital services pursuant to a reimbursement system under a demonstration project under section 1814(b), that is a freestanding facility organized primarily for treatment of and research on cancer and is not a unit of another hospital, that as of the date of the enactment of this subclause, is licensed for 162 acute care beds, and that demonstrates for the 4-year period ending on June 30, 1999, that at least 50 percent of its total discharges have a principal finding of neoplastic disease, as defined in subparagraph (E);

and, in accordance with regulations of the Secretary, does not include a psychiatric or rehabilitation unit of the hospital which is a distinct part of the hospital (as defined by the Secretary). A hospital that was classified by the Secretary on or before September 30, 1995, as a hospital described in clause (iv) shall continue to be so classified notwithstanding that it is located in the same building as, or on the same campus as, another hospital.

(C) For purposes of this subsection, for cost reporting periods beginning—

(i) on or after October 1, 1983, and before October 1, 1984, the "target percentage" is 75 percent and the "DRG percentage" is 25 percent;

(ii) on or after October 1, 1984, and before October 1, 1985, the "target percentage" is 50 percent and the "DRG percentage" is 50 percent;

(iii) on or after October 1, 1985, and before October 1, 1986, the "target percentage" is 45 percent and the "DRG percentage" is 55 percent; and

(iv) on or after October 1, 1986, and before October 1, 1987, the "target percentage" is 25 percent and the "DRG percentage" is 75 percent.

(D) For purposes of subparagraph (A)(ii)(II), the "applicable combined adjusted DRG prospective payment rate" for discharges occurring—

(i) on or after October 1, 1984, and before October 1, 1986, is a combined rate consisting of 25 percent of the national adjusted DRG prospective payment rate, and 75 percent of the regional adjusted DRG prospective payment rate, determined under paragraph (3) for such discharges; and

(ii) on or after October 1, 1986, and before October 1, 1987, is a combined rate consisting of 50 percent of the national adjusted DRG prospective payment rate, and 50 percent of the regional adjusted DRG prospective payment rate, determined under paragraph (3) for such discharges.

(E) For purposes of subclauses (II) and (III) of subparagraph (B)(v) only, the term "principal finding of neoplastic disease" means the condition established after study to be chiefly responsible for occasioning the admission of a patient to a hospital, except that only discharges with ICD–9–CM principal diagnosis codes of 140 through 239, V58.0, V58.1, V66.1, V66.2, or 990 will be considered to reflect such a principal diagnosis.

(2) The Secretary shall determine a national adjusted DRG prospective payment rate, for each inpatient hospital discharge in fiscal year 1984 involving inpatient hospital services of a subsection (d) hospital in the United States, and shall determine a regional adjusted DRG prospective payment rate for such discharges in each region, for which payment may be made under part A of this title. Each such rate shall be determined for hospitals located in urban or rural areas within the United States or within each such region, respectively, as follows:

(A) DETERMINING ALLOWABLE INDIVIDUAL HOSPITAL COSTS FOR BASE PERIOD.—The Secretary shall determine the allowable operating costs per discharge of inpatient hospital services for the hospital for the most recent cost reporting period for which data are available.

(B) UPDATING FOR FISCAL YEAR 1984.—The Secretary shall update each amount determined under subparagraph (A) for fiscal year 1984 by—

(i) updating for fiscal year 1983 by the estimated average rate of change of hospital costs industry-wide between the cost reporting period used under such subparagraph and fiscal year 1983 and the most recent case-mix data available, and

(ii) projecting for fiscal year 1984 by the applicable percentage increase (as defined in subsection (b)(3)(B)) for fiscal year 1984.

(C) STANDARDIZING AMOUNTS.—The Secretary shall standardize the amount updated under subparagraph (B) for each hospital by—

(i) excluding an estimate of indirect medical education costs (taking into account, for discharges occurring after September 30, 1986, the amendments made by section 9104(a) of the Medicare and Medicaid Budget Reconciliation Amendments of 1985), except that the Secretary shall not take into account any reduction in the amount of additional payments under paragraph (5)(B)(ii) resulting from the amendment made by section 4621(a)(1) of the Balanced Budget Act of 1997 or any additional payments under such paragraph resulting from the application of section 111 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, of section 302 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, or the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,

(ii) adjusting for variations among hospitals by area in the average hospital wage level,

(iii) adjusting for variations in case mix among hospitals, and

(iv) for discharges occurring on or after October 1, 1986, excluding an estimate of the additional payments to certain hospitals to be made under paragraph (5)(F), except that the Secretary shall not exclude additional payments under such paragraph made as a result of the enactment of section 6003(c) of the Omnibus Budget Reconciliation Act of 1989, the enactment of section 4002(b) of the Omnibus Budget Reconciliation Act of 1990, the enactment of section 303 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, or the enactment of section 402(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(D) COMPUTING URBAN AND RURAL AVERAGES.—The Secretary shall compute an average of the standardized amounts determined under subparagraph (C) for the United States and for each region—

(i) for all subsection (d) hospitals located in an urban area within the United States or that region, respectively, and

(ii) for all subsection (d) hospitals located in a rural area within the United States or that region, respectively.

For purposes of this subsection, the term "region" means one of the nine census divisions, comprising the fifty States and the District of Columbia, established by the Bureau of the Census for statistical and reporting purposes; the term "urban area" means an area within a Metropolitan Statistical Area (as defined by the Office of Management and Budget) or within such similar area as the Secretary has recognized under subsection (a) by regulation; the term "large urban area" means, with respect to a fiscal year, such an urban area which the Secretary determines (in the publications described in subsection (e)(5) before the fiscal year) has a population of more than 1,000,000 (as determined by the Secretary based on the most recent

available population data published by the Bureau of the Census); and the term "rural area" means any area outside such an area or similar area. A hospital located in a Metropolitan Statistical Area shall be deemed to be located in the region in which the largest number of the hospitals in the same Metropolitan Statistical Area are located, or, at the option of the Secretary, the region in which the majority of the inpatient discharges (with respect to which payments are made under this title) from hospitals in the same Metropolitan Statistical Area are made.

(E) REDUCING FOR VALUE OF OUTLIER PAYMENTS.—The Secretary shall reduce each of the average standardized amounts determined under subparagraph (D) by a proportion equal to the proportion (estimated by the Secretary) of the amount of payments under this subsection based on DRG prospective payment rates which are additional payments described in paragraph (5)(A) (relating to outlier payments).

(F) MAINTAINING BUDGET NEUTRALITY.—The Secretary shall adjust each of such average standardized amounts as may be required under subsection (e)(1)(B) for that fiscal year.

(G) COMPUTING DRG-SPECIFIC RATES FOR URBAN AND RURAL HOSPITALS IN THE UNITED STATES AND IN EACH REGION.—For each discharge classified within a diagnosis-related group, the Secretary shall establish a national DRG prospective payment rate and shall establish a regional DRG prospective payment rate for each region, each of which is equal—

(i) for hospitals located in an urban area in the United States or that region (respectively), to the product of—

(I) the average standardized amount (computed under subparagraph (D), reduced under subparagraph (E), and adjusted under subparagraph (F)) for hospitals located in an urban area in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group; and

(ii) for hospitals located in a rural area in the United States or that region (respectively), to the product of—

(I) the average standardized amount (computed under subparagraph (D), reduced under subparagraph (E), and adjusted under subparagraph (F)) for hospitals located in a rural area in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(H) ADJUSTING FOR DIFFERENT AREA WAGE LEVELS.—The Secretary shall adjust the proportion, (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the national and regional DRG prospective payment rates computed under subparagraph (G) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.

(3) The Secretary shall determine a national adjusted DRG prospective payment rate, for each inpatient hospital discharge in a

fiscal year after fiscal year 1984 involving inpatient hospital services of a subsection (d) hospital in the United States, and shall determine, for fiscal years before fiscal year 1997, a regional adjusted DRG prospective payment rate for such discharges in each region for which payment may be made under part A of this title. Each such rate shall be determined for hospitals located in large urban, other urban, or rural areas within the United States and within each such region, respectively, as follows:

(A) UPDATING PREVIOUS STANDARDIZED AMOUNTS.—(i) For discharges occurring in a fiscal year beginning before October 1, 1987, the Secretary shall compute an average standardized amount for hospitals located in an urban area and for hospitals located in a rural area within the United States and for hospitals located in an urban area and for hospitals located in a rural area within each region, equal to the respective average standardized amount computed for the previous fiscal year under paragraph (2)(D) or under this subparagraph, increased for the fiscal year involved by the applicable percentage increase under subsection (b)(3)(B). With respect to discharges occurring on or after October 1, 1987, the Secretary shall compute urban and rural averages on the basis of discharge weighting rather than hospital weighting, making appropriate adjustments to ensure that computation on such basis does not result in total payments under this section that are greater or less than the total payments that would have been made under this section but for this sentence, and making appropriate changes in the manner of determining the reductions under subparagraph (C)(ii).

(ii) For discharges occurring in a fiscal year beginning on or after October 1, 1987, and ending on or before September 30, 1994, the Secretary shall compute an average standardized amount for hospitals located in a large urban area, for hospitals located in a rural area, and for hospitals located in other urban areas, within the United States and within each region, equal to the respective average standardized amount computed for the previous fiscal year under this subparagraph increased by the applicable percentage increase under subsection (b)(3)(B)(i) with respect to hospitals located in the respective areas for the fiscal year involved.

(iii) For discharges occurring in the fiscal year beginning on October 1, 1994, the average standardized amount for hospitals located in a rural area shall be equal to the average standardized amount for hospitals located in an urban area. For discharges occurring on or after October 1, 1994, the Secretary shall adjust the ratio of the labor portion to non-labor portion of each average standardized amount to equal such ratio for the national average of all standardized amounts.

(iv)(I) Subject to subclause (II), for discharges occurring in a fiscal year beginning on or after October 1, 1995, the Secretary shall compute an average standardized amount for hospitals located in a large urban area and for hospitals located in other areas within the United States and within each region equal to the respective average standardized amount computed for the previous fiscal year under this subparagraph increased by the applicable percentage increase under subsection (b)(3)(B)(i)

with respect to hospitals located in the respective areas for the fiscal year involved.

(II) For discharges occurring in a fiscal year (beginning with fiscal year 2004), the Secretary shall compute a standardized amount for hospitals located in any area within the United States and within each region equal to the standardized amount computed for the previous fiscal year under this subparagraph for hospitals located in a large urban area (or, beginning with fiscal year 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B)(i) for the fiscal year involved.

(v) Average standardized amounts computed under this paragraph shall be adjusted to reflect the most recent case-mix data available.

(vi) Insofar as the Secretary determines that the adjustments under paragraph (4)(C)(i) for a previous fiscal year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under this subsection during the fiscal year that are a result of changes in the coding or classification of discharges that do not reflect real changes in case mix, the Secretary may adjust the average standardized amounts computed under this paragraph for subsequent fiscal years so as to eliminate the effect of such coding or classification changes.

(B) REDUCING FOR VALUE OF OUTLIER PAYMENTS.—The Secretary shall reduce each of the average standardized amounts determined under subparagraph (A) by a factor equal to the proportion of payments under this subsection (as estimated by the Secretary) based on DRG prospective payment amounts which are additional payments described in paragraph (5)(A) (relating to outlier payments).

(C)(i) MAINTAINING BUDGET NEUTRALITY FOR FISCAL YEAR 1985.—For discharges occurring in fiscal year 1985, the Secretary shall adjust each of such average standardized amounts as may be required under subsection (e)(1)(B) for that fiscal year.

(ii) REDUCING FOR SAVINGS FROM AMENDMENT TO INDIRECT TEACHING ADJUSTMENT FOR DISCHARGES AFTER SEPTEMBER 30, 1986.—For discharges occurring after September 30, 1986, the Secretary shall further reduce each of the average standardized amounts (in a proportion which takes into account the differing effects of the standardization effected under paragraph (2)(C)(i)) so as to provide for a reduction in the total of the payments (attributable to this paragraph) made for discharges occurring on or after October 1, 1986, of an amount equal to the estimated reduction in the payment amounts under paragraph (5)(B) that would have resulted from the enactment of the amendments made by section 9104 of the Medicare and Medicaid Budget Reconciliation Amendments of 1985 and by section 4003(a)(1) of the Omnibus Budget Reconciliation Act of 1987 if the factor described in clause (ii)(II) of paragraph (5)(B) (determined without regard to amendments made by the Omnibus Budget Reconciliation Act of 1990) were applied for discharges occurring on or after such date instead of the factor described in clause (ii) of that paragraph.

(D) COMPUTING DRG-SPECIFIC RATES FOR HOSPITALS.—For each discharge classified within a diagnosis-related group, the Secretary shall establish for the fiscal year a national DRG prospective payment rate and shall establish, for fiscal years before fiscal year 1997, a regional DRG prospective payment rate for each region which is equal—

(i) for fiscal years before fiscal year 2004, for hospitals located in a large urban area in the United States or that region (respectively), to the product of—

(I) the average standardized amount (computed under subparagraph (A), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C)) for the fiscal year for hospitals located in such a large urban area in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group;

(ii) for fiscal years before fiscal year 2004, for hospitals located in other areas in the United States or that region (respectively), to the product of—

(I) the average standardized amount (computed under subparagraph (A), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C)) for the fiscal year for hospitals located in other areas in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group; and

(iii) for a fiscal year beginning after fiscal year 2003, for hospitals located in all areas, to the product of—

(I) the applicable standardized amount (computed under subparagraph (A)), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C) for the fiscal year; and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(E) ADJUSTING FOR DIFFERENT AREA WAGE LEVELS.—

(i) IN GENERAL.—Except as provided in clause (ii) or (iii), the Secretary shall adjust the proportion, (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the DRG prospective payment rates computed under subparagraph (D) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. Not later than October 1, 1990, and October 1, 1993 (and at least every 12 months thereafter), the Secretary shall update the factor under the preceding sentence on the basis of a survey conducted by the Secretary (and updated as appropriate) of the wages and wage-related costs of subsection (d) hospitals in the United States. Not less often than once every 3 years the Secretary (through such survey or otherwise) shall measure the earnings and paid hours of employment by occupational category and shall exclude data with respect to the wages and wage-related costs incurred in furnishing skilled nursing facility serv-

ices. Any adjustments or updates made under this subparagraph for a fiscal year (beginning with fiscal year 1991) shall be made in a manner that assures that the aggregate payments under this subsection in the fiscal year are not greater or less than those that would have been made in the year without such adjustment. The Secretary shall apply the previous sentence for any period as if the amendments made by section 403(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the amendments made by section 10324(a)(1) of the Patient Protection and Affordable Care Act had not been enacted.

(ii) ALTERNATIVE PROPORTION TO BE ADJUSTED BEGINNING IN FISCAL YEAR 2005.—For discharges occurring on or after October 1, 2004, the Secretary shall substitute "62 percent" for the proportion described in the first sentence of clause (i), unless the application of this clause would result in lower payments to a hospital than would otherwise be made.

(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.

(III) FRONTIER COUNTY DEFINED.—In this clause, the term "frontier county" means a county in which the population per square mile is less than 6.

(IV) LIMITATION.—This clause shall not apply to any hospital located in a State that receives a non-labor related share adjustment under paragraph (5)(H).

(4)(A) The Secretary shall establish a classification of inpatient hospital discharges by diagnosis-related groups and a methodology for classifying specific hospital discharges within these groups.

(B) For each such diagnosis-related group the Secretary shall assign an appropriate weighting factor which reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups.

(C)(i) The Secretary shall adjust the classifications and weighting factors established under subparagraphs (A) and (B), for discharges in fiscal year 1988 and at least annually thereafter, to reflect changes in treatment patterns, technology (including a new medical service or technology under paragraph (5)(K)), and other factors which may change the relative use of hospital resources.

(ii) For discharges in fiscal year 1990, the Secretary shall reduce the weighting factor for each diagnosis-related group by 1.22 percent.

(iii) Any such adjustment under clause (i) for discharges in a fiscal year (beginning with fiscal year 1991) shall be made in a manner that assures that the aggregate payments under this sub-

section for discharges in the fiscal year are not greater or less than those that would have been made for discharges in the year without such adjustment.

(D)(i) For discharges occurring on or after October 1, 2008, the diagnosis-related group to be assigned under this paragraph for a discharge described in clause (ii) shall be a diagnosis-related group that does not result in higher payment based on the presence of a secondary diagnosis code described in clause (iv).

(ii) A discharge described in this clause is a discharge which meets the following requirements:

(I) The discharge includes a condition identified by a diagnosis code selected under clause (iv) as a secondary diagnosis.

(II) But for clause (i), the discharge would have been classified to a diagnosis-related group that results in a higher payment based on the presence of a secondary diagnosis code selected under clause (iv).

(III) At the time of admission, no code selected under clause (iv) was present.

(iii) As part of the information required to be reported by a hospital with respect to a discharge of an individual in order for payment to be made under this subsection, for discharges occurring on or after October 1, 2007, the information shall include the secondary diagnosis of the individual at admission.

(iv) By not later than October 1, 2007, the Secretary shall select diagnosis codes associated with at least two conditions, each of which codes meets all of the following requirements (as determined by the Secretary):

(I) Cases described by such code have a high cost or high volume, or both, under this title.

(II) The code results in the assignment of a case to a diagnosis-related group that has a higher payment when the code is present as a secondary diagnosis.

(III) The code describes such conditions that could reasonably have been prevented through the application of evidence-based guidelines.

The Secretary may from time to time revise (through addition or deletion of codes) the diagnosis codes selected under this clause so long as there are diagnosis codes associated with at least two conditions selected for discharges occurring during any fiscal year.

(v) In selecting and revising diagnosis codes under clause (iv), the Secretary shall consult with the Centers for Disease Control and Prevention and other appropriate entities.

(vi) Any change resulting from the application of this subparagraph shall not be taken into account in adjusting the weighting factors under subparagraph (C)(i) or in applying budget neutrality under subparagraph (C)(iii).

(5)(A)(i) For discharges occurring during fiscal years ending on or before September 30, 1997, the Secretary shall provide for an additional payment for a subsection (d) hospital for any discharge in a diagnosis-related group, the length of stay of which exceeds the mean length of stay for discharges within that group by a fixed number of days, or exceeds such mean length of stay by some fixed number of standard deviations, whichever is the fewer number of days.

(ii) For cases which are not included in clause (i), a subsection (d) hospital may request additional payments in any case where charges, adjusted to cost, exceed a fixed multiple of the applicable DRG prospective payment rate, or exceed such other fixed dollar amount, whichever is greater, or for discharges in fiscal years beginning on or after October 1, 1994, exceed the sum of the applicable DRG prospective payment rate plus any amounts payable under subparagraphs (B) and (F) plus a fixed dollar amount determined by the Secretary.

(iii) The amount of such additional payment under clauses (i) and (ii) shall be determined by the Secretary and shall (except as payments under clause (i) are required to be reduced to take into account the requirements of clause (v)) approximate the marginal cost of care beyond the cutoff point applicable under clause (i) or (ii).

(iv) The total amount of the additional payments made under this subparagraph for discharges in a fiscal year may not be less than 5 percent nor more than 6 percent of the total payments projected or estimated to be made based on DRG prospective payment rates for discharges in that year.

(v) The Secretary shall provide that—

(I) the day outlier percentage for fiscal year 1995 shall be 75 percent of the day outlier percentage for fiscal year 1994;

(II) the day outlier percentage for fiscal year 1996 shall be 50 percent of the day outlier percentage for fiscal year 1994; and

(III) the day outlier percentage for fiscal year 1997 shall be 25 percent of the day outlier percentage for fiscal year 1994.

(vi) For purposes of this subparagraph the term "day outlier percentage" means, for a fiscal year, the percentage of the total additional payments made by the Secretary under this subparagraph for discharges in that fiscal year which are additional payments under clause (i).

(B) The Secretary shall provide for an additional payment amount for subsection (d) hospitals with indirect costs of medical education, in an amount computed in the same manner as the adjustment for such costs under regulations (in effect as of January 1, 1983) under subsection (a)(2), except as follows:

(i) The amount of such additional payment shall be determined by multiplying (I) the sum of the amount determined under paragraph (1)(A)(ii)(II) (or, if applicable, the amount determined under paragraph (1)(A)(iii)) and, for cases qualifying for additional payment under subparagraph (A)(i), the amount paid to the hospital under subparagraph (A), by (II) the indirect teaching adjustment factor described in clause (ii).

(ii) For purposes of clause (i)(II), the indirect teaching adjustment factor is equal to c × (((1+r) to the nth power) − 1), where "r" is the ratio of the hospital's full-time equivalent interns and residents to beds and "n" equals .405. Subject to clause (ix), for discharges occurring—

(I) on or after October 1, 1988, and before October 1, 1997, "c" is equal to 1.89;

(II) during fiscal year 1998, "c" is equal to 1.72;

(III) during fiscal year 1999, "c" is equal to 1.6;

(IV) during fiscal year 2000, "c" is equal to 1.47;

(V) during fiscal year 2001, "c" is equal to 1.54;

(VI) during fiscal year 2002, "c" is equal to 1.6;

(VII) on or after October 1, 2002, and before April 1, 2004, "c" is equal to 1.35;

(VIII) on or after April 1, 2004, and before October 1, 2004, "c" is equal to 1.47;

(IX) during fiscal year 2005, "c" is equal to 1.42;

(X) during fiscal year 2006, "c" is equal to 1.37;

(XI) during fiscal year 2007, "c" is equal to 1.32; and

(XII) on or after October 1, 2007, "c" is equal to 1.35.

(iii) In determining such adjustment the Secretary shall not distinguish between those interns and residents who are employees of a hospital and those interns and residents who furnish services to a hospital but are not employees of such hospital.

(iv)(I) Effective for discharges occurring on or after October 1, 1997, and before July 1, 2010, all the time spent by an intern or resident in patient care activities under an approved medical residency training program at an entity in a nonhospital setting shall be counted towards the determination of full-time equivalency if the hospital incurs all, or substantially all, of the costs for the training program in that setting.

(II) Effective for discharges occurring on or after July 1, 2010, all the time spent by an intern or resident in patient care activities in a nonprovider setting shall be counted towards the determination of full-time equivalency if a hospital incurs the costs of the stipends and fringe benefits of the intern or resident during the time the intern or resident spends in that setting. If more than one hospital incurs these costs, either directly or through a third party, such hospitals shall count a proportional share of the time, as determined by written agreement between the hospitals, that a resident spends training in that setting.

(v) In determining the adjustment with respect to a hospital for discharges occurring on or after October 1, 1997, the total number of full-time equivalent interns and residents in the fields of allopathic and osteopathic medicine in either a hospital or nonhospital setting may not exceed the number (or, 130 percent of such number in the case of a hospital located in a rural area) of such full-time equivalent interns and residents in the hospital with respect to the hospital's most recent cost reporting period ending on or before December 31, 1996. Rules similar to the rules of subsection (h)(4)(F)(ii) shall apply for purposes of this clause. The provisions of subsections (h)(4)(H)(vi), (h)(7), and (h)(8) shall apply with respect to the first sentence of this clause in the same manner as they apply with respect to subsection (h)(4)(F)(i).

(vi) For purposes of clause (ii)—

(I) "r" may not exceed the ratio of the number of interns and residents, subject to the limit under clause (v), with respect to the hospital for its most recent cost reporting period to the hospital's available beds (as defined by the Secretary) during that cost reporting period, and

(II) for the hospital's cost reporting periods beginning on or after October 1, 1997, subject to the limits described in

clauses (iv) and (v), the total number of full-time equivalent residents for payment purposes shall equal the average of the actual full-time equivalent resident count for the cost reporting period and the preceding two cost reporting periods.

In the case of the first cost reporting period beginning on or after October 1, 1997, subclause (II) shall be applied by using the average for such period and the preceding cost reporting period.

(vii) If any cost reporting period beginning on or after October 1, 1997, is not equal to twelve months, the Secretary shall make appropriate modifications to ensure that the average full-time equivalent residency count pursuant to subclause (II) of clause (vi) is based on the equivalent of full twelve-month cost reporting periods.

(viii) Rules similar to the rules of subsection (h)(4)(H) shall apply for purposes of clauses (v) and (vi).

(ix) For discharges occurring on or after July 1, 2005, insofar as an additional payment amount under this subparagraph is attributable to resident positions redistributed to a hospital under subsection (h)(7)(B), in computing the indirect teaching adjustment factor under clause (ii) the adjustment shall be computed in a manner as if "c" were equal to 0.66 with respect to such resident positions.

(x) For discharges occurring on or after July 1, 2011, insofar as an additional payment amount under this subparagraph is attributable to resident positions distributed to a hospital under subsection (h)(8)(B), the indirect teaching adjustment factor shall be computed in the same manner as provided under clause (ii) with respect to such resident positions.

(x)(I) The provisions of subparagraph (K) of subsection (h)(4) shall apply under this subparagraph in the same manner as they apply under such subsection.

(II) In determining the hospital's number of full-time equivalent residents for purposes of this subparagraph, all the time spent by an intern or resident in an approved medical residency training program in non-patient care activities, such as didactic conferences and seminars, as such time and activities are defined by the Secretary, that occurs in the hospital shall be counted toward the determination of full-time equivalency if the hospital—

(aa) is recognized as a subsection (d) hospital;

(bb) is recognized as a subsection (d) Puerto Rico hospital;

(cc) is reimbursed under a reimbursement system authorized under section 1814(b)(3); or

(dd) is a provider-based hospital outpatient department.

(III) In determining the hospital's number of full-time equivalent residents for purposes of this subparagraph, all the time spent by an intern or resident in an approved medical residency training program in research activities that are not associated with the treatment or diagnosis of a particular patient, as such time

and activities are defined by the Secretary, shall not be counted toward the determination of full-time equivalency.

(C)(i) The Secretary shall provide for such exceptions and adjustments to the payment amounts established under this subsection (other than under paragraph (9)) as the Secretary deems appropriate to take into account the special needs of regional and national referral centers (including those hospitals of 275 or more beds located in rural areas). A hospital which is classified as a rural hospital may appeal to the Secretary to be classified as a rural referral center under this clause on the basis of criteria (established by the Secretary) which shall allow the hospital to demonstrate that it should be so reclassified by reason of certain of its operating characteristics being similar to those of a typical urban hospital located in the same census region and which shall not require a rural osteopathic hospital to have more than 3,000 discharges in a year in order to be classified as a rural referral center. Such characteristics may include wages, scope of services, service area, and the mix of medical specialties. The Secretary shall publish the criteria not later than August 17, 1984, for implementation by October 1, 1984. An appeal allowed under this clause must be submitted to the Secretary (in such form and manner as the Secretary may prescribe) during the quarter before the first quarter of the hospital's cost reporting period (or, in the case of a cost reporting period beginning during October 1984, during the first quarter of that period), and the Secretary must make a final determination with respect to such appeal within 60 days after the date the appeal was submitted. Any payment adjustments necessitated by a reclassification based upon the appeal shall be effective at the beginning of such cost reporting period.

(ii) The Secretary shall provide, under clause (i), for the classification of a rural hospital as a regional referral center if the hospital has a case mix index equal to or greater than the median case mix index for hospitals (other than hospitals with approved teaching programs) located in an urban area in the same region (as defined in paragraph (2)(D)), has at least 5,000 discharges a year or, if less, the median number of discharges in urban hospitals in the region in which the hospital is located (or, in the case of a rural osteopathic hospital, meets the criterion established by the Secretary under clause (i) with respect to the annual number of discharges for such hospitals), and meets any other criteria established by the Secretary under clause (i).

(D)(i) For any cost reporting period beginning on or after April 1, 1990, with respect to a subsection (d) hospital which is a sole community hospital, payment under paragraph (1)(A) shall be—

(I) an amount based on 100 percent of the hospital's target amount for the cost reporting period, as defined in subsection (b)(3)(C), or

(II) the amount determined under paragraph (1)(A)(iii),

whichever results in greater payment to the hospital.

(ii) In the case of a sole community hospital that experiences, in a cost reporting period compared to the previous cost reporting period, a decrease of more than 5 percent in its total number of inpatient cases due to circumstances beyond its control, the Secretary shall provide for such adjustment to the payment amounts under

this subsection (other than under paragraph (9)) as may be necessary to fully compensate the hospital for the fixed costs it incurs in the period in providing inpatient hospital services, including the reasonable cost of maintaining necessary core staff and services.

(iii) For purposes of this title, the term "sole community hospital" means any hospital—

(I) that the Secretary determines is located more than 35 road miles from another hospital,

(II) that, by reason of factors such as the time required for an individual to travel to the nearest alternative source of appropriate inpatient care (in accordance with standards promulgated by the Secretary), location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of inpatient hospital services reasonably available to individuals in a geographic area who are entitled to benefits under part A, or

(III) that is located in a rural area and designated by the Secretary as an essential access community hospital under section 1820(i)(1) as in effect on September 30, 1997.

(iv) The Secretary shall promulgate a standard for determining whether a hospital meets the criteria for classification as a sole community hospital under clause (iii)(II) because of the time required for an individual to travel to the nearest alternative source of appropriate inpatient care.

(v) If the Secretary determines that, in the case of a hospital located in a rural area and designated by the Secretary as an essential access community hospital under section 1820(i)(1) as in effect on September 30, 1997, the hospital has incurred increases in reasonable costs during a cost reporting period as a result of becoming a member of a rural health network (as defined in section 1820(d)) in the State in which it is located, and in incurring such increases, the hospital will increase its costs for subsequent cost reporting periods, the Secretary shall increase the hospital's target amount under subsection (b)(3)(C) to account for such incurred increases.

(E)(i) The Secretary shall estimate the amount of reimbursement made for services described in section 1862(a)(14) with respect to which payment was made under part B in the base reporting periods referred to in paragraph (2)(A) and with respect to which payment is no longer being made.

(ii) The Secretary shall provide for an adjustment to the payment for subsection (d) hospitals in each fiscal year so as appropriately to reflect the net amount described in clause (i).

(F)(i) Subject to subsection (r), for discharges occurring on or after May 1, 1986, the Secretary shall provide, in accordance with this subparagraph, for an additional payment amount for each subsection (d) hospital which—

(I) serves a significantly disproportionate number of low-income patients (as defined in clause (v)), or

(II) is located in an urban area, has 100 or more beds, and can demonstrate that its net inpatient care revenues (excluding any of such revenues attributable to this title or State plans approved under title XIX), during the cost reporting period in which the discharges occur, for indigent care from State and local government sources exceed 30 percent of its total of such net inpatient care revenues during the period.

(ii) Subject to clause (ix), the amount of such payment for each discharge shall be determined by multiplying (I) the sum of the amount determined under paragraph (1)(A)(ii)(II) (or, if applicable, the amount determined under paragraph (1)(A)(iii)) and, for cases qualifying for additional payment under subparagraph (A)(i), the amount paid to the hospital under subparagraph (A) for that discharge, by (II) the disproportionate share adjustment percentage established under clause (iii) or (iv) for the cost reporting period in which the discharge occurs.

(iii) The disproportionate share adjustment percentage for a cost reporting period for a hospital described in clause (i)(II) is equal to 35 percent.

(iv) The disproportionate share adjustment percentage for a cost reporting period for a hospital that is not described in clause (i)(II) and that—

(I) is located in an urban area and has 100 or more beds or is described in the second sentence of clause (v), is equal to the percent determined in accordance with the applicable formula described in clause (vii);

(II) is located in an urban area and has less than 100 beds, is equal to 5 percent or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xiii);

(III) is located in a rural area and is not described in subclause (IV) or (V) or in the second sentence of clause (v), is equal to 4 percent or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xii);

(IV) is located in a rural area, is classified as a rural referral center under subparagraph (C), and is classified as a sole community hospital under subparagraph (D), is equal to 10 percent or, if greater, the percent determined in accordance with the applicable formula described in clause (viii) or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, the greater of the percentages determined under clause (x) or (xi);

(V) is located in a rural area, is classified as a rural referral center under subparagraph (C), and is not classified as a sole community hospital under subparagraph (D), is equal to the percent determined in accordance with the applicable formula described in clause (viii) or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xi); or

(VI) is located in a rural area, is classified as a sole community hospital under subparagraph (D), and is not classified as a rural referral center under subparagraph (C), is 10 percent or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (x).

(v) In this subparagraph, a hospital "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals, or exceeds—

(I) 15 percent, if the hospital is located in an urban area and has 100 or more beds,

(II) 30 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and has more than 100 beds, or is located in a rural area and is classified as a sole community hospital under subparagraph (D),

(III) 40 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in an urban area and has less than 100 beds, or

(IV) 45 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and is not described in subclause (II).

A hospital located in a rural area and with 500 or more beds also "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals or exceeds a percentage specified by the Secretary.

(vi) In this subparagraph, the term "disproportionate patient percentage" means, with respect to a cost reporting period of a hospital, the sum of—

(I) the fraction (expressed as a percentage), the numerator of which is the number of such hospital's patient days for such period which were made up of patients who (for such days) were entitled to benefits under part A of this title and were entitled to supplementary security income benefits (excluding any State supplementation) under title XVI of this Act, and the denominator of which is the number of such hospital's patient days for such fiscal year which were made up of patients who (for such days) were entitled to benefits under part A of this title, and

(II) the fraction (expressed as a percentage), the numerator of which is the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under title XIX, but who were not entitled to benefits under part A of this title, and the denominator of which is the total number of the hospital's patient days for such period.

In determining under subclause (II) the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under title XIX, the Secretary may, to the extent and for the period the Secretary determines appropriate, include patient days of patients not so eligible but who are regarded as such because they receive benefits under a demonstration project approved under title XI.

(vii) The formula used to determine the disproportionate share adjustment percentage for a cost reporting period for a hospital described in clause (iv)(I) is—

(I) in the case of such a hospital with a disproportionate patient percentage (as defined in clause (vi)) greater than 20.2—

(a) for discharges occurring on or after April 1, 1990, and on or before December 31, 1990, (P–20.2)(.65) + 5.62,

(b) for discharges occurring on or after January 1, 1991, and on or before September 30, 1993, (P–20.2)(.7) + 5.62,

(c) for discharges occurring on or after October 1, 1993, and on or before September 30, 1994, (P–20.2)(.8) + 5.88, and

(d) for discharges occurring on or after October 1, 1994, (P–20.2)(.825) + 5.88; or

(II) in the case of any other such hospital—

(a) for discharges occurring on or after April 1, 1990, and on or before December 31, 1990, (P–15)(.6) + 2.5,

(b) for discharges occurring on or after January 1, 1991, and on or before September 30, 1993, (P–15)(.6) + 2.5,

(c) for discharges occurring on or after October 1, 1993, (P–15)(.65) + 2.5,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(viii) Subject to clause (xiv), the formula used to determine the disproportionate share adjustment percentage for a cost reporting period for a hospital described in clause (iv)(IV) or (iv)(V) is the percentage determined in accordance with the following formula:(P–30)(.6) + 4.0, where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(ix) In the case of discharges occurring—

(I) during fiscal year 1998, the additional payment amount otherwise determined under clause (ii) shall be reduced by 1 percent;

(II) during fiscal year 1999, such additional payment amount shall be reduced by 2 percent;

(III) during fiscal years 2000 and 2001, such additional payment amount shall be reduced by 3 percent and 2 percent, respectively;

(IV) during fiscal year 2002, such additional payment amount shall be reduced by 3 percent; and

(V) during fiscal year 2003 and each subsequent fiscal year, such additional payment amount shall be reduced by 0 percent.

(x) Subject to clause (xiv), for purposes of clause (iv)(VI) (relating to sole community hospitals), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P–15)(.65) + 2.5;

(II) is equal to or exceeds 19.3, but is less than 30.0, such adjustment percentage is equal to 5.25 percent; or

(III) is equal to or exceeds 30, such adjustment percentage is equal to 10 percent,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xi) Subject to clause (xiv), for purposes of clause (iv)(V) (relating to rural referral centers), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P–15)(.65) + 2.5;

(II) is equal to or exceeds 19.3, but is less than 30.0, such adjustment percentage is equal to 5.25 percent; or

(III) is equal to or exceeds 30, such adjustment percentage is determined in accordance with the following formula: (P–30)(.6) + 5.25,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xii) Subject to clause (xiv), for purposes of clause (iv)(III) (relating to small rural hospitals generally), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P–15)(.65) + 2.5; or

(II) is equal to or exceeds 19.3, such adjustment percentage is equal to 5.25 percent,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xiii) Subject to clause (xiv), for purposes of clause (iv)(II) (relating to urban hospitals with less than 100 beds), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P–15)(.65) + 2.5; or

(II) is equal to or exceeds 19.3, such adjustment percentage is equal to 5.25 percent,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xiv)(I) In the case of discharges occurring on or after April 1, 2004, subject to subclause (II), there shall be substituted for the disproportionate share adjustment percentage otherwise determined under clause (iv) (other than subclause (I)) or under clause (viii), (x), (xi), (xii), or (xiii), the disproportionate share adjustment percentage determined under clause (vii) (relating to large, urban hospitals).

(II) Under subclause (I), the disproportionate share adjustment percentage shall not exceed 12 percent for a hospital that is not classified as a rural referral center under subparagraph (C) or, in the case of discharges occurring on or after October 1, 2006, as a medicare-dependent, small rural hospital under subparagraph (G)(iv).

(G)(i) For any cost reporting period beginning on or after April 1, 1990, and before October 1, 1994, or discharges occurring on or after October 1, 1997, and before October 1, 2017, in the case of a subsection (d) hospital which is a medicare-dependent, small rural hospital, payment under paragraph (1)(A) shall be equal to the sum of the amount determined under clause (ii) and the amount determined under paragraph (1)(A)(iii).

(ii) The amount determined under this clause is—

(I) for discharges occurring during the 36-month period beginning with the first day of the cost reporting period that begins on or after April 1, 1990, the amount by which the hospital's target amount for the cost reporting period (as defined in subsection (b)(3)(D)) exceeds the amount determined under paragraph (1)(A)(iii); and

(II) for discharges occurring during any subsequent cost reporting period (or portion thereof) and before October 1, 1994, or discharges occurring on or after October 1, 1997, and before October 1, 2017, 50 percent (or 75 percent in the case of discharges occurring on or after October 1, 2006) of the amount by which the hospital's target amount for the cost reporting period or for discharges in the fiscal year (as defined in subsection (b)(3)(D)) exceeds the amount determined under paragraph (1)(A)(iii).

(iii) In the case of a medicare dependent, small rural hospital that experiences, in a cost reporting period compared to the previous cost reporting period, a decrease of more than 5 percent in its total number of inpatient cases due to circumstances beyond its control, the Secretary shall provide for such adjustment to the payment amounts under this subsection (other than under paragraph (9)) as may be necessary to fully compensate the hospital for the fixed costs it incurs in the period in providing inpatient hospital services, including the reasonable cost of maintaining necessary core staff and services.

(iv) The term "medicare-dependent, small rural hospital" means, with respect to any cost reporting period to which clause (i) applies, any hospital—

(I) located in a rural area,

(II) that has not more than 100 beds,

(III) that is not classified as a sole community hospital under subparagraph (D), and

(IV) for which not less than 60 percent of its inpatient days or discharges during the cost reporting period beginning in fiscal year 1987, or two of the three most recently audited cost reporting periods for which the Secretary has a settled cost report, were attributable to inpatients entitled to benefits under part A.

(H) The Secretary may provide for such adjustments to the payment amounts under this subsection as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii.

(I)(i) The Secretary shall provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate.

(ii) In making adjustments under clause (i) for transfer cases (as defined by the Secretary) in a fiscal year, not taking in account the effect of subparagraph (J), the Secretary may make adjustments to each of the average standardized amounts determined under paragraph (3) to assure that the aggregate payments made under this subsection for such fiscal year are not greater or lesser than those that would have otherwise been made in such fiscal year.

(J)(i) The Secretary shall treat the term "transfer case" (as defined in subparagraph (I)(ii)) as including the case of a qualified discharge (as defined in clause (ii)), which is classified within a diagnosis-related group described in clause (iii), and which occurs on or after October 1, 1998. In the case of a qualified discharge for which a substantial portion of the costs of care are incurred in the early days of the inpatient stay (as defined by the Secretary), in no case may the payment amount otherwise provided under this subsection exceed an amount equal to the sum of—

(I) 50 percent of the amount of payment under this subsection for transfer cases (as established under subparagraph (I)(i)), and

(II) 50 percent of the amount of payment which would have been made under this subsection with respect to the qualified discharge if no transfer were involved.

(ii) For purposes of clause (i), subject to clause (iii), the term "qualified discharge" means a discharge classified with a diagnosis-related group (described in clause (iii)) of an individual from a subsection (d) hospital, if upon such discharge the individual—

(I) is admitted as an inpatient to a hospital or hospital unit that is not a subsection (d) hospital for the provision of inpatient hospital services;

(II) is admitted to a skilled nursing facility;

(III) is provided home health services from a home health agency, if such services relate to the condition or diagnosis for which such individual received inpatient hospital services from the subsection (d) hospital, and if such services are provided within an appropriate period (as determined by the Secretary); or

(IV) for discharges occurring on or after October 1, 2000, the individual receives post discharge services described in clause (iv)(I).

(iii) Subject to clause (iv), a diagnosis-related group described in this clause is—

(I) 1 of 10 diagnosis-related groups selected by the Secretary based upon a high volume of discharges classified within such groups and a disproportionate use of post discharge services described in clause (ii); and

(II) a diagnosis-related group specified by the Secretary under clause (iv)(II).

(iv) The Secretary shall include in the proposed rule published under subsection (e)(5)(A) for fiscal year 2001, a description of the effect of this subparagraph. The Secretary may include in the proposed rule (and in the final rule published under paragraph (6)) for fiscal year 2001 or a subsequent fiscal year, a description of—

(I) post-discharge services not described in subclauses (I), (II), and (III) of clause (ii), the receipt of which results in a qualified discharge; and

(II) diagnosis-related groups described in clause (iii)(I) in addition to the 10 selected under such clause.

(K)(i) Effective for discharges beginning on or after October 1, 2001, the Secretary shall establish a mechanism to recognize the costs of new medical services and technologies under the payment system established under this subsection. Such mechanism shall be established after notice and opportunity for public comment (in the publications required by subsection (e)(5) for a fiscal year or otherwise). Such mechanism shall be modified to meet the requirements of clause (viii).

(ii) The mechanism established pursuant to clause (i) shall—

(I) apply to a new medical service or technology if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate (applying a threshold specified by the

Secretary that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation for the diagnosis-related group involved);

(II) provide for the collection of data with respect to the costs of a new medical service or technology described in subclause (I) for a period of not less than two years and not more than three years beginning on the date on which an inpatient hospital code is issued with respect to the service or technology;

(III) provide for additional payment to be made under this subsection with respect to discharges involving a new medical service or technology described in subclause (I) that occur during the period described in subclause (II) in an amount that adequately reflects the estimated average cost of such service or technology; and

(IV) provide that discharges involving such a service or technology that occur after the close of the period described in subclause (II) will be classified within a new or existing diagnosis-related group with a weighting factor under paragraph (4)(B) that is derived from cost data collected with respect to discharges occurring during such period.

(iii) For purposes of clause (ii)(II), the term "inpatient hospital code" means any code that is used with respect to inpatient hospital services for which payment may be made under this subsection and includes an alphanumeric code issued under the International Classification of Diseases, 9th Revision, Clinical Modification ("ICD–9–CM") and its subsequent revisions.

(iv) For purposes of clause (ii)(III), the term "additional payment" means, with respect to a discharge for a new medical service or technology described in clause (ii)(I), an amount that exceeds the prospective payment rate otherwise applicable under this subsection to discharges involving such service or technology that would be made but for this subparagraph.

(v) The requirement under clause (ii)(III) for an additional payment may be satisfied by means of a new-technology group (described in subparagraph (L)), an add-on payment, a payment adjustment, or any other similar mechanism for increasing the amount otherwise payable with respect to a discharge under this subsection. The Secretary may not establish a separate fee schedule for such additional payment for such services and technologies, by utilizing a methodology established under subsection (a) or (h) of section 1834 to determine the amount of such additional payment, or by other similar mechanisms or methodologies.

(vi) For purposes of this subparagraph and subparagraph (L), a medical service or technology will be considered a "new medical service or technology" if the service or technology *if additional payment has never been made under this subsection pursuant to subparagraph (M) with respect to the service or technology* meets criteria established by the Secretary after notice and an opportunity for public comment.

(vii) Under the mechanism under this subparagraph, the Secretary shall provide for the addition of new diagnosis and procedure codes in April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-

related group classification) under this subsection until the fiscal year that begins after such date.

(viii) The mechanism established pursuant to clause (i) shall be adjusted to provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of individuals entitled to benefits under part A as follows:

(I) The Secretary shall make public and periodically update a list of all the services and technologies for which an application for additional payment under this subparagraph is pending.

(II) The Secretary shall accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.

(III) The Secretary shall provide for a meeting at which organizations representing hospitals, physicians, such individuals, manufacturers, and any other interested party may present comments, recommendations, and data to the clinical staff of the Centers for Medicare & Medicaid Services before publication of a notice of proposed rulemaking regarding whether service or technology represents a substantial improvement.

(ix) Before establishing any add-on payment under this subparagraph with respect to a new technology, the Secretary shall seek to identify one or more diagnosis-related groups associated with such technology, based on similar clinical or anatomical characteristics and the cost of the technology. Within such groups the Secretary shall assign an eligible new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care of using the new technology. No add-on payment under this subparagraph shall be made with respect to such new technology and this clause shall not affect the application of paragraph (4)(C)(iii).

(L)(i) In establishing the mechanism under subparagraph (K), the Secretary may establish new-technology groups into which a new medical service or technology will be classified if, based on the estimated average costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate.

(ii) Such groups—

(I) shall not be based on the costs associated with a specific new medical service or technology; but

(II) shall, in combination with the applicable standardized amounts and the weighting factors assigned to such groups under paragraph (4)(B), reflect such cost cohorts as the Secretary determines are appropriate for all new medical services and technologies that are likely to be provided as inpatient hospital services in a fiscal year.

(iii) The methodology for classifying specific hospital discharges within a diagnosis-related group under paragraph (4)(A) or a new-technology group shall provide that a specific hospital discharge may not be classified within both a diagnosis-related group and a new-technology group.

(M)(i) As part of the annual rulemaking under this subsection for payment for subsection (d) hospitals for each fiscal year beginning with fiscal year 2018, the Secretary shall—

(I) include publication of a list of the new antimicrobial drugs for such fiscal year; and

(II) with respect to discharges by eligible hospitals that involve a drug so published, provide for an additional payment to be made under this subsection in accordance with the provisions of this subparagraph.

(ii) Additional payments may not be made for a drug under this subparagraph—

(I) other than during the 5-fiscal-year period beginning with the fiscal year for which the drug is first included in the publication described in clause (i)(I); and

(II) with respect to which payment has ever been made pursuant to subparagraph (K).

(iii) For purposes of this subparagraph, the term "new antimicrobial drug" means a product that is approved for use, or a product for which an indication is first approved for use, by the Food and Drug Administration on or after December 1, 2014, and that the Food and Drug Administration determines—

(I) either—

(aa) is intended to treat an infection caused by, or likely to be caused by, a qualifying pathogen (as defined under section 505E(f) of the Federal Food, Drug, and Cosmetic Act); or

(bb) meets the definition of a qualified infectious disease product under section 505E(g) of the Federal Food, Drug, and Cosmetic Act; and

(II) is intended to treat an infection—

(aa) for which there is an unmet medical need; and

(bb) which is associated with high rates of mortality or significant patient morbidity, as determined in consultation with the Director of the Centers for Disease Control and Prevention and the infectious disease professional community.Such determination may be revoked only upon a finding that the request for such determination contained an untrue statement of material fact.

(iv) For purposes of this subparagraph, the term "eligible hospital" means a subsection (d) hospital that participates in the National Healthcare Safety Network of the Centers for Disease Control and Prevention (or, to the extent a similar surveillance system reporting program that includes reporting about antimicrobial drugs is determined by the Secretary to be available to such hospitals, such similar surveillance system as the Secretary may specify).

(v)(I) Subject to the succeeding provisions of this clause, the additional payment under this subparagraph, with respect to a drug, shall be in the amount provided for such drug under section 1847A.

(II) The Secretary shall, as part of the rulemaking referred to in clause (i) for each fiscal year, estimate—

(aa) the total amount of the additional payments that will be made under this subsection pursuant to this subparagraph for discharges in such fiscal year without regard to the application of subclause (III); and

(bb) the total program payments to be made under this subsection for all discharges in such fiscal year.

(III) If the estimated total amount described in subclause (II)(aa) for a fiscal year exceeds the applicable percentage of the estimated total program payments described in subclause (II)(bb) for such fiscal year, the Secretary shall reduce in a pro rata manner the amount of each additional payment under this subsection pursuant to this subparagraph for such fiscal year in order to ensure that the total amount of the additional payments under this subsection pursuant to this subparagraph for such fiscal year do not exceed the applicable percentage of the estimated total program payments described in subclause (II)(bb) for such fiscal year.

(IV) For purposes of subclause (III), the term "applicable percentage" means 0.03 percent.

(6) The Secretary shall provide for publication in the Federal Register, on or before the August 1 before each fiscal year (beginning with fiscal year 1984), of a description of the methodology and data used in computing the adjusted DRG prospective payment rates under this subsection, including any adjustments required under subsection (e)(1)(B).

(7) There shall be no administrative or judicial review under section 1878 or otherwise of—

(A) the determination of the requirement, or the proportional amount, of any adjustment effected pursuant to subsection (e)(1) or the determination of the applicable percentage increase under paragraph (12)(A)(ii),

(B) the establishment of diagnosis-related groups, of the methodology for the classification of discharges within such groups, and of the appropriate weighting factors thereof under paragraph (4), including the selection and revision of codes under paragraph (4)(D), and

(C) the determination of whether services provided prior to a patient's inpatient admission are related to the admission (as described in subsection (a)(4)).

(8)(A) In the case of any hospital which is located in an area which is, at any time after April 20, 1983, reclassified from an urban to a rural area, payments to such hospital for the first two cost reporting periods for which such reclassification is effective shall be made as follows:

(i) For the first such cost reporting period, payment shall be equal to the amount payable to such hospital for such reporting period on the basis of the rural classification, plus an amount equal to two-thirds of the amount (if any) by which—

(I) the amount which would have been payable to such hospital for such reporting period on the basis of an urban classification, exceeds

(II) the amount payable to such hospital for such reporting period on the basis of the rural classification.

(ii) For the second such cost reporting period, payment shall be equal to the amount payable to such hospital for such reporting period on the basis of the rural classification, plus an amount equal to one-third of the amount (if any) by which—

(I) the amount which would have been payable to such hospital for such reporting period on the basis of an urban classification, exceeds

(II) the amount payable to such hospital for such reporting period on the basis of the rural classification.

(B)(i) For purposes of this subsection, the Secretary shall treat a hospital located in a rural county adjacent to one or more urban areas as being located in the urban metropolitan statistical area to which the greatest number of workers in the county commute, if the rural county would otherwise be considered part of an urban area, under the standards for designating Metropolitan Statistical Areas (and for designating New England County Metropolitan Areas) described in clause (ii), if the commuting rates used in determining outlying counties (or, for New England, similar recognized areas) were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or counties of all contiguous Metropolitan Statistical Areas (or New England County Metropolitan Areas).

(ii) The standards described in this clause for cost reporting periods beginning in a fiscal year—

(I) before fiscal year 2003, are the standards published in the Federal Register on January 3, 1980, or, at the election of the hospital with respect to fiscal years 2001 and 2002, standards so published on March 30, 1990; and

(II) after fiscal year 2002, are the standards published in the Federal Register by the Director of the Office of Management and Budget based on the most recent available decennial population data.

Subparagraphs (C) and (D) shall not apply with respect to the application of subclause (I).

(C)(i) If the application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10), by treating hospitals located in a rural county or counties as being located in an urban area, or by treating hospitals located in one urban area as being located in another urban area—

(I) reduces the wage index for that urban area (as applied under this subsection) by 1 percentage point or less, the Secretary, in calculating such wage index under this subsection, shall exclude those hospitals so treated, or

(II) reduces the wage index for that urban area by more than 1 percentage point (as applied under this subsection), the Secretary shall calculate and apply such wage index under this subsection separately to hospitals located in such urban area (excluding all the hospitals so treated) and to the hospitals so treated (as if such hospitals were located in such urban area).

(ii) If the application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10), by treating hospitals located in a rural county or counties as not being located in the rural area in a State, reduces the wage index for that rural area (as applied under this subsection), the Secretary shall calculate and apply such wage index under this subsection as if the hospitals so treated had not been excluded from calculation of the wage index for that rural area.

(iii) The application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary

under paragraph (10) may not result in the reduction of any county's wage index to a level below the wage index for rural areas in the State in which the county is located.

(iv) The application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or of the Secretary under paragraph (10) may not result in a reduction in an urban area's wage index if—

(I) the urban area has a wage index below the wage index for rural areas in the State in which it is located; or

(II) the urban area is located in a State that is composed of a single urban area.

(v) This subparagraph shall apply with respect to discharges occurring in a fiscal year only if the Secretary uses a method for making adjustments to the DRG prospective payment rate for area differences in hospital wage levels under paragraph (3)(E) for the fiscal year that is based on the use of Metropolitan Statistical Area classifications.

(D) The Secretary shall make a proportional adjustment in the standardized amounts determined under paragraph (3) to assure that the provisions of subparagraphs (B) and (C) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10) do not result in aggregate payments under this section that are greater or less than those that would otherwise be made.

(E)(i) For purposes of this subsection, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital described in clause (ii), the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located.

(ii) For purposes of clause (i), a subsection (d) hospital described in this clause is a subsection (d) hospital that is located in an urban area (as defined in paragraph (2)(D)) and satisfies any of the following criteria:

(I) The hospital is located in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)).

(II) The hospital is located in an area designated by any law or regulation of such State as a rural area (or is designated by such State as a rural hospital).

(III) The hospital would qualify as a rural, regional, or national referral center under paragraph (5)(C) or as a sole community hospital under paragraph (5)(D) if the hospital were located in a rural area.

(IV) The hospital meets such other criteria as the Secretary may specify.

(9)(A) Notwithstanding section 1814(b) but subject to the provisions of section 1813, the amount of the payment with respect to the operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges is equal to the sum of—

(i) the applicable Puerto Rico percentage (specified in subparagraph (E)) of the Puerto Rico adjusted DRG prospective

payment rate (determined under subparagraph (B) or (C)) for such discharges,

(ii) the applicable Federal percentage (specified in subparagraph (E)) of—

(I) for discharges beginning in a fiscal year beginning on or after October 1, 1997, and before October 1, 2003, the discharge-weighted average of—

(aa) the national adjusted DRG prospective payment rate (determined under paragraph (3)(D)) for hospitals located in a large urban area,

(bb) such rate for hospitals located in other urban areas, and

(cc) such rate for hospitals located in a rural area, for such discharges, adjusted in the manner provided in paragraph (3)(E) for different area wage levels; and

(II) for discharges in a fiscal year beginning on or after October 1, 2003, the national DRG prospective payment rate determined under paragraph (3)(D)(iii) for hospitals located in any area for such discharges, adjusted in the manner provided in paragraph (3)(E) for different area wage levels.

As used in this section, the term "subsection (d) Puerto Rico hospital" means a hospital that is located in Puerto Rico and that would be a subsection (d) hospital (as defined in paragraph (1)(B)) if it were located in one of the 50 States.

(B) The Secretary shall determine a Puerto Rico adjusted DRG prospective payment rate, for each inpatient hospital discharge in fiscal year 1988 involving inpatient hospital services of a subsection (d) Puerto Rico hospital for which payment may be made under part A of this title. Such rate shall be determined for such hospitals located in urban or rural areas within Puerto Rico, as follows:

(i) The Secretary shall determine the target amount (as defined in subsection (b)(3)(A)) for the hospital for the cost reporting period beginning in fiscal year 1987 and increase such amount by prorating the applicable percentage increase (as defined in subsection (b)(3)(B)) to update the amount to the midpoint in fiscal year 1988.

(ii) The Secretary shall standardize the amount determined under clause (i) for each hospital by—

(I) excluding an estimate of indirect medical education costs,

(II) adjusting for variations among hospitals by area in the average hospital wage level,

(III) adjusting for variations in case mix among hospitals, and

(IV) excluding an estimate of the additional payments to certain subsection (d) Puerto Rico hospitals to be made under subparagraph (D)(iii) (relating to disproportionate share payments).

(iii) The Secretary shall compute a discharge weighted average of the standardized amounts determined under clause (ii) for all hospitals located in an urban area and for all hospitals located in a rural area (as such terms are defined in paragraph (2)(D)).

(iv) The Secretary shall reduce the average standardized amount by a proportion equal to the proportion (estimated by the Secretary) of the amount of payments under this paragraph which are additional payments described in subparagraph (D)(i) (relating to outlier payments).

(v) For each discharge classified within a diagnosis-related group for hospitals located in an urban or rural area, respectively, the Secretary shall establish a Puerto Rico DRG prospective payment rate equal to the product of—

(I) the average standardized amount (computed under clause (iii) and reduced under clause (iv)) for hospitals located in an urban or rural area, respectively, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(vi) The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the Puerto Rico DRG prospective payment rate computed under clause (v) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the Puerto Rican average hospital wage level.

(C) The Secretary shall determine a Puerto Rico adjusted DRG prospective payment rate, for each inpatient hospital discharge after fiscal year 1988 involving inpatient hospital services of a subsection (d) Puerto Rico hospital for which payment may be made under part A of this title. Such rate shall be determined for hospitals located in urban or rural areas within Puerto Rico as follows:

(i)(I) For discharges in a fiscal year after fiscal year 1988 and before fiscal year 2004, the Secretary shall compute an average standardized amount for hospitals located in an urban area and for hospitals located in a rural area equal to the respective average standardized amount computed for the previous fiscal year under subparagraph (B)(iii) or under this clause, increased for fiscal year 1989 by the applicable percentage increase under subsection (b)(3)(B), and adjusted for subsequent fiscal years in accordance with the final determination of the Secretary under subsection (e)(4), and adjusted to reflect the most recent case-mix data available.

(II) For discharges occurring in a fiscal year (beginning with fiscal year 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for fiscal year 2003 for hospitals in a large urban area (or, beginning with fiscal year 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved.

(ii) The Secretary shall reduce each of the average standardized amounts (or for fiscal year 2004 and thereafter, the average standardized amount) by a proportion equal to the proportion (estimated by the Secretary) of the amount of payments under this paragraph which are additional payments described in subparagraph (D)(i) (relating to outlier payments).

(iii) For each discharge classified within a diagnosis-related group for hospitals located in an urban or rural area, respectively, the Secretary shall establish a Puerto Rico DRG prospective payment rate equal to the product of—

(I) the average standardized amount (computed under clause (i) and reduced under clause (ii)), and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(iv)(I) The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the Puerto Rico DRG prospective payment rate computed under clause (iii) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the Puerto Rico average hospital wage level. The second and third sentences of paragraph (3)(E)(i) shall apply to subsection (d) Puerto Rico hospitals under this clause in the same manner as they apply to subsection (d) hospitals under such paragraph and, for purposes of this clause, any reference in such paragraph to a subsection (d) hospital is deemed a reference to a subsection (d) Puerto Rico hospital.

(II) For discharges occurring on or after October 1, 2004, the Secretary shall substitute "62 percent" for the proportion described in the first sentence of clause (i), unless the application of this subclause would result in lower payments to a hospital than would otherwise be made.

(D) The following provisions of paragraph (5) shall apply to subsection (d) Puerto Rico hospitals receiving payment under this paragraph in the same manner and to the extent as they apply to subsection (d) hospitals receiving payment under this subsection:

(i) Subparagraph (A) (relating to outlier payments).

(ii) Subparagraph (B) (relating to payments for indirect medical education costs), except that for this purpose the sum of the amount determined under subparagraph (A) of this paragraph and the amount paid to the hospital under clause (i) of this subparagraph shall be substituted for the sum referred to in paragraph (5)(B)(i)(I).

(iii) Subparagraph (F) (relating to disproportionate share payments), except that for this purpose the sum described in clause (ii) of this subparagraph shall be substituted for the sum referred to in paragraph (5)(F)(ii)(I).

(iv) Subparagraph (H) (relating to exceptions and adjustments).

(E) For purposes of subparagraph (A), for discharges occurring—

(i) on or after October 1, 1987, and before October 1, 1997, the applicable Puerto Rico percentage is 75 percent and the applicable Federal percentage is 25 percent;

(ii) on or after October 1, 1997, and before April 1, 2004, the applicable Puerto Rico percentage is 50 percent and the applicable Federal percentage is 50 percent;

(iii) on or after April 1, 2004, and before October 1, 2004, the applicable Puerto Rico percentage is 37.5 percent and the applicable Federal percentage is 62.5 percent; and

(iv) on or after October 1, 2004, the applicable Puerto Rico percentage is 25 percent and the applicable Federal percentage is 75 percent.

(10)(A) There is hereby established the Medicare Geographic Classification Review Board (hereinafter in this paragraph referred to as the "Board").

(B)(i) The Board shall be composed of 5 members appointed by the Secretary without regard to the provisions of title 5, United States Code, governing appointments in the competitive service. Two of such members shall be representative of subsection (d) hospitals located in a rural area under paragraph (2)(D). At least 1 member shall be knowledgeable in the field of analyzing costs with respect to the provision of inpatient hospital services.

(ii) The Secretary shall make initial appointments to the Board as provided in this paragraph within 180 days after the date of the enactment of this paragraph.

(C)(i) The Board shall consider the application of any subsection (d) hospital requesting that the Secretary change the hospital's geographic classification for purposes of determining for a fiscal year—

(I) the hospital's average standardized amount under paragraph (2)(D), or

(II) the factor used to adjust the DRG prospective payment rate for area differences in hospital wage levels that applies to such hospital under paragraph (3)(E).

(ii) A hospital requesting a change in geographic classification under clause (i) for a fiscal year shall submit its application to the Board not later than the first day of the 13-month period ending on September 30 of the preceding fiscal year.

(iii)(I) The Board shall render a decision on an application submitted under clause (i) not later than 180 days after the deadline referred to in clause (ii).

(II) Appeal of decisions of the Board shall be subject to the provisions of section 557b of title 5, United States Code. The Secretary shall issue a decision on such an appeal not later than 90 days after the date on which the appeal is filed. The decision of the Secretary shall be final and shall not be subject to judicial review.

(D)(i) The Secretary shall publish guidelines to be utilized by the Board in rendering decisions on applications submitted under this paragraph, and shall include in such guidelines the following:

(I) Guidelines for comparing wages, taking into account (to the extent the Secretary determines appropriate) occupational mix, in the area in which the hospital is classified and the area in which the hospital is applying to be classified.

(II) Guidelines for determining whether the county in which the hospital is located should be treated as being a part of a particular Metropolitan Statistical Area.

(III) Guidelines for considering information provided by an applicant with respect to the effects of the hospital's geographic classification on access to inpatient hospital services by medicare beneficiaries.

(IV) Guidelines for considering the appropriateness of the criteria used to define New England County Metropolitan Areas.

(ii) Notwithstanding clause (i), if the Secretary uses a method for making adjustments to the DRG prospective payment rate for area

differences in hospital wage levels under paragraph (3)(E) that is not based on the use of Metropolitan Statistical Area classifications, the Secretary may revise the guidelines published under clause (i) to the extent such guidelines are used to determine the appropriateness of the geographic area in which the hospital is determined to be located for purposes of making such adjustments.

(iii) Under the guidelines published by the Secretary under clause (i), in the case of a hospital which has ever been classified by the Secretary as a rural referral center under paragraph (5)(C), the Board may not reject the application of the hospital under this paragraph on the basis of any comparison between the average hourly wage of the hospital and the average hourly wage of hospitals in the area in which it is located.

(iv) The Secretary shall publish the guidelines described in clause (i) by July 1, 1990.

(v) Any decision of the Board to reclassify a subsection (d) hospital for purposes of the adjustment factor described in subparagraph (C)(i)(II) for fiscal year 2001 or any fiscal year thereafter shall be effective for a period of 3 fiscal years, except that the Secretary shall establish procedures under which a subsection (d) hospital may elect to terminate such reclassification before the end of such period.

(vi) Such guidelines shall provide that, in making decisions on applications for reclassification for the purposes described in clause (v) for fiscal year 2003 and any succeeding fiscal year, the Board shall base any comparison of the average hourly wage for the hospital with the average hourly wage for hospitals in an area on—

(I) an average of the average hourly wage amount for the hospital from the most recently published hospital wage survey data of the Secretary (as of the date on which the hospital applies for reclassification) and such amount from each of the two immediately preceding surveys; and

(II) an average of the average hourly wage amount for hospitals in such area from the most recently published hospital wage survey data of the Secretary (as of the date on which the hospital applies for reclassification) and such amount from each of the two immediately preceding surveys.

(E)(i) The Board shall have full power and authority to make rules and establish procedures, not inconsistent with the provisions of this title or regulations of the Secretary, which are necessary or appropriate to carry out the provisions of this paragraph. In the course of any hearing the Board may administer oaths and affirmations. The provisions of subsections (d) and (e) of section 205 with respect to subpenas shall apply to the Board to the same extent as such provisions apply to the Secretary with respect to title II.

(ii) The Board is authorized to engage such technical assistance and to receive such information as may be required to carry out its functions, and the Secretary shall, in addition, make available to the Board such secretarial, clerical, and other assistance as the Board may require to carry out its functions.

(F)(i) Each member of the Board who is not an officer or employee of the Federal Government shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for grade GS–18 of the General Schedule under section 5332 of title 5, United States Code, for each day (including travel

time) during which such member is engaged in the performance of the duties of the Board. Each member of the Board who is an officer or employee of the United States shall serve without compensation in addition to that received for service as an officer or employee of the United States.

(ii) Members of the Board shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Board.

(11) ADDITIONAL PAYMENTS FOR MANAGED CARE ENROLLEES.—

(A) IN GENERAL.—For portions of cost reporting periods occurring on or after January 1, 1998, the Secretary shall provide for an additional payment amount for each applicable discharge of any subsection (d) hospital that has an approved medical residency training program.

(B) APPLICABLE DISCHARGE.—For purposes of this paragraph, the term "applicable discharge" means the discharge of any individual who is enrolled under a risk-sharing contract with an eligible organization under section 1876 and who is entitled to benefits under part A or any individual who is enrolled with a Medicare+Choice organization under part C.

(C) DETERMINATION OF AMOUNT.—The amount of the payment under this paragraph with respect to any applicable discharge shall be equal to the applicable percentage (as defined in subsection (h)(3)(D)(ii)) of the estimated average per discharge amount that would otherwise have been paid under paragraph (5)(B) if the individuals had not been enrolled as described in subparagraph (B).

(D) SPECIAL RULE FOR HOSPITALS UNDER REIMBURSEMENT SYSTEM.—The Secretary shall establish rules for the application of this paragraph to a hospital reimbursed under a reimbursement system authorized under section 1814(b)(3) in the same manner as it would apply to the hospital if it were not reimbursed under such section.

(12) PAYMENT ADJUSTMENT FOR LOW-VOLUME HOSPITALS.—

(A) IN GENERAL.—In addition to any payments calculated under this section for a subsection (d) hospital, for discharges occurring during a fiscal year (beginning with fiscal year 2005), the Secretary shall provide for an additional payment amount to each low-volume hospital (as defined in subparagraph (C)(i)) for discharges occurring during that fiscal year that is equal to the applicable percentage increase (determined under subparagraph (B) or (D) for the hospital involved) in the amount paid to such hospital under this section for such discharges (determined without regard to this paragraph).

(B) APPLICABLE PERCENTAGE INCREASE.—For discharges occurring in fiscal years 2005 through 2010 and for discharges occurring in fiscal year 2018 and subsequent fiscal years, the Secretary shall determine an applicable percentage increase for purposes of subparagraph (A) as follows:

(i) The Secretary shall determine the empirical relationship for subsection (d) hospitals between the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges.

(ii) The applicable percentage increase shall be determined based upon such relationship in a manner that reflects, based upon the number of such discharges for a subsection (d) hospital, such additional incremental costs.

(iii) In no case shall the applicable percentage increase exceed 25 percent.

(C) DEFINITIONS.—

(i) LOW-VOLUME HOSPITAL.—For purposes of this paragraph, the term "low-volume hospital" means, for a fiscal year, a subsection (d) hospital (as defined in paragraph (1)(B)) that the Secretary determines is located more than 25 road miles (or, with respect to fiscal years 2011 through 2017, 15 road miles) from another subsection (d) hospital and has less than 800 discharges (or, with respect to fiscal years 2011 through 2017, 1,600 discharges of individuals entitled to, or enrolled for, benefits under part A) during the fiscal year or portion of fiscal year.

(ii) DISCHARGE.—For purposes of subparagraph (B) and clause (i), the term "discharge" means an inpatient acute care discharge of an individual regardless of whether the individual is entitled to benefits under part A.

(D) TEMPORARY APPLICABLE PERCENTAGE INCREASE.—For discharges occurring in fiscal years 2011 through 2017, 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 or the portion of fiscal year to 0 percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal year.

(13)(A) In order to recognize commuting patterns among geographic areas, the Secretary shall establish a process through application or otherwise for an increase of the wage index applied under paragraph (3)(E) for subsection (d) hospitals located in a qualifying county described in subparagraph (B) in the amount computed under subparagraph (D) based on out-migration of hospital employees who reside in that county to any higher wage index area.

(B) The Secretary shall establish criteria for a qualifying county under this subparagraph based on the out-migration referred to in subparagraph (A) and differences in the area wage indices. Under such criteria the Secretary shall, utilizing such data as the Secretary determines to be appropriate, establish—

(i) a threshold percentage, established by the Secretary, of the weighted average of the area wage index or indices for the higher wage index areas involved;

(ii) a threshold (of not less than 10 percent) for minimum out-migration to a higher wage index area or areas; and

(iii) a requirement that the average hourly wage of the hospitals in the qualifying county equals or exceeds the average hourly wage of all the hospitals in the area in which the qualifying county is located.

(C) For purposes of this paragraph, the term "higher wage index area" means, with respect to a county, an area with a wage index that exceeds that of the county.

(D) The increase in the wage index under subparagraph (A) for a qualifying county shall be equal to the percentage of the hospital employees residing in the qualifying county who are employed in any higher wage index area multiplied by the sum of the products, for each higher wage index area of—

(i) the difference between—

(I) the wage index for such higher wage index area, and

(II) the wage index of the qualifying county; and

(ii) the number of hospital employees residing in the qualifying county who are employed in such higher wage index area divided by the total number of hospital employees residing in the qualifying county who are employed in any higher wage index area.

(E) The process under this paragraph may be based upon the process used by the Medicare Geographic Classification Review Board under paragraph (10). As the Secretary determines to be appropriate to carry out such process, the Secretary may require hospitals (including subsection (d) hospitals and other hospitals) and critical access hospitals, as required under section 1866(a)(1)(T), to submit data regarding the location of residence, or the Secretary may use data from other sources.

(F) A wage index increase under this paragraph shall be effective for a period of 3 fiscal years, except that the Secretary shall establish procedures under which a subsection (d) hospital may elect to waive the application of such wage index increase.

(G) A hospital in a county that has a wage index increase under this paragraph for a period and that has not waived the application of such an increase under subparagraph (F) is not eligible for reclassification under paragraph (8) or (10) during that period.

(H) Any increase in a wage index under this paragraph for a county shall not be taken into account for purposes of—

(i) computing the wage index for portions of the wage index area (not including the county) in which the county is located; or

(ii) applying any budget neutrality adjustment with respect to such index under paragraph (8)(D).

(I) The thresholds described in subparagraph (B), data on hospital employees used under this paragraph, and any determination of the Secretary under the process described in subparagraph (E) shall be final and shall not be subject to judicial review.

(e)(1)(A) For cost reporting periods of hospitals beginning in fiscal year 1984 or fiscal year 1985, the Secretary shall provide for such proportional adjustment in the applicable percentage increase (oth-

erwise applicable to the periods under subsection (b)(3)(B)) as may be necessary to assure that—

(i) the aggregate payment amounts otherwise provided under subsection (d)(1)(A)(i)(I) for that fiscal year for operating costs of inpatient hospital services of hospitals (excluding payments made under section 1866(a)(1)(F)),

are not greater or less than—

(ii) the target percentage (as defined in subsection (d)(1)(C)) of the payment amounts which would have been payable for such services for those same hospitals for that fiscal year under this section under the law as in effect before the date of the enactment of the Social Security Amendments of 1983 (excluding payments made under section 1866(a)(1)(F));

except that the adjustment made under this subparagraph shall apply only to subsection (d) hospitals and shall not apply for purposes of making computations under subsection (d)(2)(B)(ii) or subsection (d)(3)(A).

(B) For discharges occurring in fiscal year 1984 or fiscal year 1985, the Secretary shall provide under subsections (d)(2)(F) and (d)(3)(C) for such equal proportional adjustment in each of the average standardized amounts otherwise computed for that fiscal year as may be necessary to assure that—

(i) the aggregate payment amounts otherwise provided under subsection (d)(1)(A)(i)(II) and (d)(5) for that fiscal year for operating costs of inpatient hospital services of hospitals (excluding payments made under section 1866(a)(1)(F)),

are not greater or less than—

(ii) the DRG percentage (as defined in subsection (d)(1)(C)) of the payment amounts which would have been payable for such services for those same hospitals for that fiscal year under this section under the law as in effect before the date of the enactment of the Social Security Amendments of 1983 (excluding payments made under section 1866(a)(1)(F)).

(C) For discharges occurring in fiscal year 1988, the Secretary shall provide for such equal proportional adjustment in each of the average standardized amounts otherwise computed under subsection (d)(3) for that fiscal year as may be necessary to assure that—

(i) the aggregate payment amounts otherwise provided under subsections (d)(1)(A)(iii), (d)(5), and (d)(9) for that fiscal year for operating costs of inpatient hospital services of subsection (d) hospitals and subsection (d) Puerto Rico hospitals,

are not greater or less than—

(ii) the payment amounts that would have been payable for such services for those same hospitals for that fiscal year but for the enactment of the amendments made by section 9304 of the Omnibus Budget Reconciliation Act of 1986.

(4)(A) Taking into consideration the recommendations of the Commission, the Secretary shall recommend for each fiscal year (beginning with fiscal year 1988) an appropriate change factor for inpatient hospital services for discharges in that fiscal year which will take into account amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. The appropriate change factor may be different for all large urban subsection (d) hospitals, other urban subsection (d)

hospitals, urban subsection (d) Puerto Rico hospitals, rural subsection (d) hospitals, and rural subsection (d) Puerto Rico hospitals, and all other hospitals and units not paid under subsection (d), and may vary among such other hospitals and units.

(B) In addition to the recommendation made under subparagraph (A), the Secretary shall, taking into consideration the recommendations of the Commission under paragraph (2)(B), recommend for each fiscal year (beginning with fiscal year 1992) other appropriate changes in each existing reimbursement policy under this title under which payments to an institution are based upon prospectively determined rates.

(5) The Secretary shall cause to have published in the Federal Register, not later than—

(A) the April 1 before each fiscal year (beginning with fiscal year 1986), the Secretary's proposed recommendations under paragraph (4) for that fiscal year for public comment, and

(B) the August 1 before such fiscal year after such consideration of public comment on the proposal as is feasible in the time available, the Secretary's final recommendations under such paragraph for that year.

The Secretary shall include in the publication referred to in subparagraph (A) for a fiscal year the report of the Commission's recommendations submitted under paragraph (3) for that fiscal year. To the extent that the Secretary's recommendations under paragraph (4) differ from the Commission's recommendations for that fiscal year, the Secretary shall include in the publication referred to in subparagraph (A) an explanation of the Secretary's grounds for not following the Commission's recommendations.

(f)(1)(A) The Secretary shall maintain a system for the reporting of costs of hospitals receiving payments computed under subsection (d).

(B)(i) Subject to clause (ii), the Secretary shall place into effect a standardized electronic cost reporting format for hospitals under this title.

(ii) The Secretary may delay or waive the implementation of such format in particular instances where such implementation would result in financial hardship (in particular with respect to hospitals with a small percentage of inpatients entitled to benefits under this title).

(2) If the Secretary determines, based upon information supplied by a quality improvement organization under part B of title XI, that a hospital, in order to circumvent the payment method established under subsection (b) or (d) of this section, has taken an action that results in the admission of individuals entitled to benefits under part A unnecessarily, unnecessary multiple admissions of the same such individuals, or other inappropriate medical or other practices with respect to such individuals, the Secretary may—

(A) deny payment (in whole or in part) under part A with respect to inpatient hospital services provided with respect to such an unnecessary admission (or subsequent admission of the same individual), or

(B) require the hospital to take other corrective action necessary to prevent or correct the inappropriate practice.

(3) The provisions of subsections (c) through (g) of section 1128 shall apply to determinations made under paragraph (2) in the

same manner as they apply to exclusions effected under section 1128(b)(13).

(g)(1)(A) Notwithstanding section 1861(v), instead of any amounts that are otherwise payable under this title with respect to the reasonable costs of subsection (d) hospitals and subsection (d) Puerto Rico hospitals for capital-related costs of inpatient hospital services, the Secretary shall, for hospital cost reporting periods beginning on or after October 1, 1991, provide for payments for such costs in accordance with a prospective payment system established by the Secretary. Aggregate payments made under subsection (d) and this subsection during fiscal years 1992 through 1995 shall be reduced in a manner that results in a reduction (as estimated by the Secretary) in the amount of such payments equal to a 10 percent reduction in the amount of payments attributable to capital-related costs that would otherwise have been made during such fiscal year had the amount of such payments been based on reasonable costs (as defined in section 1861(v)). For discharges occurring after September 30, 1993, the Secretary shall reduce by 7.4 percent the unadjusted standard Federal capital payment rate (as described in 42 CFR 412.308(c), as in effect on the date of the enactment of the Omnibus Budget Reconciliation Act of 1993) and shall (for hospital cost reporting periods beginning on or after October 1, 1993) redetermine which payment methodology is applied to the hospital under such system to take into account such reduction. In addition to the reduction described in the preceding sentence, for discharges occurring on or after October 1, 1997, the Secretary shall apply the budget neutrality adjustment factor used to determine the Federal capital payment rate in effect on September 30, 1995 (as described in section 412.352 of title 42 of the Code of Federal Regulations), to (i) the unadjusted standard Federal capital payment rate (as described in section 412.308(c) of that title, as in effect on September 30, 1997), and (ii) the unadjusted hospital-specific rate (as described in section 412.328(e)(1) of that title, as in effect on September 30, 1997), and, for discharges occurring on or after October 1, 1997, and before October 1, 2002, reduce the rates described in clauses (i) and (ii) by 2.1 percent.

(B) Such system—

(i) shall provide for (I) a payment on a per discharge basis, and (II) an appropriate weighting of such payment amount as relates to the classification of the discharge;

(ii) may provide for an adjustment to take into account variations in the relative costs of capital and construction for the different types of facilities or areas in which they are located;

(iii) may provide for such exceptions (including appropriate exceptions to reflect capital obligations) as the Secretary determines to be appropriate, and

(iv) may provide for suitable adjustment to reflect hospital occupancy rate.

(C) In this paragraph, the term "capital-related costs" has the meaning given such term by the Secretary under subsection (a)(4) as of September 30, 1987, and does not include a return on equity capital.

(2)(A) The Secretary shall provide that the amount which is allowable, with respect to reasonable costs of inpatient hospital services for which payment may be made under this title, for a return

on equity capital for hospitals shall, for cost reporting periods beginning on or after the date of the enactment of this subsection, be equal to amounts otherwise allowable under regulations in effect on March 1, 1983, except that the rate of return to be recognized shall be equal to the applicable percentage (described in subparagraph (B)) of the average of the rates of interest, for each of the months any part of which is included in the reporting period, on obligations issued for purchase by the Federal Hospital Insurance Trust Fund.

(B) In this paragraph, the "applicable percentage" is—

(i) 75 percent, for cost reporting periods beginning during fiscal year 1987,

(ii) 50 percent, for cost reporting periods beginning during fiscal year 1988,

(iii) 25 percent, for cost reporting periods beginning during fiscal year 1989, and

(iv) 0 percent, for cost reporting periods beginning on or after October 1, 1989.

(3)(A) Except as provided in subparagraph (B), in determining the amount of the payments that may be made under this title with respect to all the capital-related costs of inpatient hospital services of a subsection (d) hospital and a subsection (d) Puerto Rico hospital, the Secretary shall reduce the amounts of such payments otherwise established under this title by—

(i) 3.5 percent for payments attributable to portions of cost reporting periods occurring during fiscal year 1987,

(ii) 7 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during fiscal year 1988 on or after October 1, 1987, and before January 1, 1988,

(iii) 12 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) in fiscal year 1988, occurring on or after January 1, 1988,

(iv) 15 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during fiscal year 1989, and

(v) 15 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during the period beginning January 1, 1990, and ending September 30, 1991.

(B) Subparagraph (A) shall not apply to payments with respect to the capital-related costs of any hospital that is a sole community hospital (as defined in subsection (d)(5)(D)(iii)) or a critical access hospital (as defined in section 1861(mm)(1)).

(4) In determining the amount of the payments that are attributable to portions of cost reporting periods occurring during fiscal years 1998 through 2002 and that may be made under this title with respect to capital-related costs of inpatient hospital services of a hospital which is described in clause (i), (ii), or (iv) of subsection (d)(1)(B) or a unit described in the matter after clause (v) of such subsection, the Secretary shall reduce the amounts of such payments otherwise determined under this title by 15 percent.

(h) PAYMENTS FOR DIRECT GRADUATE MEDICAL EDUCATION COSTS.—

(1) SUBSTITUTION OF SPECIAL PAYMENT RULES.—Notwithstanding section 1861(v), instead of any amounts that are otherwise payable under this title with respect to the reasonable costs of hospitals for direct graduate medical education costs, the Secretary shall provide for payments for such costs in accordance with paragraph (3) of this subsection. In providing for such payments, the Secretary shall provide for an allocation of such payments between part A and part B (and the trust funds established under the respective parts) as reasonably reflects the proportion of direct graduate medical education costs of hospitals associated with the provision of services under each respective part.

(2) DETERMINATION OF HOSPITAL-SPECIFIC APPROVED FTE RESIDENT AMOUNTS.—The Secretary shall determine, for each hospital with an approved medical residency training program, an approved FTE resident amount for each cost reporting period beginning on or after July 1, 1985, as follows:

(A) DETERMINING ALLOWABLE AVERAGE COST PER FTE RESIDENT IN A HOSPITAL'S BASE PERIOD.—The Secretary shall determine, for the hospital's cost reporting period that began during fiscal year 1984, the average amount recognized as reasonable under this title for direct graduate medical education costs of the hospital for each full-time-equivalent resident.

(B) UPDATING TO THE FIRST COST REPORTING PERIOD.—

(i) IN GENERAL.—The Secretary shall update each average amount determined under subparagraph (A) by the percentage increase in the consumer price index during the 12-month cost reporting period described in such subparagraph.

(ii) EXCEPTION.—The Secretary shall not perform an update under clause (i) in the case of a hospital if the hospital's reporting period, described in subparagraph (A), began on or after July 1, 1984, and before October 1, 1984.

(C) AMOUNT FOR FIRST COST REPORTING PERIOD.—For the first cost reporting period of the hospital beginning on or after July 1, 1985, the approved FTE resident amount for the hospital is equal to the amount determined under subparagraph (B) increased by 1 percent.

(D) AMOUNT FOR SUBSEQUENT COST REPORTING PERIODS.—

(i) IN GENERAL.—Except as provided in a subsequent clause, for each subsequent cost reporting period, the approved FTE resident amount for the hospital is equal to the approved FTE resident amount determined under this paragraph for the previous cost reporting period updated, through the midpoint of the period, by projecting the estimated percentage change in the consumer price index during the 12-month period ending at that midpoint, with appropriate adjustments to reflect previous under-or over-estimations under this subparagraph in the projected percentage change in the consumer price index.

(ii) FREEZE IN UPDATE FOR FISCAL YEARS 1994 AND 1995.—For cost reporting periods beginning during fiscal year 1994 or fiscal year 1995, the approved FTE resident amount for a hospital shall not be updated under clause (i) for a resident who is not a primary care resident (as defined in paragraph (5)(H)) or a resident enrolled in an approved medical residency training program in obstetrics and gynecology.

(iii) FLOOR FOR LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—The approved FTE resident amount for a hospital for the cost reporting period beginning during fiscal year 2001 shall not be less than 70 percent, and for the cost reporting period beginning during fiscal year 2002 shall not be less than 85 percent, of the locality adjusted national average per resident amount computed under subparagraph (E) for the hospital and period.

(iv) ADJUSTMENT IN RATE OF INCREASE FOR HOSPITALS WITH FTE APPROVED AMOUNT ABOVE 140 PERCENT OF LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—

(I) FREEZE FOR FISCAL YEARS 2001 AND 2002 AND 2004 THROUGH 2013.—For a cost reporting period beginning during fiscal year 2001 or fiscal year 2002 or during the period beginning with fiscal year 2004 and ending with fiscal year 2013, if the approved FTE resident amount for a hospital for the preceding cost reporting period exceeds 140 percent of the locality adjusted national average per resident amount computed under subparagraph (E) for that hospital and period, subject to subclause (III), the approved FTE resident amount for the period involved shall be the same as the approved FTE resident amount for the hospital for such preceding cost reporting period.

(II) 2 PERCENT DECREASE IN UPDATE FOR FISCAL YEARS 2003, 2004, AND 2005.—For the cost reporting period beginning during fiscal year 2003, if the approved FTE resident amount for a hospital for the preceding cost reporting period exceeds 140 percent of the locality adjusted national average per resident amount computed under subparagraph (E) for that hospital and preceding period, the approved FTE resident amount for the period involved shall be updated in the manner described in subparagraph (D)(i) except that, subject to subclause (III), the consumer price index applied for a 12-month period shall be reduced (but not below zero) by 2 percentage points.

(III) NO ADJUSTMENT BELOW 140 PERCENT.—In no case shall subclause (I) or (II) reduce an approved FTE resident amount for a hospital for a cost reporting period below 140 percent of the locality adjusted national average per resident

amount computed under subparagraph (E) for such hospital and period.

(E) DETERMINATION OF LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—The Secretary shall determine a locality adjusted national average per resident amount with respect to a cost reporting period of a hospital beginning during a fiscal year as follows:

(i) DETERMINING HOSPITAL SINGLE PER RESIDENT AMOUNT.—The Secretary shall compute for each hospital operating an approved graduate medical education program a single per resident amount equal to the average (weighted by number of full-time equivalent residents, as determined under paragraph (4)) of the primary care per resident amount and the non-primary care per resident amount computed under paragraph (2) for cost reporting periods ending during fiscal year 1997.

(ii) STANDARDIZING PER RESIDENT AMOUNTS.—The Secretary shall compute a standardized per resident amount for each such hospital by dividing the single per resident amount computed under clause (i) by an average of the 3 geographic index values (weighted by the national average weight for each of the work, practice expense, and malpractice components) as applied under section 1848(e) for 1999 for the fee schedule area in which the hospital is located.

(iii) COMPUTING OF WEIGHTED AVERAGE.—The Secretary shall compute the average of the standardized per resident amounts computed under clause (ii) for such hospitals, with the amount for each hospital weighted by the average number of full-time equivalent residents at such hospital (as determined under paragraph (4)).

(iv) COMPUTING NATIONAL AVERAGE PER RESIDENT AMOUNT.—The Secretary shall compute the national average per resident amount, for a hospital's cost reporting period that begins during fiscal year 2001, equal to the weighted average computed under clause (iii) increased by the estimated percentage increase in the consumer price index for all urban consumers during the period beginning with the month that represents the midpoint of the cost reporting periods described in clause (i) and ending with the midpoint of the hospital's cost reporting period that begins during fiscal year 2001.

(v) ADJUSTING FOR LOCALITY.—The Secretary shall compute the product of—

(I) the national average per resident amount computed under clause (iv) for the hospital, and

(II) the geographic index value average (described and applied under clause (ii)) for the fee schedule area in which the hospital is located.

(vi) COMPUTING LOCALITY ADJUSTED AMOUNT.—The locality adjusted national per resident amount for a hospital for—

(I) the cost reporting period beginning during fiscal year 2001 is the product computed under clause (v); or

(II) each subsequent cost reporting period is equal to the locality adjusted national per resident amount for the hospital for the previous cost reporting period (as determined under this clause) updated, through the midpoint of the period, by projecting the estimated percentage change in the consumer price index for all urban consumers during the 12-month period ending at that midpoint.

(F) TREATMENT OF CERTAIN HOSPITALS.—In the case of a hospital that did not have an approved medical residency training program or was not participating in the program under this title for a cost reporting period beginning during fiscal year 1984, the Secretary shall, for the first such period for which it has such a residency training program and is participating under this title, provide for such approved FTE resident amount as the Secretary determines to be appropriate, based on approved FTE resident amounts for comparable programs.

(3) HOSPITAL PAYMENT AMOUNT PER RESIDENT.—

(A) IN GENERAL.—The payment amount, for a hospital cost reporting period beginning on or after July 1, 1985, is equal to the product of—

(i) the aggregate approved amount (as defined in subparagraph (B)) for that period, and

(ii) the hospital's medicare patient load (as defined in subparagraph (C)) for that period.

(B) AGGREGATE APPROVED AMOUNT.—As used in subparagraph (A), the term "aggregate approved amount" means, for a hospital cost reporting period, the product of—

(i) the hospital's approved FTE resident amount (determined under paragraph (2)) for that period, and

(ii) the weighted average number of full-time-equivalent residents (as determined under paragraph (4)) in the hospital's approved medical residency training programs in that period.

The Secretary shall reduce the aggregate approved amount to the extent payment is made under subsection (k) for residents included in the hospital's count of full-time equivalent residents.

(C) MEDICARE PATIENT LOAD.—As used in subparagraph (A), the term "medicare patient load" means, with respect to a hospital's cost reporting period, the fraction of the total number of inpatient-bed-days (as established by the Secretary) during the period which are attributable to patients with respect to whom payment may be made under part A.

(D) PAYMENT FOR MANAGED CARE ENROLLEES.—

(i) IN GENERAL.—For portions of cost reporting periods occurring on or after January 1, 1998, the Secretary shall provide for an additional payment amount under this subsection for services furnished to individ-

uals who are enrolled under a risk-sharing contract with an eligible organization under section 1876 and who are entitled to part A or with a Medicare+Choice organization under part C. The amount of such a payment shall equal, subject to clause (iii), the applicable percentage of the product of—

(I) the aggregate approved amount (as defined in subparagraph (B)) for that period; and

(II) the fraction of the total number of inpatient-bed days (as established by the Secretary) during the period which are attributable to such enrolled individuals.

(ii) APPLICABLE PERCENTAGE.—For purposes of clause (i), the applicable percentage is—

(I) 20 percent in 1998,

(II) 40 percent in 1999,

(III) 60 percent in 2000,

(IV) 80 percent in 2001, and

(V) 100 percent in 2002 and subsequent years.

(iii) PROPORTIONAL REDUCTION FOR NURSING AND ALLIED HEALTH EDUCATION.—The Secretary shall estimate a proportional adjustment in payments to all hospitals determined under clauses (i) and (ii) for portions of cost reporting periods beginning in a year (beginning with 2000) such that the proportional adjustment reduces payments in an amount for such year equal to the total additional payment amounts for nursing and allied health education determined under subsection (l) for portions of cost reporting periods occurring in that year.

(iv) SPECIAL RULE FOR HOSPITALS UNDER REIMBURSEMENT SYSTEM.—The Secretary shall establish rules for the application of this subparagraph to a hospital reimbursed under a reimbursement system authorized under section 1814(b)(3) in the same manner as it would apply to the hospital if it were not reimbursed under such section.

(4) DETERMINATION OF FULL-TIME-EQUIVALENT RESIDENTS.—

(A) RULES.—The Secretary shall establish rules consistent with this paragraph for the computation of the number of full-time- equivalent residents in an approved medical residency training program.

(B) ADJUSTMENT FOR PART-YEAR OR PART-TIME RESIDENTS.—Such rules shall take into account individuals who serve as residents for only a portion of a period with a hospital or simultaneously with more than one hospital.

(C) WEIGHTING FACTORS FOR CERTAIN RESIDENTS.—Subject to subparagraph (D), such rules shall provide, in calculating the number of full-time-equivalent residents in an approved residency program—

(i) before July 1, 1986, for each resident the weighting factor is 1.00,

(ii) on or after July 1, 1986, for a resident who is in the resident's initial residency period (as defined in paragraph (5)(F)), the weighting factor is 1.00,

(iii) on or after July 1, 1986, and before July 1, 1987, for a resident who is not in the resident's initial residency period (as defined in paragraph (5)(F)), the weighting factor is .75, and

(iv) on or after July 1, 1987, for a resident who is not in the resident's initial residency period (as defined in paragraph (5)(F)), the weighting factor is .50.

(D) FOREIGN MEDICAL GRADUATES REQUIRED TO PASS FMGEMS EXAMINATION.—

(i) IN GENERAL.—Except as provided in clause (ii), such rules shall provide that, in the case of an individual who is a foreign medical graduate (as defined in paragraph (5)(D)), the individual shall not be counted as a resident on or after July 1, 1986, unless—

(I) the individual has passed the FMGEMS examination (as defined in paragraph (5)(E)), or

(II) the individual has previously received certification from, or has previously passed the examination of, the Educational Commission for Foreign Medical Graduates.

(ii) TRANSITION FOR CURRENT FMGS.—On or after July 1, 1986, but before July 1, 1987, in the case of a foreign medical graduate who—

(I) has served as a resident before July 1, 1986, and is serving as a resident after that date, but

(II) has not passed the FMGEMS examination or a previous examination of the Educational Commission for Foreign Medical Graduates before July 1, 1986,

the individual shall be counted as a resident at a rate equal to one-half of the rate at which the individual would otherwise be counted.

(E) COUNTING TIME SPENT IN OUTPATIENT SETTINGS.—Subject to subparagraphs (J) and (K), such rules shall provide that only time spent in activities relating to patient care shall be counted and that—

(i) effective for cost reporting periods beginning before July 1, 2010, all the time;

(ii) effective for cost reporting periods beginning on or after July 1, 2010, all the time so spent by a resident shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if a hospital incurs the costs of the stipends and fringe benefits of the resident during the time the resident spends in that setting. If more than one hospital incurs these costs, either directly or through a third party, such hospitals shall count a proportional share of the time, as determined by written agreement between the hospitals, that a resident spends training in that setting.

so spent by a resident under an approved medical residency training program shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if the hos-

pital incurs all, or substantially all, of the costs for the training program in that setting.

Any hospital claiming under this subparagraph for time spent in a nonprovider setting shall maintain and make available to the Secretary records regarding the amount of such time and such amount in comparison with amounts of such time in such base year as the Secretary shall specify.

(F) LIMITATION ON NUMBER OF RESIDENTS IN ALLOPATHIC AND OSTEOPATHIC MEDICINE.—

(i) IN GENERAL.—Such rules shall provide that for purposes of a cost reporting period beginning on or after October 1, 1997, subject to paragraphs (7) and (8), the total number of full-time equivalent residents before application of weighting factors (as determined under this paragraph) with respect to a hospital's approved medical residency training program in the fields of allopathic medicine and osteopathic medicine may not exceed the number (or, 130 percent of such number in the case of a hospital located in a rural area) of such full-time equivalent residents for the hospital's most recent cost reporting period ending on or before December 31, 1996.

(ii) COUNTING PRIMARY CARE RESIDENTS ON CERTAIN APPROVED LEAVES OF ABSENCE IN BASE YEAR FTE COUNT.—

(I) IN GENERAL.—In determining the number of such full-time equivalent residents for a hospital's most recent cost reporting period ending on or before December 31, 1996, for purposes of clause (i), the Secretary shall count an individual to the extent that the individual would have been counted as a primary care resident for such period but for the fact that the individual, as determined by the Secretary, was on maternity or disability leave or a similar approved leave of absence.

(II) LIMITATION TO 3 FTE RESIDENTS FOR ANY HOSPITAL.—The total number of individuals counted under subclause (I) for a hospital may not exceed 3 full-time equivalent residents.

(G) COUNTING INTERNS AND RESIDENTS FOR FY 1998 AND SUBSEQUENT YEARS.—

(i) IN GENERAL.—For cost reporting periods beginning during fiscal years beginning on or after October 1, 1997, subject to the limit described in subparagraph (F), the total number of full-time equivalent residents for determining a hospital's graduate medical education payment shall equal the average of the actual full-time equivalent resident counts for the cost reporting period and the preceding two cost reporting periods.

(ii) ADJUSTMENT FOR SHORT PERIODS.—If any cost reporting period beginning on or after October 1, 1997, is not equal to twelve months, the Secretary shall make appropriate modifications to ensure that the av-

erage full-time equivalent resident counts pursuant to clause (i) are based on the equivalent of full twelve-month cost reporting periods.

(iii) TRANSITION RULE FOR 1998.—In the case of a hospital's first cost reporting period beginning on or after October 1, 1997, clause (i) shall be applied by using the average for such period and the preceding cost reporting period.

(H) SPECIAL RULES FOR APPLICATION OF SUBPARAGRAPHS (F) AND (G).—

(i) NEW FACILITIES.—The Secretary shall, consistent with the principles of subparagraphs (F) and (G) and subject to paragraphs (7) and (8), prescribe rules for the application of such subparagraphs in the case of medical residency training programs established on or after January 1, 1995. In promulgating such rules for purposes of subparagraph (F), the Secretary shall give special consideration to facilities that meet the needs of underserved rural areas.

(ii) AGGREGATION.—The Secretary may prescribe rules which allow institutions which are members of the same affiliated group (as defined by the Secretary) to elect to apply the limitation of subparagraph (F) on an aggregate basis.

(iii) DATA COLLECTION.—The Secretary may require any entity that operates a medical residency training program and to which subparagraphs (F) and (G) apply to submit to the Secretary such additional information as the Secretary considers necessary to carry out such subparagraphs.

(iv) NONRURAL HOSPITALS OPERATING TRAINING PROGRAMS IN RURAL AREAS.—In the case of a hospital that is not located in a rural area but establishes separately accredited approved medical residency training programs (or rural tracks) in an rural area or has an accredited training program with an integrated rural track, the Secretary shall adjust the limitation under subparagraph (F) in an appropriate manner insofar as it applies to such programs in such rural areas in order to encourage the training of physicians in rural areas.

(v) SPECIAL PROVIDER AGREEMENT.—If an entity enters into a provider agreement pursuant to section 1866(a) to provide hospital services on the same physical site previously used by Medicare Provider No. 05–0578—

(I) the limitation on the number of total full time equivalent residents under subparagraph (F) and clauses (v) and (vi)(I) of subsection (d)(5)(B) applicable to such provider shall be equal to the limitation applicable under such provisions to Provider No. 05–0578 for its cost reporting period ending on June 30, 2006; and

(II) the provisions of subparagraph (G) and subsection (d)(5)(B)(vi)(II) shall not be applicable to

such provider for the first three cost reporting years in which such provider trains residents under any approved medical residency training program.

(vi) REDISTRIBUTION OF RESIDENCY SLOTS AFTER A HOSPITAL CLOSES.—

(I) IN GENERAL.—Subject to the succeeding provisions of this clause, the Secretary shall, by regulation, establish a process under which, in the case where a hospital (other than a hospital described in clause (v)) with an approved medical residency program closes on or after a date that is 2 years before the date of enactment of this clause, the Secretary shall increase the otherwise applicable resident limit under this paragraph for other hospitals in accordance with this clause.

(II) PRIORITY FOR HOSPITALS IN CERTAIN AREAS.—Subject to the succeeding provisions of this clause, in determining for which hospitals the increase in the otherwise applicable resident limit is provided under such process, the Secretary shall distribute the increase to hospitals in the following priority order (with preference given within each category to hospitals that are members of the same affiliated group (as defined by the Secretary under clause (ii)) as the closed hospital):

(aa) First, to hospitals located in the same core-based statistical area as, or a core-based statistical area contiguous to, the hospital that closed.

(bb) Second, to hospitals located in the same State as the hospital that closed.

(cc) Third, to hospitals located in the same region of the country as the hospital that closed.

(dd) Fourth, only if the Secretary is not able to distribute the increase to hospitals described in item (cc), to qualifying hospitals in accordance with the provisions of paragraph (8).

(III) REQUIREMENT HOSPITAL LIKELY TO FILL POSITION WITHIN CERTAIN TIME PERIOD.—The Secretary may only increase the otherwise applicable resident limit of a hospital under such process if the Secretary determines the hospital has demonstrated a likelihood of filling the positions made available under this clause within 3 years.

(IV) LIMITATION.—The aggregate number of increases in the otherwise applicable resident limits for hospitals under this clause shall be equal to the number of resident positions in the approved medical residency programs that closed on or after the date described in subclause (I).

(V) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the implementation of this clause.

(J) TREATMENT OF CERTAIN NONPROVIDER AND DIDACTIC ACTIVITIES.—Such rules shall provide that all time spent by an intern or resident in an approved medical residency training program in a nonprovider setting that is primarily engaged in furnishing patient care (as defined in paragraph (5)(K)) in non-patient care activities, such as didactic conferences and seminars, but not including research not associated with the treatment or diagnosis of a particular patient, as such time and activities are defined by the Secretary, shall be counted toward the determination of full-time equivalency.

(K) TREATMENT OF CERTAIN OTHER ACTIVITIES.—In determining the hospital's number of full-time equivalent residents for purposes of this subsection, all the time that is spent by an intern or resident in an approved medical residency training program on vacation, sick leave, or other approved leave, as such time is defined by the Secretary, and that does not prolong the total time the resident is participating in the approved program beyond the normal duration of the program shall be counted toward the determination of full-time equivalency.

(5) DEFINITIONS AND SPECIAL RULES.—As used in this subsection:

(A) APPROVED MEDICAL RESIDENCY TRAINING PROGRAM.—The term "approved medical residency training program" means a residency or other postgraduate medical training program participation in which may be counted toward certification in a specialty or subspecialty and includes formal postgraduate training programs in geriatric medicine approved by the Secretary.

(B) CONSUMER PRICE INDEX.—The term "consumer price index" refers to the Consumer Price Index for All Urban Consumers (United States city average), as published by the Secretary of Commerce.

(C) DIRECT GRADUATE MEDICAL EDUCATION COSTS.—The term "direct graduate medical education costs" means direct costs of approved educational activities for approved medical residency training programs.

(D) FOREIGN MEDICAL GRADUATE.—The term "foreign medical graduate" means a resident who is not a graduate of—

(i) a school of medicine accredited by the Liaison Committee on Medical Education of the American Medical Association and the Association of American Medical Colleges (or approved by such Committee as meeting the standards necessary for such accreditation),

(ii) a school of osteopathy accredited by the American Osteopathic Association, or approved by such Association as meeting the standards necessary for such accreditation, or

(iii) a school of dentistry or podiatry which is accredited (or meets the standards for accreditation) by an organization recognized by the Secretary for such purpose.

(E) FMGEMS EXAMINATION.—The term "FMGEMS examination" means parts I and II of the Foreign Medical Graduate Examination in the Medical Sciences or any successor examination recognized by the Secretary for this purpose.

(F) INITIAL RESIDENCY PERIOD.—The term "initial residency period" means the period of board eligibility, except that—

(i) except as provided in clause (ii), in no case shall the initial period of residency exceed an aggregate period of formal training of more than five years for any individual, and

(ii) a period, of not more than two years, during which an individual is in a geriatric residency or fellowship program or a preventive medicine residency or fellowship program which meets such criteria as the Secretary may establish, shall be treated as part of the initial residency period, but shall not be counted against any limitation on the initial residency period.

Subject to subparagraph (G)(v), the initial residency period shall be determined, with respect to a resident, as of the time the resident enters the residency training program.

(G) PERIOD OF BOARD ELIGIBILITY.—

(i) GENERAL RULE.—Subject to clauses (ii), (iii), (iv), and (v), the term "period of board eligibility" means, for a resident, the minimum number of years of formal training necessary to satisfy the requirements for initial board eligibility in the particular specialty for which the resident is training.

(ii) APPLICATION OF 1985–1986 DIRECTORY.—Except as provided in clause (iii), the period of board eligibility shall be such period specified in the 1985–1986 Directory of Residency Training Programs published by the Accreditation Council on Graduate Medical Education.

(iii) CHANGES IN PERIOD OF BOARD ELIGIBILITY.—On or after July 1, 1989, if the Accreditation Council on Graduate Medical Education, in its Directory of Residency Training Programs—

(I) increases the minimum number of years of formal training necessary to satisfy the requirements for a specialty, above the period specified in its 1985–1986 Directory, the Secretary may increase the period of board eligibility for that specialty, but not to exceed the period of board eligibility specified in that later Directory, or

(II) decreases the minimum number of years of formal training necessary to satisfy the requirements for a specialty, below the period specified in its 1985–1986 Directory, the Secretary may decrease the period of board eligibility for that spe-

cialty, but not below the period of board eligibility specified in that later Directory.

(iv) SPECIAL RULE FOR CERTAIN PRIMARY CARE COMBINED RESIDENCY PROGRAMS.—(I) In the case of a resident enrolled in a combined medical residency training program in which all of the individual programs (that are combined) are for training a primary care resident (as defined in subparagraph (H)), the period of board eligibility shall be the minimum number of years of formal training required to satisfy the requirements for initial board eligibility in the longest of the individual programs plus one additional year.

(II) A resident enrolled in a combined medical residency training program that includes an obstetrics and gynecology program shall qualify for the period of board eligibility under subclause (I) if the other programs such resident combines with such obstetrics and gynecology program are for training a primary care resident.

(v) CHILD NEUROLOGY TRAINING PROGRAMS.—In the case of a resident enrolled in a child neurology residency training program, the period of board eligibility and the initial residency period shall be the period of board eligibility for pediatrics plus 2 years.

(H) PRIMARY CARE RESIDENT.—The term "primary care resident" means a resident enrolled in an approved medical residency training program in family medicine, general internal medicine, general pediatrics, preventive medicine, geriatric medicine, or osteopathic general practice.

(I) RESIDENT.—The term "resident" includes an intern or other participant in an approved medical residency training program.

(J) ADJUSTMENTS FOR CERTAIN FAMILY PRACTICE RESIDENCY PROGRAMS.—

(i) IN GENERAL.—In the case of an approved medical residency training program (meeting the requirements of clause (ii)) of a hospital which received funds from the United States, a State, or a political subdivision of a State or an instrumentality of such a State or political subdivision (other than payments under this title or a State plan under title XIX) for the program during the cost reporting period that began during fiscal year 1984, the Secretary shall—

(I) provide for an average amount under paragraph (2)(A) that takes into account the Secretary's estimate of the amount that would have been recognized as reasonable under this title if the hospital had not received such funds, and

(II) reduce the payment amount otherwise provided under this subsection in an amount equal to the proportion of such program funds received during the cost reporting period involved that is allocable to this title.

(ii) ADDITIONAL REQUIREMENTS.—A hospital's approved medical residency program meets the requirements of this clause if—

(I) the program is limited to training for family and community medicine;

(II) the program is the only approved medical residency program of the hospital; and

(III) the average amount determined under paragraph (2)(A) for the hospital (as determined without regard to the increase in such amount described in clause (i)(I)) does not exceed $10,000.

(K) NONPROVIDER SETTING THAT IS PRIMARILY ENGAGED IN FURNISHING PATIENT CARE.—The term "nonprovider setting that is primarily engaged in furnishing patient care" means a nonprovider setting in which the primary activity is the care and treatment of patients, as defined by the Secretary.

(6) INCENTIVE PAYMENT UNDER PLANS FOR VOLUNTARY REDUCTION IN NUMBER OF RESIDENTS.—

(A) IN GENERAL.—In the case of a voluntary residency reduction plan for which an application is approved under subparagraph (B), subject to subparagraph (F), each hospital which is part of the qualifying entity submitting the plan shall be paid an applicable hold harmless percentage (as specified in subparagraph (E)) of the sum of—

(i) the amount (if any) by which—

(I) the amount of payment which would have been made under this subsection if there had been a 5-percent reduction in the number of full-time equivalent residents in the approved medical education training programs of the hospital as of June 30, 1997, exceeds

(II) the amount of payment which is made under this subsection, taking into account the reduction in such number effected under the reduction plan; and

(ii) the amount of the reduction in payment under subsection (d)(5)(B) for the hospital that is attributable to the reduction in number of residents effected under the plan below 95 percent of the number of full-time equivalent residents in such programs of the hospital as of June 30, 1997.

The determination of the amounts under clauses (i) and (ii) for any year shall be made on the basis of the provisions of this title in effect on the application deadline date for the first calendar year to which the reduction plan applies.

(B) APPROVAL OF PLAN APPLICATIONS.—The Secretary may not approve the application of an qualifying entity unless—

(i) the application is submitted in a form and manner specified by the Secretary and by not later than November 1, 1999,

(ii) the application provides for the operation of a plan for the reduction in the number of full-time equivalent residents in the approved medical residency

training programs of the entity consistent with the requirements of subparagraph (D);

(iii) the entity elects in the application the period of residency training years (not greater than 5) over which the reduction will occur;

(iv) the entity will not reduce the proportion of its residents in primary care (to the total number of residents) below such proportion as in effect as of the applicable time described in subparagraph (D)(v); and

(v) the Secretary determines that the application and the entity and such plan meet such other requirements as the Secretary specifies in regulations.

(C) QUALIFYING ENTITY.—For purposes of this paragraph, any of the following may be a qualifying entity:

(i) Individual hospitals operating one or more approved medical residency training programs.

(ii) Two or more hospitals that operate such programs and apply for treatment under this paragraph as a single qualifying entity.

(iii) A qualifying consortium (as described in section 4628 of the Balanced Budget Act of 1997).

(D) RESIDENCY REDUCTION REQUIREMENTS.—

(i) INDIVIDUAL HOSPITAL APPLICANTS.—In the case of a qualifying entity described in subparagraph (C)(i), the number of full-time equivalent residents in all the approved medical residency training programs operated by or through the entity shall be reduced as follows:

(I) If the base number of residents exceeds 750 residents, by a number equal to at least 20 percent of such base number.

(II) Subject to subclause (IV), if the base number of residents exceeds 600 but is less than 750 residents, by 150 residents.

(III) Subject to subclause (IV), if the base number of residents does not exceed 600 residents, by a number equal to at least 25 percent of such base number.

(IV) In the case of a qualifying entity which is described in clause (v) and which elects treatment under this subclause, by a number equal to at least 20 percent of the base number.

(ii) JOINT APPLICANTS.—In the case of a qualifying entity described in subparagraph (C)(ii), the number of full-time equivalent residents in the aggregate for all the approved medical residency training programs operated by or through the entity shall be reduced as follows:

(I) Subject to subclause (II), by a number equal to at least 25 percent of the base number.

(II) In the case of such a qualifying entity which is described in clause (v) and which elects treatment under this subclause, by a number equal to at least 20 percent of the base number.

(iii) CONSORTIA.—In the case of a qualifying entity described in subparagraph (C)(iii), the number of full-time equivalent residents in the aggregate for all the approved medical residency training programs operated by or through the entity shall be reduced by a number equal to at least 20 percent of the base number.

(iv) MANNER OF REDUCTION.—The reductions specified under the preceding provisions of this subparagraph for a qualifying entity shall be below the base number of residents for that entity and shall be fully effective not later than the 5th residency training year in which the application under subparagraph (B) is effective.

(v) ENTITIES PROVIDING ASSURANCE OF INCREASE IN PRIMARY CARE RESIDENTS.—An entity is described in this clause if—

(I) the base number of residents for the entity is less than 750 or the entity is described in subparagraph (C)(ii); and

(II) the entity represents in its application under subparagraph (B) that it will increase the number of full-time equivalent residents in primary care by at least 20 percent (from such number included in the base number of residents) by not later than the 5th residency training year in which the application under subparagraph (B) is effective.

If a qualifying entity fails to comply with the representation described in subclause (II) by the end of such 5th residency training year, the entity shall be subject to repayment of all amounts paid under this paragraph, in accordance with procedures established to carry out subparagraph (F).

(vi) BASE NUMBER OF RESIDENTS DEFINED.—For purposes of this paragraph, the term "base number of residents" means, with respect to a qualifying entity (or its participating hospitals) operating approved medical residency training programs, the number of full-time equivalent residents in such programs (before application of weighting factors) of the entity as of the most recent residency training year ending before June 30, 1997, or, if less, for any subsequent residency training year that ends before the date the entity makes application under this paragraph.

(E) APPLICABLE HOLD HARMLESS PERCENTAGE.—For purposes of subparagraph (A), the "applicable hold harmless percentage" for the—

(i) first and second residency training years in which the reduction plan is in effect, 100 percent,

(ii) third such year, 75 percent,

(iii) fourth such year, 50 percent, and

(iv) fifth such year, 25 percent.

(F) PENALTY FOR NONCOMPLIANCE.—

(i) IN GENERAL.—No payment may be made under this paragraph to a hospital for a residency training year if the hospital has failed to reduce the number of full-time equivalent residents (in the manner required under subparagraph (D)) to the number agreed to by the Secretary and the qualifying entity in approving the application under this paragraph with respect to such year.

(ii) INCREASE IN NUMBER OF RESIDENTS IN SUBSEQUENT YEARS.—If payments are made under this paragraph to a hospital, and if the hospital increases the number of full-time equivalent residents above the number of such residents permitted under the reduction plan as of the completion of the plan, then, as specified by the Secretary, the entity is liable for repayment to the Secretary of the total amounts paid under this paragraph to the entity.

(G) TREATMENT OF ROTATING RESIDENTS.—In applying this paragraph, the Secretary shall establish rules regarding the counting of residents who are assigned to institutions the medical residency training programs in which are not covered under approved applications under this paragraph.

(7) REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.—

(A) REDUCTION IN LIMIT BASED ON UNUSED POSITIONS.—

(i) PROGRAMS SUBJECT TO REDUCTION.—

(I) IN GENERAL.—Except as provided in subclause (II), if a hospital's reference resident level (specified in clause (ii)) is less than the otherwise applicable resident limit (as defined in subparagraph (C)(ii)), effective for portions of cost reporting periods occurring on or after July 1, 2005, the otherwise applicable resident limit shall be reduced by 75 percent of the difference between such otherwise applicable resident limit and such reference resident level.

(II) EXCEPTION FOR SMALL RURAL HOSPITALS.—This subparagraph shall not apply to a hospital located in a rural area (as defined in subsection (d)(2)(D)(ii)) with fewer than 250 acute care inpatient beds.

(ii) REFERENCE RESIDENT LEVEL.—

(I) IN GENERAL.—Except as otherwise provided in subclauses (II) and (III), the reference resident level specified in this clause for a hospital is the resident level for the most recent cost reporting period of the hospital ending on or before September 30, 2002, for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary.

(II) USE OF MOST RECENT ACCOUNTING PERIOD TO RECOGNIZE EXPANSION OF EXISTING PROGRAMS.—If a hospital submits a timely request to increase its resident level due to an expansion of an existing residency training program that is not

reflected on the most recent settled cost report, after audit and subject to the discretion of the Secretary, the reference resident level for such hospital is the resident level for the cost reporting period that includes July 1, 2003, as determined by the Secretary.

(III) EXPANSIONS UNDER NEWLY APPROVED PROGRAMS.—Upon the timely request of a hospital, the Secretary shall adjust the reference resident level specified under subclause (I) or (II) to include the number of medical residents that were approved in an application for a medical residency training program that was approved by an appropriate accrediting organization (as determined by the Secretary) before January 1, 2002, but which was not in operation during the cost reporting period used under subclause (I) or (II), as the case may be, as determined by the Secretary.

(iii) AFFILIATION.—The provisions of clause (i) shall be applied to hospitals which are members of the same affiliated group (as defined by the Secretary under paragraph (4)(H)(ii)) as of July 1, 2003.

(B) REDISTRIBUTION.—

(i) IN GENERAL.—The Secretary is authorized to increase the otherwise applicable resident limit for each qualifying hospital that submits a timely application under this subparagraph by such number as the Secretary may approve for portions of cost reporting periods occurring on or after July 1, 2005. The aggregate number of increases in the otherwise applicable resident limits under this subparagraph may not exceed the Secretary's estimate of the aggregate reduction in such limits attributable to subparagraph (A).

(ii) CONSIDERATIONS IN REDISTRIBUTION.—In determining for which hospitals the increase in the otherwise applicable resident limit is provided under clause (i), the Secretary shall take into account the demonstrated likelihood of the hospital filling the positions within the first 3 cost reporting periods beginning on or after July 1, 2005, made available under this subparagraph, as determined by the Secretary.

(iii) PRIORITY FOR RURAL AND SMALL URBAN AREAS.—In determining for which hospitals and residency training programs an increase in the otherwise applicable resident limit is provided under clause (i), the Secretary shall distribute the increase to programs of hospitals located in the following priority order:

(I) First, to hospitals located in rural areas (as defined in subsection (d)(2)(D)(ii)).

(II) Second, to hospitals located in urban areas that are not large urban areas (as defined for purposes of subsection (d)).

(III) Third, to other hospitals in a State if the residency training program involved is in a spe-

cialty for which there are not other residency training programs in the State.

Increases of residency limits within the same priority category under this clause shall be determined by the Secretary.

(iv) LIMITATION.—In no case shall more than 25 full-time equivalent additional residency positions be made available under this subparagraph with respect to any hospital.

(v) APPLICATION OF LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—With respect to additional residency positions in a hospital attributable to the increase provided under this subparagraph, notwithstanding any other provision of this subsection, the approved FTE resident amount is deemed to be equal to the locality adjusted national average per resident amount computed under paragraph (4)(E) for that hospital.

(vi) CONSTRUCTION.—Nothing in this subparagraph shall be construed as permitting the redistribution of reductions in residency positions attributable to voluntary reduction programs under paragraph (6), under a demonstration project approved as of October 31, 2003, under the authority of section 402 of Public Law 90–248, or as affecting the ability of a hospital to establish new medical residency training programs under paragraph (4)(H).

(C) RESIDENT LEVEL AND LIMIT DEFINED.—In this paragraph:

(i) RESIDENT LEVEL.—The term "resident level" means, with respect to a hospital, the total number of full-time equivalent residents, before the application of weighting factors (as determined under paragraph (4)), in the fields of allopathic and osteopathic medicine for the hospital.

(ii) OTHERWISE APPLICABLE RESIDENT LIMIT.—The term "otherwise applicable resident limit" means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph.

(D) ADJUSTMENT BASED ON SETTLED COST REPORT.—In the case of a hospital with a dual accredited osteopathic and allopathic family practice program for which—

(i) the otherwise applicable resident limit was reduced under subparagraph (A)(i)(I); and

(ii) such reduction was based on a reference resident level that was determined using a cost report and where a revised or corrected notice of program reimbursement was issued for such cost report between September 1, 2006 and September 15, 2006, whether as a result of an appeal or otherwise, and the reference resident level under such settled cost report is higher than the level used for the reduction under subparagraph (A)(i)(I);

the Secretary shall apply subparagraph (A)(i)(I) using the higher resident reference level and make any necessary adjustments to such reduction. Any such necessary adjustments shall be effective for portions of cost reporting periods occurring on or after July 1, 2005.

(E) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, with respect to determinations made under this this paragraph, paragraph (8), or paragraph (4)(H)(vi).

(8) DISTRIBUTION OF ADDITIONAL RESIDENCY POSITIONS.—

(A) REDUCTIONS IN LIMIT BASED ON UNUSED POSITIONS.—

(i) IN GENERAL.—Except as provided in clause (ii), if a hospital's reference resident level (as defined in subparagraph (H)(i)) is less than the otherwise applicable resident limit (as defined in subparagraph (H)(iii)), effective for portions of cost reporting periods occurring on or after July 1, 2011, the otherwise applicable resident limit shall be reduced by 65 percent of the difference between such otherwise applicable resident limit and such reference resident level.

(ii) EXCEPTIONS.—This subparagraph shall not apply to—

(I) a hospital located in a rural area (as defined in subsection (d)(2)(D)(ii)) with fewer than 250 acute care inpatient beds;

(II) a hospital that was part of a qualifying entity which had a voluntary residency reduction plan approved under paragraph (6)(B) or under the authority of section 402 of Public Law 90–248, if the hospital demonstrates to the Secretary that it has a specified plan in place for filling the unused positions by not later than 2 years after the date of enactment of this paragraph; or

(III) a hospital described in paragraph (4)(H)(v).

(B) DISTRIBUTION.—

(i) IN GENERAL.—The Secretary shall increase the otherwise applicable resident limit for each qualifying hospital that submits an application under this subparagraph by such number as the Secretary may approve for portions of cost reporting periods occurring on or after July 1, 2011. The aggregate number of increases in the otherwise applicable resident limit under this subparagraph shall be equal to the aggregate reduction in such limits attributable to subparagraph (A) (as estimated by the Secretary).

(ii) REQUIREMENTS.—Subject to clause (iii), a hospital that receives an increase in the otherwise applicable resident limit under this subparagraph shall ensure, during the 5-year period beginning on the date of such increase, that—

(I) the number of full-time equivalent primary care residents, as defined in paragraph (5)(H) (as determined by the Secretary), excluding any additional positions under subclause (II), is not less than the average number of full-time equivalent

primary care residents (as so determined) during the 3 most recent cost reporting periods ending prior to the date of enactment of this paragraph; and

(II) not less than 75 percent of the positions attributable to such increase are in a primary care or general surgery residency (as determined by the Secretary).

The Secretary may determine whether a hospital has met the requirements under this clause during such 5-year period in such manner and at such time as the Secretary determines appropriate, including at the end of such 5-year period.

(iii) REDISTRIBUTION OF POSITIONS IF HOSPITAL NO LONGER MEETS CERTAIN REQUIREMENTS.—In the case where the Secretary determines that a hospital described in clause (ii) does not meet either of the requirements under subclause (I) or (II) of such clause, the Secretary shall—

(I) reduce the otherwise applicable resident limit of the hospital by the amount by which such limit was increased under this paragraph; and

(II) provide for the distribution of positions attributable to such reduction in accordance with the requirements of this paragraph.

(C) CONSIDERATIONS IN REDISTRIBUTION.—In determining for which hospitals the increase in the otherwise applicable resident limit is provided under subparagraph (B), the Secretary shall take into account—

(i) the demonstration likelihood of the hospital filling the positions made available under this paragraph within the first 3 cost reporting periods beginning on or after July 1, 2011, as determined by the Secretary; and

(ii) whether the hospital has an accredited rural training track (as described in paragraph (4)(H)(iv)).

(D) PRIORITY FOR CERTAIN AREAS.—In determining for which hospitals the increase in the otherwise applicable resident limit is provided under subparagraph (B), subject to subparagraph (E), the Secretary shall distribute the increase to hospitals based on the following factors:

(i) Whether the hospital is located in a State with a resident-to-population ratio in the lowest quartile (as determined by the Secretary).

(ii) Whether the hospital is located in a State, a territory of the United States, or the District of Columbia that is among the top 10 States, territories, or Districts in terms of the ratio of—

(I) the total population of the State, territory, or District living in an area designated (under such section 332(a)(1)(A)) as a health professional shortage area (as of the date of enactment of this paragraph); to

(II) the total population of the State, territory, or District (as determined by the Secretary based

on the most recent available population data published by the Bureau of the Census).

(iii) Whether the hospital is located in a rural area (as defined in subsection (d)(2)(D)(ii)).

(E) RESERVATION OF POSITIONS FOR CERTAIN HOSPITALS.—

(i) IN GENERAL.—Subject to clause (ii), the Secretary shall reserve the positions available for distribution under this paragraph as follows:

(I) 70 percent of such positions for distribution to hospitals described in clause (i) of subparagraph (D).

(II) 30 percent of such positions for distribution to hospitals described in clause (ii) and (iii) of such subparagraph.

(ii) EXCEPTION IF POSITIONS NOT REDISTRIBUTED BY JULY 1, 2011.—In the case where the Secretary does not distribute positions to hospitals in accordance with clause (i) by July 1, 2011, the Secretary shall distribute such positions to other hospitals in accordance with the considerations described in subparagraph (C) and the priority described in subparagraph (D).

(F) LIMITATION.—A hospital may not receive more than 75 full-time equivalent additional residency positions under this paragraph.

(G) APPLICATION OF PER RESIDENT AMOUNTS FOR PRIMARY CARE AND NONPRIMARY CARE.—With respect to additional residency positions in a hospital attributable to the increase provided under this paragraph, the approved FTE per resident amounts are deemed to be equal to the hospital per resident amounts for primary care and nonprimary care computed under paragraph (2)(D) for that hospital.

(H) DEFINITIONS.—In this paragraph:

(i) REFERENCE RESIDENT LEVEL.—The term "reference resident level" means, with respect to a hospital, the highest resident level for any of the 3 most recent cost reporting periods (ending before the date of the enactment of this paragraph) of the hospital for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary.

(ii) RESIDENT LEVEL.—The term "resident level" has the meaning given such term in paragraph (7)(C)(i).

(iii) OTHERWISE APPLICABLE RESIDENT LIMIT.—The term "otherwise applicable resident limit" means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph but taking into account paragraph (7)(A).

(I) AFFILIATION.—The provisions of this paragraph shall be applied to hospitals which are members of the same affiliated group (as defined by the Secretary under paragraph (4)(H)(ii)) and the reference resident level for each

such hospital shall be the reference resident level with respect to the cost reporting period that results in the smallest difference between the reference resident level and the otherwise applicable resident limit.

(i) AVOIDING DUPLICATIVE PAYMENTS TO HOSPITALS PARTICIPATING IN RURAL DEMONSTRATION PROGRAMS.—The Secretary shall reduce any payment amounts otherwise determined under this section to the extent necessary to avoid duplication of any payment made under section 4005(e) of the Omnibus Budget Reconciliation Act of 1987.

(j) PROSPECTIVE PAYMENT FOR INPATIENT REHABILITATION SERVICES.—

(1) PAYMENT DURING TRANSITION PERIOD.—

(A) IN GENERAL.—Notwithstanding section 1814(b), but subject to the provisions of section 1813, the amount of the payment with respect to the operating and capital costs of inpatient hospital services of a rehabilitation hospital or a rehabilitation unit (in this subsection referred to as a "rehabilitation facility"), other than a facility making an election under subparagraph (F) in a cost reporting period beginning on or after October 1, 2000, and before October 1, 2002, is equal to the sum of—

(i) the TEFRA percentage (as defined in subparagraph (C)) of the amount that would have been paid under part A with respect to such costs if this subsection did not apply, and

(ii) the prospective payment percentage (as defined in subparagraph (C)) of the product of (I) the per unit payment rate established under this subsection for the fiscal year in which the payment unit of service occurs, and (II) the number of such payment units occurring in the cost reporting period.

(B) FULLY IMPLEMENTED SYSTEM.—Notwithstanding section 1814(b), but subject to the provisions of section 1813, the amount of the payment with respect to the operating and capital costs of inpatient hospital services of a rehabilitation facility for a payment unit in a cost reporting period beginning on or after October 1, 2002, or, in the case of a facility making an election under subparagraph (F), for any cost reporting period described in such subparagraph, is equal to the per unit payment rate established under this subsection for the fiscal year in which the payment unit of service occurs.

(C) TEFRA AND PROSPECTIVE PAYMENT PERCENTAGES SPECIFIED.—For purposes of subparagraph (A), for a cost reporting period beginning—

(i) on or after October 1, 2000, and before October 1, 2001, the "TEFRA percentage" is 66⅔ percent and the "prospective payment percentage" is 33⅓ percent; and

(ii) on or after October 1, 2001, and before October 1, 2002, the "TEFRA percentage" is 33⅓ percent and the "prospective payment percentage" is 66⅔ percent.

(D) PAYMENT UNIT.—For purposes of this subsection, the term "payment unit" means a discharge.

(E) CONSTRUCTION RELATING TO TRANSFER AUTHORITY.—Nothing in this subsection shall be construed as preventing the Secretary from providing for an adjustment to payments to take into account the early transfer of a patient from a rehabilitation facility to another site of care.

(F) ELECTION TO APPLY FULL PROSPECTIVE PAYMENT SYSTEM.—A rehabilitation facility may elect, not later than 30 days before its first cost reporting period for which the payment methodology under this subsection applies to the facility, to have payment made to the facility under this subsection under the provisions of subparagraph (B) (rather than subparagraph (A)) for each cost reporting period to which such payment methodology applies.

(2) PATIENT CASE MIX GROUPS.—

(A) ESTABLISHMENT.—The Secretary shall establish—

(i) classes of patient discharges of rehabilitation facilities by functional-related groups (each in this subsection referred to as a "case mix group"), based on impairment, age, comorbidities, and functional capability of the patient and such other factors as the Secretary deems appropriate to improve the explanatory power of functional independence measure-function related groups; and

(ii) a method of classifying specific patients in rehabilitation facilities within these groups.

(B) WEIGHTING FACTORS.—For each case mix group the Secretary shall assign an appropriate weighting which reflects the relative facility resources used with respect to patients classified within that group compared to patients classified within other groups.

(C) ADJUSTMENTS FOR CASE MIX.—

(i) IN GENERAL.—The Secretary shall from time to time adjust the classifications and weighting factors established under this paragraph as appropriate to reflect changes in treatment patterns, technology, case mix, number of payment units for which payment is made under this title, and other factors which may affect the relative use of resources. Such adjustments shall be made in a manner so that changes in aggregate payments under the classification system are a result of real changes and are not a result of changes in coding that are unrelated to real changes in case mix.

(ii) ADJUSTMENT.—Insofar as the Secretary determines that such adjustments for a previous fiscal year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under the classification system during the fiscal year that are a result of changes in the coding or classification of patients that do not reflect real changes in case mix, the Secretary shall adjust the per payment unit payment rate for subsequent years so as to eliminate the effect of such coding or classification changes.

(D) DATA COLLECTION.—The Secretary is authorized to require rehabilitation facilities that provide inpatient hospital services to submit such data as the Secretary deems necessary to establish and administer the prospective payment system under this subsection.

(3) PAYMENT RATE.—

(A) IN GENERAL.—The Secretary shall determine a prospective payment rate for each payment unit for which such rehabilitation facility is entitled to receive payment under this title. Subject to subparagraph (B), such rate for payment units occurring during a fiscal year shall be based on the average payment per payment unit under this title for inpatient operating and capital costs of rehabilitation facilities using the most recent data available (as estimated by the Secretary as of the date of establishment of the system) adjusted—

(i) by updating such per-payment-unit amount to the fiscal year involved by the weighted average of the applicable percentage increases provided under subsection (b)(3)(B)(ii) (for cost reporting periods beginning during the fiscal year) covering the period from the midpoint of the period for such data through the midpoint of fiscal year 2000 and by an increase factor (described in subparagraph (C)) specified by the Secretary for subsequent fiscal years up to the fiscal year involved;

(ii) by reducing such rates by a factor equal to the proportion of payments under this subsection (as estimated by the Secretary) based on prospective payment amounts which are additional payments described in paragraph (4) (relating to outlier and related payments);

(iii) for variations among rehabilitation facilities by area under paragraph (6);

(iv) by the weighting factors established under paragraph (2)(B); and

(v) by such other factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities.

(B) BUDGET NEUTRAL RATES.—The Secretary shall establish the prospective payment amounts under this subsection for payment units during fiscal years 2001 and 2002 at levels such that, in the Secretary's estimation, the amount of total payments under this subsection for such fiscal years (including any payment adjustments pursuant to paragraphs (4) and (6) but not taking into account any payment adjustment resulting from an election permitted under paragraph (1)(F)) shall be equal to 98 percent for fiscal year 2001 and 100 percent for fiscal year 2002 of the amount of payments that would have been made under this title during the fiscal years for operating and capital costs of rehabilitation facilities had this subsection not been enacted. In establishing such payment amounts, the Secretary shall consider the effects of the prospective pay-

ment system established under this subsection on the total number of payment units from rehabilitation facilities and other factors described in subparagraph (A).

(C) INCREASE FACTOR.—

(i) IN GENERAL.—For purposes of this subsection for payment units in each fiscal year (beginning with fiscal year 2001), the Secretary shall establish an increase factor subject to clauses (ii) and (iii). Such factor shall be based on an appropriate percentage increase in a market basket of goods and services comprising services for which payment is made under this subsection, which may be the market basket percentage increase described in subsection (b)(3)(B)(iii). The increase factor to be applied under this subparagraph for each of fiscal years 2008 and 2009 shall be 0 percent.

(ii) PRODUCTIVITY AND OTHER ADJUSTMENT.—Subject to clause (iii), after establishing the increase factor described in clause (i) for a fiscal year, the Secretary shall reduce such increase factor—

(I) for fiscal year 2012 and each subsequent fiscal year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(II) for each of fiscal years 2010 through 2019, by the other adjustment described in subparagraph (D).

The application of this clause may result in the increase factor under this subparagraph being less than 0.0 for a fiscal year, and may result in payment rates under this subsection for a fiscal year being less than such payment rates for the preceding fiscal year.

(iii) SPECIAL RULE FOR FISCAL YEAR 2018.—The increase factor to be applied under this subparagraph for fiscal year 2018, after the application of clause (ii), shall be 1 percent.

(D) OTHER ADJUSTMENT.—For purposes of subparagraph (C)(ii)(II), the other adjustment described in this subparagraph is—

(i) for each of fiscal years 2010 and 2011, 0.25 percentage point;

(ii) for each of fiscal years 2012 and 2013, 0.1 percentage point;

(iii) for fiscal year 2014, 0.3 percentage point;

(iv) for each of fiscal years 2015 and 2016, 0.2 percentage point; and

(v) for each of fiscal years 2017, 2018, and 2019, 0.75 percentage point.

(4) OUTLIER AND SPECIAL PAYMENTS.—

(A) OUTLIERS.—

(i) IN GENERAL.—The Secretary may provide for an additional payment to a rehabilitation facility for patients in a case mix group, based upon the patient being classified as an outlier based on an unusual length of stay, costs, or other factors specified by the Secretary.

(ii) PAYMENT BASED ON MARGINAL COST OF CARE.—The amount of such additional payment under clause (i) shall be determined by the Secretary and shall approximate the marginal cost of care beyond the cutoff point applicable under clause (i).

(iii) TOTAL PAYMENTS.—The total amount of the additional payments made under this subparagraph for payment units in a fiscal year may not exceed 5 percent of the total payments projected or estimated to be made based on prospective payment rates for payment units in that year.

(B) ADJUSTMENT.—The Secretary may provide for such adjustments to the payment amounts under this subsection as the Secretary deems appropriate to take into account the unique circumstances of rehabilitation facilities located in Alaska and Hawaii.

(5) PUBLICATION.—The Secretary shall provide for publication in the Federal Register, on or before August 1 before each fiscal year (beginning with fiscal year 2001), of the classification and weighting factors for case mix groups under paragraph (2) for such fiscal year and a description of the methodology and data used in computing the prospective payment rates under this subsection for that fiscal year.

(6) AREA WAGE ADJUSTMENT.—The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of rehabilitation facilities' costs which are attributable to wages and wage-related costs, of the prospective payment rates computed under paragraph (3) for area differences in wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for such facilities. Not later than October 1, 2001 (and at least every 36 months thereafter), the Secretary shall update the factor under the preceding sentence on the basis of information available to the Secretary (and updated as appropriate) of the wages and wage-related costs incurred in furnishing rehabilitation services. Any adjustments or updates made under this paragraph for a fiscal year shall be made in a manner that assures that the aggregated payments under this subsection in the fiscal year are not greater or less than those that would have been made in the year without such adjustment.

(7) QUALITY REPORTING.—

(A) REDUCTION IN UPDATE FOR FAILURE TO REPORT.—

(i) IN GENERAL.—For purposes of fiscal year 2014 and each subsequent fiscal year, in the case of a rehabilitation facility that does not submit data to the Secretary in accordance with subparagraphs (C) and (F) with respect to such a fiscal year, after determining the increase factor described in paragraph (3)(C), and after application of subparagraphs (C)(iii) and (D) of paragraph (3), the Secretary shall reduce such increase factor for payments for discharges occurring during such fiscal year by 2 percentage points.

(ii) SPECIAL RULE.—The application of this subparagraph may result in the increase factor described in

paragraph (3)(C) being less than 0.0 for a fiscal year, and may result in payment rates under this subsection for a fiscal year being less than such payment rates for the preceding fiscal year.

(B) NONCUMULATIVE APPLICATION.—Any reduction under subparagraph (A) shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the payment amount under this subsection for a subsequent fiscal year.

(C) SUBMISSION OF QUALITY DATA.—Subject to subparagraph (G), for fiscal year 2014 and each subsequent fiscal year, each rehabilitation facility shall submit to the Secretary data on quality measures specified under subparagraph (D). Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(D) QUALITY MEASURES.—

(i) IN GENERAL.—Subject to clause (ii), any measure specified by the Secretary under this subparagraph must have been endorsed by the entity with a contract under section 1890(a).

(ii) EXCEPTION.—In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(iii) TIME FRAME.—Not later than October 1, 2012, the Secretary shall publish the measures selected under this subparagraph that will be applicable with respect to fiscal year 2014.

(E) PUBLIC AVAILABILITY OF DATA SUBMITTED.—The Secretary shall establish procedures for making data submitted under subparagraph (C) and subparagraph (F)(i) available to the public. Such procedures shall ensure that a rehabilitation facility has the opportunity to review the data that is to be made public with respect to the facility prior to such data being made public. The Secretary shall report quality measures that relate to services furnished in inpatient settings in rehabilitation facilities on the Internet website of the Centers for Medicare & Medicaid Services.

(F) SUBMISSION OF ADDITIONAL DATA.—

(i) IN GENERAL.—For the fiscal year beginning on the specified application date (as defined in subsection (a)(2)(E) of section 1899B), as applicable with respect to inpatient rehabilitation facilities and quality measures under subsection (c)(1) of such section and measures under subsection (d)(1) of such section, and each subsequent fiscal year, in addition to such data on the quality measures described in subparagraph (C), each rehabilitation facility shall submit to the Secretary

data on the quality measures under such subsection (c)(1) and any necessary data specified by the Secretary under such subsection (d)(1).

(ii) STANDARDIZED PATIENT ASSESSMENT DATA.—For fiscal year 2019 and each subsequent fiscal year, in addition to such data described in clause (i), each rehabilitation facility shall submit to the Secretary standardized patient assessment data required under subsection (b)(1) of section 1899B.

(iii) SUBMISSION.—Such data shall be submitted in the form and manner, and at the time, specified by the Secretary for purposes of this subparagraph.

(G) NON-DUPLICATION.—To the extent data submitted under subparagraph (F) duplicates other data required to be submitted under subparagraph (C), the submission of such data under subparagraph (F) shall be in lieu of the submission of such data under subparagraph (C). The previous sentence shall not apply insofar as the Secretary determines it is necessary to avoid a delay in the implementation of section 1899B, taking into account the different specified application dates under subsection (a)(2)(E) of such section.

(8) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise of the establishment of—

(A) case mix groups, of the methodology for the classification of patients within such groups, and of the appropriate weighting factors thereof under paragraph (2),

(B) the prospective payment rates under paragraph (3),

(C) outlier and special payments under paragraph (4), and

(D) area wage adjustments under paragraph (6).

(k) PAYMENT TO NONHOSPITAL PROVIDERS.—

(1) IN GENERAL.—For cost reporting periods beginning on or after October 1, 1997, the Secretary may establish rules for payment to qualified nonhospital providers for their direct costs of medical education, if those costs are incurred in the operation of an approved medical residency training program described in subsection (h). Such rules shall specify the amounts, form, and manner in which such payments will be made and the portion of such payments that will be made from each of the trust funds under this title.

(2) QUALIFIED NONHOSPITAL PROVIDERS.—For purposes of this subsection, the term "qualified nonhospital providers" means—

(A) a Federally qualified health center, as defined in section 1861(aa)(4);

(B) a rural health clinic, as defined in section 1861(aa)(2);

(C) Medicare+Choice organizations; and

(D) such other providers (other than hospitals) as the Secretary determines to be appropriate.

(l) PAYMENT FOR NURSING AND ALLIED HEALTH EDUCATION FOR MANAGED CARE ENROLLEES.—

(1) IN GENERAL.—For portions of cost reporting periods occurring in a year (beginning with 2000), the Secretary shall provide for an additional payment amount for any hospital that receives payments for the costs of approved educational activities for nurse and allied health professional training under section 1861(v)(1).

(2) PAYMENT AMOUNT.—The additional payment amount under this subsection for each hospital for portions of cost reporting periods occurring in a year shall be an amount specified by the Secretary in a manner consistent with the following:

(A) DETERMINATION OF MANAGED CARE ENROLLEE PAYMENT RATIO FOR GRADUATE MEDICAL EDUCATION PAYMENTS.—The Secretary shall estimate the ratio of payments for all hospitals for portions of cost reporting periods occurring in the year under subsection (h)(3)(D) to total direct graduate medical education payments estimated for such portions of periods under subsection (h)(3).

(B) APPLICATION TO FEE-FOR-SERVICE NURSING AND ALLIED HEALTH EDUCATION PAYMENTS.—Such ratio shall be applied to the Secretary's estimate of total payments for nursing and allied health education determined under section 1861(v) for portions of cost reporting periods occurring in the year to determine a total amount of additional payments for nursing and allied health education to be distributed to hospitals under this subsection for portions of cost reporting periods occurring in the year; except that in no case shall such total amount exceed $60,000,000 in any year.

(C) APPLICATION TO HOSPITAL.—The amount of payment under this subsection to a hospital for portions of cost reporting periods occurring in a year is equal to the total amount of payments determined under subparagraph (B) for the year multiplied by the ratio of—

(i) the product of (I) the Secretary's estimate of the ratio of the amount of payments made under section 1861(v) to the hospital for nursing and allied health education activities for the hospital's cost reporting period ending in the second preceding fiscal year, to the hospital's total inpatient days for such period, and (II) the total number of inpatient days (as established by the Secretary) for such period which are attributable to services furnished to individuals who are enrolled under a risk sharing contract with an eligible organization under section 1876 and who are entitled to benefits under part A or who are enrolled with a Medicare+Choice organization under part C; to

(ii) the sum of the products determined under clause (i) for such cost reporting periods.

(m) PROSPECTIVE PAYMENT FOR LONG-TERM CARE HOSPITALS.—

(1) REFERENCE TO ESTABLISHMENT AND IMPLEMENTATION OF SYSTEM.—For provisions related to the establishment and implementation of a prospective payment system for payments under this title for inpatient hospital services furnished by a long-term care hospital described in subsection (d)(1)(B)(iv), see

section 123 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000.

(2) UPDATE FOR RATE YEAR 2008.—In implementing the system described in paragraph (1) for discharges occurring during the rate year ending in 2008 for a hospital, the base rate for such discharges for the hospital shall be the same as the base rate for discharges for the hospital occurring during the rate year ending in 2007.

(3) IMPLEMENTATION FOR RATE YEAR 2010 AND SUBSEQUENT YEARS.—

(A) IN GENERAL.—Subject to subparagraph (C), in implementing the system described in paragraph (1) for rate year 2010 and each subsequent rate year, any annual update to a standard Federal rate for discharges for the hospital during the rate year, shall be reduced—

(i) for rate year 2012 and each subsequent rate year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(ii) for each of rate years 2010 through 2019, by the other adjustment described in paragraph (4).

(B) SPECIAL RULE.—The application of this paragraph may result in such annual update being less than 0.0 for a rate year, and may result in payment rates under the system described in paragraph (1) for a rate year being less than such payment rates for the preceding rate year.

(C) ADDITIONAL SPECIAL RULE.—For fiscal year 2018, the annual update under subparagraph (A) for the fiscal year, after application of clauses (i) and (ii) of subparagraph (A), shall be 1 percent.

(4) OTHER ADJUSTMENT.—For purposes of paragraph (3)(A)(ii), the other adjustment described in this paragraph is—

(A) for rate year 2010, 0.25 percentage point;

(B) for rate year 2011, 0.50 percentage point;

(C) for each of the rate years beginning in 2012 and 2013, 0.1 percentage point;

(D) for rate year 2014, 0.3 percentage point;

(E) for each of rate years 2015 and 2016, 0.2 percentage point; and

(F) for each of rate years 2017, 2018, and 2019, 0.75 percentage point.

(5) QUALITY REPORTING.—

(A) REDUCTION IN UPDATE FOR FAILURE TO REPORT.—

(i) IN GENERAL.—Under the system described in paragraph (1), for rate year 2014 and each subsequent rate year, in the case of a long-term care hospital that does not submit data to the Secretary in accordance with subparagraphs (C) and (F) with respect to such a rate year, any annual update to a standard Federal rate for discharges for the hospital during the rate year, and after application of paragraph (3), shall be reduced by 2 percentage points.

(ii) SPECIAL RULE.—The application of this subparagraph may result in such annual update being less

than 0.0 for a rate year, and may result in payment rates under the system described in paragraph (1) for a rate year being less than such payment rates for the preceding rate year.

(B) NONCUMULATIVE APPLICATION.—Any reduction under subparagraph (A) shall apply only with respect to the rate year involved and the Secretary shall not take into account such reduction in computing the payment amount under the system described in paragraph (1) for a subsequent rate year.

(C) SUBMISSION OF QUALITY DATA.—Subject to subparagraph (G), for rate year 2014 and each subsequent rate year, each long-term care hospital shall submit to the Secretary data on quality measures specified under subparagraph (D). Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(D) QUALITY MEASURES.—

(i) IN GENERAL.—Subject to clause (ii), any measure specified by the Secretary under this subparagraph must have been endorsed by the entity with a contract under section 1890(a).

(ii) EXCEPTION.—In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(iii) TIME FRAME.—Not later than October 1, 2012, the Secretary shall publish the measures selected under this subparagraph that will be applicable with respect to rate year 2014.

(iv) ADDITIONAL QUALITY MEASURES.—Not later than October 1, 2015, the Secretary shall establish a functional status quality measure for change in mobility among inpatients requiring ventilator support.

(E) PUBLIC AVAILABILITY OF DATA SUBMITTED.—The Secretary shall establish procedures for making data submitted under subparagraph (C) and subparagraph (F)(i) available to the public. Such procedures shall ensure that a long-term care hospital has the opportunity to review the data that is to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures that relate to services furnished in inpatient settings in long-term care hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(F) SUBMISSION OF ADDITIONAL DATA.—

(i) IN GENERAL.—For the rate year beginning on the specified application date (as defined in subsection (a)(2)(E) of section 1899B), as applicable with respect to long-term care hospitals and quality measures

under subsection (c)(1) of such section and measures under subsection (d)(1) of such section, and each subsequent rate year, in addition to the data on the quality measures described in subparagraph (C), each long-term care hospital (other than a hospital classified under subsection (d)(1)(B)(iv)(II)) shall submit to the Secretary data on the quality measures under such subsection (c)(1) and any necessary data specified by the Secretary under such subsection (d)(1).

(ii) STANDARDIZED PATIENT ASSESSMENT DATA.—For rate year 2019 and each subsequent rate year, in addition to such data described in clause (i), each long-term care hospital (other than a hospital classified under subsection (d)(1)(B)(iv)(II)) shall submit to the Secretary standardized patient assessment data required under subsection (b)(1) of section 1899B.

(iii) SUBMISSION.—Such data shall be submitted in the form and manner, and at the time, specified by the Secretary for purposes of this subparagraph.

(G) NON-DUPLICATION.—To the extent data submitted under subparagraph (F) duplicates other data required to be submitted under subparagraph (C), the submission of such data under subparagraph (F) shall be in lieu of the submission of such data under subparagraph (C). The previous sentence shall not apply insofar as the Secretary determines it is necessary to avoid a delay in the implementation of section 1899B, taking into account the different specified application dates under subsection (a)(2)(E) of such section.

(6) APPLICATION OF SITE NEUTRAL IPPS PAYMENT RATE IN CERTAIN CASES.—

(A) GENERAL APPLICATION OF SITE NEUTRAL IPPS PAYMENT AMOUNT FOR DISCHARGES FAILING TO MEET APPLICABLE CRITERIA.—

(i) IN GENERAL.—For a discharge in cost reporting periods beginning on or after October 1, 2015, except as provided in clause (ii) and subparagraph (C), payment under this title to a long-term care hospital for inpatient hospital services shall be made at the applicable site neutral payment rate (as defined in subparagraph (B)).

(ii) EXCEPTION FOR CERTAIN DISCHARGES MEETING CRITERIA.—Clause (i) shall not apply (and payment shall be made to a long-term care hospital without regard to this paragraph) for a discharge if—

(I) the discharge meets the ICU criterion under clause (iii) or the ventilator criterion under clause (iv); and

(II) the discharge does not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation.

(iii) INTENSIVE CARE UNIT (ICU) CRITERION.—

(I) IN GENERAL.—The criterion specified in this clause (in this paragraph referred to as the "ICU criterion"), for a discharge from a long-term care

hospital, is that the stay in the long-term care hospital ending with such discharge was immediately preceded by a discharge from a stay in a subsection (d) hospital that included at least 3 days in an intensive care unit (ICU), as determined by the Secretary.

(II) DETERMINING ICU DAYS.—In determining intensive care unit days under subclause (I), the Secretary shall use data from revenue center codes 020x or 021x (or such successor codes as the Secretary may establish).

(iv) VENTILATOR CRITERION.—The criterion specified in this clause (in this paragraph referred to as the "ventilator criterion"), for a discharge from a long-term care hospital, is that—

(I) the stay in the long-term care hospital ending with such discharge was immediately preceded by a discharge from a stay in a subsection (d) hospital; and

(II) the individual discharged was assigned to a Medicare-Severity-Long-Term-Care-Diagnosis-Related-Group (MS–LTC–DRG) based on the receipt of ventilator services of at least 96 hours.

(B) APPLICABLE SITE NEUTRAL PAYMENT RATE DEFINED.—

(i) IN GENERAL.—In this paragraph, the term "applicable site neutral payment rate" means—

(I) for discharges in cost reporting periods beginning during fiscal year 2016 or fiscal year 2017, the blended payment rate specified in clause (iii); and

(II) for discharges in cost reporting periods beginning during fiscal year 2018 or a subsequent fiscal year, the site neutral payment rate (as defined in clause (ii)).

(ii) SITE NEUTRAL PAYMENT RATE DEFINED.—In this paragraph, the term "site neutral payment rate" means the lower of—

(I) the IPPS comparable per diem amount determined under paragraph (d)(4) of section 412.529 of title 42, Code of Federal Regulations, including any applicable outlier payments under section 412.525 of such title; or

(II) 100 percent of the estimated cost for the services involved.

(iii) BLENDED PAYMENT RATE.—The blended payment rate specified in this clause, for a long-term care hospital for inpatient hospital services for a discharge, is comprised of—

(I) half of the site neutral payment rate (as defined in clause (ii)) for the discharge; and

(II) half of the payment rate that would otherwise be applicable to such discharge without regard to this paragraph, as determined by the Secretary.

(C) LIMITING PAYMENT FOR ALL HOSPITAL DISCHARGES TO SITE NEUTRAL PAYMENT RATE FOR HOSPITALS FAILING TO MEET APPLICABLE LTCH DISCHARGE THRESHOLDS.—

(i) NOTICE OF LTCH DISCHARGE PAYMENT PERCENTAGE.—For cost reporting periods beginning during or after fiscal year 2016, the Secretary shall inform each long-term care hospital of its LTCH discharge payment percentage (as defined in clause (iv)) for such period.

(ii) LIMITATION.—For cost reporting periods beginning during or after fiscal year 2020, if the Secretary determines for a long-term care hospital that its LTCH discharge payment percentage for the period is not at least 50 percent—

(I) the Secretary shall inform the hospital of such fact; and

(II) subject to clause (iii), for all discharges in the hospital in each succeeding cost reporting period, the payment amount under this subsection shall be the payment amount that would apply under subsection (d) for the discharge if the hospital were a subsection (d) hospital.

(iii) PROCESS FOR REINSTATEMENT.—The Secretary shall establish a process whereby a long-term care hospital may seek to and have the provisions of subclause (II) of clause (ii) discontinued with respect to that hospital.

(iv) LTCH DISCHARGE PAYMENT PERCENTAGE.—In this subparagraph, the term "LTCH discharge payment percentage" means, with respect to a long-term care hospital for a cost reporting period beginning during or after fiscal year 2020, the ratio (expressed as a percentage) of—

(I) the number of Medicare fee-for-service discharges for such hospital and period for which payment is not made at the site neutral payment rate, to

(II) the total number of Medicare fee-for-service discharges for such hospital and period.

(D) INCLUSION OF SUBSECTION (d) PUERTO RICO HOSPITALS.—In this paragraph, any reference in this paragraph to a subsection (d) hospital shall be deemed to include a reference to a subsection (d) Puerto Rico hospital.

(n) INCENTIVES FOR ADOPTION AND MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY.—

(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, with respect to inpatient hospital services furnished by an eligible hospital during a payment year (as defined in paragraph (2)(G)), if the eligible hospital is a meaningful EHR user (as determined under paragraph (3)) for the EHR reporting period with respect to such year, in addition to the amount otherwise paid under this section, there also shall be paid to the eligible hospital, from the Federal Hospital Insurance Trust Fund established under section 1817, an amount

equal to the applicable amount specified in paragraph (2)(A) for the hospital for such payment year.

(2) PAYMENT AMOUNT.—

(A) IN GENERAL.—Subject to the succeeding subparagraphs of this paragraph, the applicable amount specified in this subparagraph for an eligible hospital for a payment year is equal to the product of the following:

(i) INITIAL AMOUNT.—The sum of—

(I) the base amount specified in subparagraph (B); plus

(II) the discharge related amount specified in subparagraph (C) for a 12-month period selected by the Secretary with respect to such payment year.

(ii) MEDICARE SHARE.—The Medicare share as specified in subparagraph (D) for the eligible hospital for a period selected by the Secretary with respect to such payment year.

(iii) TRANSITION FACTOR.—The transition factor specified in subparagraph (E) for the eligible hospital for the payment year.

(B) BASE AMOUNT.—The base amount specified in this subparagraph is $2,000,000.

(C) DISCHARGE RELATED AMOUNT.—The discharge related amount specified in this subparagraph for a 12-month period selected by the Secretary shall be determined as the sum of the amount, estimated based upon total discharges for the eligible hospital (regardless of any source of payment) for the period, for each discharge up to the 23,000th discharge as follows:

(i) For the first through 1,149th discharge, $0.

(ii) For the 1,150th through the 23,000th discharge, $200.

(iii) For any discharge greater than the 23,000th, $0.

(D) MEDICARE SHARE.—The Medicare share specified under this subparagraph for an eligible hospital for a period selected by the Secretary for a payment year is equal to the fraction—

(i) the numerator of which is the sum (for such period and with respect to the eligible hospital) of—

(I) the estimated number of inpatient-bed-days (as established by the Secretary) which are attributable to individuals with respect to whom payment may be made under part A; and

(II) the estimated number of inpatient-bed-days (as so established) which are attributable to individuals who are enrolled with a Medicare Advantage organization under part C; and

(ii) the denominator of which is the product of—

(I) the estimated total number of inpatient-bed-days with respect to the eligible hospital during such period; and

(II) the estimated total amount of the eligible hospital's charges during such period, not including any charges that are attributable to charity

care (as such term is used for purposes of hospital cost reporting under this title), divided by the estimated total amount of the hospital's charges during such period.

Insofar as the Secretary determines that data are not available on charity care necessary to calculate the portion of the formula specified in clause (ii)(II), the Secretary shall use data on uncompensated care and may adjust such data so as to be an appropriate proxy for charity care including a downward adjustment to eliminate bad debt data from uncompensated care data. In the absence of the data necessary, with respect to a hospital, for the Secretary to compute the amount described in clause (ii)(II), the amount under such clause shall be deemed to be 1. In the absence of data, with respect to a hospital, necessary to compute the amount described in clause (i)(II), the amount under such clause shall be deemed to be 0.

(E) TRANSITION FACTOR SPECIFIED.—

(i) IN GENERAL.—Subject to clause (ii), the transition factor specified in this subparagraph for an eligible hospital for a payment year is as follows:

(I) For the first payment year for such hospital, 1.

(II) For the second payment year for such hospital, ¾.

(III) For the third payment year for such hospital, ½.

(IV) For the fourth payment year for such hospital, ¼.

(V) For any succeeding payment year for such hospital, 0.

(ii) PHASE DOWN FOR ELIGIBLE HOSPITALS FIRST ADOPTING EHR AFTER 2013.—If the first payment year for an eligible hospital is after 2013, then the transition factor specified in this subparagraph for a payment year for such hospital is the same as the amount specified in clause (i) for such payment year for an eligible hospital for which the first payment year is 2013. If the first payment year for an eligible hospital is after 2015 then the transition factor specified in this subparagraph for such hospital and for such year and any subsequent year shall be 0.

(F) FORM OF PAYMENT.—The payment under this subsection for a payment year may be in the form of a single consolidated payment or in the form of such periodic installments as the Secretary may specify.

(G) PAYMENT YEAR DEFINED.—

(i) IN GENERAL.—For purposes of this subsection, the term "payment year" means a fiscal year beginning with fiscal year 2011.

(ii) FIRST, SECOND, ETC. PAYMENT YEAR.—The term "first payment year" means, with respect to inpatient hospital services furnished by an eligible hospital, the first fiscal year for which an incentive payment is made for such services under this subsection. The

terms "second payment year", "third payment year", and "fourth payment year" mean, with respect to an eligible hospital, each successive year immediately following the first payment year for that hospital.

(3) MEANINGFUL EHR USER.—

(A) IN GENERAL.—For purposes of paragraph (1), an eligible hospital shall be treated as a meaningful EHR user for an EHR reporting period for a payment year (or, for purposes of subsection (b)(3)(B)(ix), for an EHR reporting period under such subsection for a fiscal year) if each of the following requirements are met:

(i) MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY.—The eligible hospital demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period the hospital is using certified EHR technology in a meaningful manner.

(ii) INFORMATION EXCHANGE.—The eligible hospital demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period such certified EHR technology is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination, and the hospital demonstrates (through a process specified by the Secretary, such as the use of an attestation) that the hospital has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of the certified EHR technology.

(iii) REPORTING ON MEASURES USING EHR.—Subject to subparagraph (B)(ii) and using such certified EHR technology, the eligible hospital submits information for such period, in a form and manner specified by the Secretary, on such clinical quality measures and such other measures as selected by the Secretary under subparagraph (B)(i).

The Secretary shall seek to improve the use of electronic health records and health care quality over time by requiring more stringent measures of meaningful use selected under this paragraph.

(B) REPORTING ON MEASURES.—

(i) SELECTION.—The Secretary shall select measures for purposes of subparagraph (A)(iii) but only consistent with the following:

(I) The Secretary shall provide preference to clinical quality measures that have been selected for purposes of applying subsection (b)(3)(B)(viii) or that have been endorsed by the entity with a contract with the Secretary under section 1890(a).

(II) Prior to any measure (other than a clinical quality measure that has been selected for purposes of applying subsection (b)(3)(B)(viii)) being selected under this subparagraph, the Secretary

shall publish in the Federal Register such measure and provide for a period of public comment on such measure.

(ii) LIMITATIONS.—The Secretary may not require the electronic reporting of information on clinical quality measures under subparagraph (A)(iii) unless the Secretary has the capacity to accept the information electronically, which may be on a pilot basis.

(iii) COORDINATION OF REPORTING OF INFORMATION.—In selecting such measures, and in establishing the form and manner for reporting measures under subparagraph (A)(iii), the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required, including reporting under subsection (b)(3)(B)(viii).

(C) DEMONSTRATION OF MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY AND INFORMATION EXCHANGE.—

(i) IN GENERAL.—An eligible hospital may satisfy the demonstration requirement of clauses (i) and (ii) of subparagraph (A) through means specified by the Secretary, which may include—

(I) an attestation;

(II) the submission of claims with appropriate coding (such as a code indicating that inpatient care was documented using certified EHR technology);

(III) a survey response;

(IV) reporting under subparagraph (A)(iii); and

(V) other means specified by the Secretary.

(ii) USE OF PART D DATA.—Notwithstanding sections 1860D–15(d)(2)(B) and 1860D–15(f)(2), the Secretary may use data regarding drug claims submitted for purposes of section 1860D–15 that are necessary for purposes of subparagraph (A).

(4) APPLICATION.—

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

(i) the methodology and standards for determining payment amounts under this subsection and payment adjustments under subsection (b)(3)(B)(ix), including selection of periods under paragraph (2) for determining, and making estimates or using proxies of, discharges under paragraph (2)(C) and inpatient-bed-days, hospital charges, charity charges, and Medicare share under paragraph (2)(D);

(ii) the methodology and standards for determining a meaningful EHR user under paragraph (3), including selection of measures under paragraph (3)(B), specification of the means of demonstrating meaningful EHR use under paragraph (3)(C), and the hardship exception under subsection (b)(3)(B)(ix)(II); and

(iii) the specification of EHR reporting periods under paragraph (6)(B) and the selection of the form of payment under paragraph (2)(F).

(B) POSTING ON WEBSITE.—The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services, in an easily understandable format, a list of the names of the eligible hospitals that are meaningful EHR users under this subsection or subsection (b)(3)(B)(ix) (and a list of the names of critical access hospitals to which paragraph (3) or (4) of section 1814(l) applies), and other relevant data as determined appropriate by the Secretary. The Secretary shall ensure that an eligible hospital (or critical access hospital) has the opportunity to review the other relevant data that are to be made public with respect to the hospital (or critical access hospital) prior to such data being made public.

(5) CERTIFIED EHR TECHNOLOGY DEFINED.—The term "certified EHR technology" has the meaning given such term in section 1848(o)(4).

(6) DEFINITIONS.—For purposes of this subsection:

(A) EHR REPORTING PERIOD.—The term "EHR reporting period" means, with respect to a payment year, any period (or periods) as specified by the Secretary.

(B) ELIGIBLE HOSPITAL.—The term "eligible hospital" means a subsection (d) hospital.

(o) HOSPITAL VALUE-BASED PURCHASING PROGRAM.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, the Secretary shall establish a hospital value-based purchasing program (in this subsection referred to as the "Program") under which value-based incentive payments are made in a fiscal year to hospitals that meet the performance standards under paragraph (3) for the performance period for such fiscal year (as established under paragraph (4)) *and, for performance periods for fiscal year 2018 or a subsequent fiscal year, that provide a demonstration described in subparagraph (D) to the Secretary*.

(B) PROGRAM TO BEGIN IN FISCAL YEAR 2013.—The Program shall apply to payments for discharges occurring on or after October 1, 2012.

(C) APPLICABILITY OF PROGRAM TO HOSPITALS.—

(i) IN GENERAL.—For purposes of this subsection, subject to clause (ii), the term "hospital" means a subsection (d) hospital (as defined in subsection (d)(1)(B)).

(ii) EXCLUSIONS.—The term "hospital" shall not include, with respect to a fiscal year, a hospital—

(I) that is subject to the payment reduction under subsection (b)(3)(B)(viii)(I) for such fiscal year;

(II) for which, during the performance period for such fiscal year, the Secretary has cited deficiencies that pose immediate jeopardy to the health or safety of patients;

(III) for which there are not a minimum number (as determined by the Secretary) of measures that apply to the hospital for the performance period for such fiscal year; or

(IV) for which there are not a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for such fiscal year.

(iii) INDEPENDENT ANALYSIS.—For purposes of determining the minimum numbers under subclauses (III) and (IV) of clause (ii), the Secretary shall have conducted an independent analysis of what numbers are appropriate.

(iv) EXEMPTION.—In the case of a hospital that is paid under section 1814(b)(3), the Secretary may exempt such hospital from the application of this subsection if the State which is paid under such section submits an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under this subsection.

(D) DEMONSTRATION DESCRIBED.—The demonstration described in this subparagraph is a demonstration, through means such as an attestation, that the hospital has not taken any action described in subsection (a)(2) of section 3010A of the Public Health Service Act, with respect to the use of any certified EHR technology.

(2) MEASURES.—

(A) IN GENERAL.—The Secretary shall select measures, other than measures of readmissions, for purposes of the Program. Such measures shall be selected from the measures specified under subsection (b)(3)(B)(viii).

(B) REQUIREMENTS.—

(i) FOR FISCAL YEAR 2013.—For value-based incentive payments made with respect to discharges occurring during fiscal year 2013, the Secretary shall ensure the following:

(I) CONDITIONS OR PROCEDURES.—Measures are selected under subparagraph (A) that cover at least the following 5 specific conditions or procedures:

(aa) Acute myocardial infarction (AMI).

(bb) Heart failure.

(cc) Pneumonia.

(dd) Surgeries, as measured by the Surgical Care Improvement Project (formerly referred to as "Surgical Infection Prevention" for discharges occurring before July 2006).

(ee) Healthcare-associated infections, as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent Healthcare-Associated Infections (or any successor plan) of the Department of Health and Human Services.

(II) HCAHPS.—Measures selected under subparagraph (A) shall be related to the Hospital Consumer Assessment of Healthcare Providers and Systems survey (HCAHPS).

(ii) INCLUSION OF EFFICIENCY MEASURES.—For value-based incentive payments made with respect to discharges occurring during fiscal year 2014 or a subsequent fiscal year, the Secretary shall ensure that measures selected under subparagraph (A) include efficiency measures, including measures of "Medicare spending per beneficiary". Such measures shall be adjusted for factors such as age, sex, race, severity of illness, and other factors that the Secretary determines appropriate.

(C) LIMITATIONS.—

(i) TIME REQUIREMENT FOR PRIOR REPORTING AND NOTICE.—The Secretary may not select a measure under subparagraph (A) for use under the Program with respect to a performance period for a fiscal year (as established under paragraph (4)) unless such measure has been specified under subsection (b)(3)(B)(viii) and included on the Hospital Compare Internet website for at least 1 year prior to the beginning of such performance period.

(ii) MEASURE NOT APPLICABLE UNLESS HOSPITAL FURNISHES SERVICES APPROPRIATE TO THE MEASURE.—A measure selected under subparagraph (A) shall not apply to a hospital if such hospital does not furnish services appropriate to such measure.

(D) REPLACING MEASURES.—Subclause (VI) of subsection (b)(3)(B)(viii) shall apply to measures selected under subparagraph (A) in the same manner as such subclause applies to measures selected under such subsection.

(3) PERFORMANCE STANDARDS.—

(A) ESTABLISHMENT.—The Secretary shall establish performance standards with respect to measures selected under paragraph (2) for a performance period for a fiscal year (as established under paragraph (4)).

(B) ACHIEVEMENT AND IMPROVEMENT.—The performance standards established under subparagraph (A) shall include levels of achievement and improvement.

(C) TIMING.—The Secretary shall establish and announce the performance standards under subparagraph (A) not later than 60 days prior to the beginning of the performance period for the fiscal year involved.

(D) CONSIDERATIONS IN ESTABLISHING STANDARDS.—In establishing performance standards with respect to measures under this paragraph, the Secretary shall take into account appropriate factors, such as—

(i) practical experience with the measures involved, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods;

(ii) historical performance standards;

(iii) improvement rates; and

(iv) the opportunity for continued improvement.

(4) PERFORMANCE PERIOD.—For purposes of the Program, the Secretary shall establish the performance period for a fiscal

year. Such performance period shall begin and end prior to the beginning of such fiscal year.

(5) HOSPITAL PERFORMANCE SCORE.—

(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall develop a methodology for assessing the total performance of each hospital based on performance standards with respect to the measures selected under paragraph (2) for a performance period (as established under paragraph (4)). Using such methodology, the Secretary shall provide for an assessment (in this subsection referred to as the "hospital performance score") for each hospital for each performance period.

(B) APPLICATION.—

(i) APPROPRIATE DISTRIBUTION.—The Secretary shall ensure that the application of the methodology developed under subparagraph (A) results in an appropriate distribution of value-based incentive payments under paragraph (6) among hospitals achieving different levels of hospital performance scores, with hospitals achieving the highest hospital performance scores receiving the largest value-based incentive payments.

(ii) HIGHER OF ACHIEVEMENT OR IMPROVEMENT.—The methodology developed under subparagraph (A) shall provide that the hospital performance score is determined using the higher of its achievement or improvement score for each measure.

(iii) WEIGHTS.—The methodology developed under subparagraph (A) shall provide for the assignment of weights for categories of measures as the Secretary determines appropriate.

(iv) NO MINIMUM PERFORMANCE STANDARD.—The Secretary shall not set a minimum performance standard in determining the hospital performance score for any hospital.

(v) REFLECTION OF MEASURES APPLICABLE TO THE HOSPITAL.—The hospital performance score for a hospital shall reflect the measures that apply to the hospital.

(6) CALCULATION OF VALUE-BASED INCENTIVE PAYMENTS.—

(A) IN GENERAL.—In the case of a hospital that the Secretary determines meets (or exceeds) the performance standards under paragraph (3) for the performance period for a fiscal year (as established under paragraph (4)), the Secretary shall increase the base operating DRG payment amount (as defined in paragraph (7)(D)), as determined after application of paragraph (7)(B)(i), for a hospital for each discharge occurring in such fiscal year by the value-based incentive payment amount.

(B) VALUE-BASED INCENTIVE PAYMENT AMOUNT.—The value-based incentive payment amount for each discharge of a hospital in a fiscal year shall be equal to the product of—

(i) the base operating DRG payment amount (as defined in paragraph (7)(D)) for the discharge for the hospital for such fiscal year; and

(ii) the value-based incentive payment percentage specified under subparagraph (C) for the hospital for such fiscal year.

(C) VALUE-BASED INCENTIVE PAYMENT PERCENTAGE.—

(i) IN GENERAL.—The Secretary shall specify a value-based incentive payment percentage for a hospital for a fiscal year.

(ii) REQUIREMENTS.—In specifying the value-based incentive payment percentage for each hospital for a fiscal year under clause (i), the Secretary shall ensure that—

(I) such percentage is based on the hospital performance score of the hospital under paragraph (5); and

(II) the total amount of value-based incentive payments under this paragraph to all hospitals in such fiscal year is equal to the total amount available for value-based incentive payments for such fiscal year under paragraph (7)(A), as estimated by the Secretary.

(7) FUNDING FOR VALUE-BASED INCENTIVE PAYMENTS.—

(A) AMOUNT.—The total amount available for value-based incentive payments under paragraph (6) for all hospitals for a fiscal year shall be equal to the total amount of reduced payments for all hospitals under subparagraph (B) for such fiscal year, as estimated by the Secretary.

(B) ADJUSTMENT TO PAYMENTS.—

(i) IN GENERAL.—The Secretary shall reduce the base operating DRG payment amount (as defined in subparagraph (D)) for a hospital for each discharge in a fiscal year (beginning with fiscal year 2013) by an amount equal to the applicable percent (as defined in subparagraph (C)) of the base operating DRG payment amount for the discharge for the hospital for such fiscal year. The Secretary shall make such reductions for all hospitals in the fiscal year involved, regardless of whether or not the hospital has been determined by the Secretary to have earned a value-based incentive payment under paragraph (6) for such fiscal year.

(ii) NO EFFECT ON OTHER PAYMENTS.—Payments described in items (aa) and (bb) of subparagraph (D)(i)(II) for a hospital shall be determined as if this subsection had not been enacted.

(C) APPLICABLE PERCENT DEFINED.—For purposes of subparagraph (B), the term "applicable percent" means—

(i) with respect to fiscal year 2013, 1.0 percent;

(ii) with respect to fiscal year 2014, 1.25 percent;

(iii) with respect to fiscal year 2015, 1.5 percent;

(iv) with respect to fiscal year 2016, 1.75 percent; and

(v) with respect to fiscal year 2017 and succeeding fiscal years, 2 percent.

(D) BASE OPERATING DRG PAYMENT AMOUNT DEFINED.—

(i) IN GENERAL.—Except as provided in clause (ii), in this subsection, the term "base operating DRG pay-

ment amount" means, with respect to a hospital for a fiscal year—

(I) the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (q)) for a discharge if this subsection did not apply; reduced by

(II) any portion of such payment amount that is attributable to—

(aa) payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d); and

(bb) such other payments under subsection (d) determined appropriate by the Secretary.

(ii) SPECIAL RULES FOR CERTAIN HOSPITALS.—

(I) SOLE COMMUNITY HOSPITALS AND MEDICARE-DEPENDENT, SMALL RURAL HOSPITALS.—In the case of a medicare-dependent, small rural hospital (with respect to discharges occurring during fiscal year 2012 and 2013) or a sole community hospital, in applying subparagraph (A)(i), the payment amount that would otherwise be made under subsection (d) shall be determined without regard to subparagraphs (I) and (L) of subsection (b)(3) and subparagraphs (D) and (G) of subsection (d)(5).

(II) HOSPITALS PAID UNDER SECTION 1814.—In the case of a hospital that is paid under section 1814(b)(3), the term "base operating DRG payment amount" means the payment amount under such section.

(8) ANNOUNCEMENT OF NET RESULT OF ADJUSTMENTS.—Under the Program, the Secretary shall, not later than 60 days prior to the fiscal year involved, inform each hospital of the adjustments to payments to the hospital for discharges occurring in such fiscal year under paragraphs (6) and (7)(B)(i).

(9) NO EFFECT IN SUBSEQUENT FISCAL YEARS.—The value-based incentive payment under paragraph (6) and the payment reduction under paragraph (7)(B)(i) shall each apply only with respect to the fiscal year involved, and the Secretary shall not take into account such value-based incentive payment or payment reduction in making payments to a hospital under this section in a subsequent fiscal year.

(10) PUBLIC REPORTING.—

(A) HOSPITAL SPECIFIC INFORMATION.—

(i) IN GENERAL.—The Secretary shall make information available to the public regarding the performance of individual hospitals under the Program, including—

(I) the performance of the hospital with respect to each measure that applies to the hospital;

(II) the performance of the hospital with respect to each condition or procedure; and

(III) the hospital performance score assessing the total performance of the hospital.

(ii) OPPORTUNITY TO REVIEW AND SUBMIT CORRECTIONS.—The Secretary shall ensure that a hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to the

hospital under clause (i) prior to such information being made public.

(iii) WEBSITE.—Such information shall be posted on the Hospital Compare Internet website in an easily understandable format.

(B) AGGREGATE INFORMATION.—The Secretary shall periodically post on the Hospital Compare Internet website aggregate information on the Program, including—

(i) the number of hospitals receiving value-based incentive payments under paragraph (6) and the range and total amount of such value-based incentive payments; and

(ii) the number of hospitals receiving less than the maximum value-based incentive payment available to the hospital for the fiscal year involved and the range and amount of such payments.

(11) IMPLEMENTATION.—

(A) APPEALS.—The Secretary shall establish a process by which hospitals may appeal the calculation of a hospital's performance assessment with respect to the performance standards established under paragraph (3)(A) and the hospital performance score under paragraph (5). The Secretary shall ensure that such process provides for resolution of such appeals in a timely manner.

(B) LIMITATION ON REVIEW.—Except as provided in subparagraph (A), there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

(i) The methodology used to determine the amount of the value-based incentive payment under paragraph (6) and the determination of such amount.

(ii) The determination of the amount of funding available for such value-based incentive payments under paragraph (7)(A) and the payment reduction under paragraph (7)(B)(i).

(iii) The establishment of the performance standards under paragraph (3) and the performance period under paragraph (4).

(iv) The measures specified under subsection (b)(3)(B)(viii) and the measures selected under paragraph (2).

(v) The methodology developed under paragraph (5) that is used to calculate hospital performance scores and the calculation of such scores.

(vi) The validation methodology specified in subsection (b)(3)(B)(viii)(XI).

(C) CONSULTATION WITH SMALL HOSPITALS.—The Secretary shall consult with small rural and urban hospitals on the application of the Program to such hospitals.

(12) PROMULGATION OF REGULATIONS.—The Secretary shall promulgate regulations to carry out the Program, including the selection of measures under paragraph (2), the methodology developed under paragraph (5) that is used to calculate hospital performance scores, and the methodology used to determine

the amount of value-based incentive payments under paragraph (6).

(p) ADJUSTMENT TO HOSPITAL PAYMENTS FOR HOSPITAL ACQUIRED CONDITIONS.—

(1) IN GENERAL.—In order to provide an incentive for applicable hospitals to reduce hospital acquired conditions under this title, with respect to discharges from an applicable hospital occurring during fiscal year 2015 or a subsequent fiscal year, the amount of payment under this section or section 1814(b)(3), as applicable, for such discharges during the fiscal year shall be equal to 99 percent of the amount of payment that would otherwise apply to such discharges under this section or section 1814(b)(3) (determined after the application of subsections (o) and (q) and section 1814(l)(4) but without regard to this subsection).

(2) APPLICABLE HOSPITALS.—

(A) IN GENERAL.—For purposes of this subsection, the term "applicable hospital" means a subsection (d) hospital that meets the criteria described in subparagraph (B).

(B) CRITERIA DESCRIBED.—

(i) IN GENERAL.—The criteria described in this subparagraph, with respect to a subsection (d) hospital, is that the subsection (d) hospital is in the top quartile of all subsection (d) hospitals, relative to the national average, of hospital acquired conditions during the applicable period, as determined by the Secretary.

(ii) RISK ADJUSTMENT.—In carrying out clause (i), the Secretary shall establish and apply an appropriate risk adjustment methodology.

(C) EXEMPTION.—In the case of a hospital that is paid under section 1814(b)(3), the Secretary may exempt such hospital from the application of this subsection if the State which is paid under such section submits an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under this subsection.

(3) HOSPITAL ACQUIRED CONDITIONS.—For purposes of this subsection, the term "hospital acquired condition" means a condition identified for purposes of subsection (d)(4)(D)(iv) and any other condition determined appropriate by the Secretary that an individual acquires during a stay in an applicable hospital, as determined by the Secretary.

(4) APPLICABLE PERIOD.—In this subsection, the term "applicable period" means, with respect to a fiscal year, a period specified by the Secretary.

(5) REPORTING TO HOSPITALS.—Prior to fiscal year 2015 and each subsequent fiscal year, the Secretary shall provide confidential reports to applicable hospitals with respect to hospital acquired conditions of the applicable hospital during the applicable period.

(6) REPORTING HOSPITAL SPECIFIC INFORMATION.—

(A) IN GENERAL.—The Secretary shall make information available to the public regarding hospital acquired conditions of each applicable hospital.

(B) OPPORTUNITY TO REVIEW AND SUBMIT CORRECTIONS.—The Secretary shall ensure that an applicable hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to the hospital under subparagraph (A) prior to such information being made public.

(C) WEBSITE.—Such information shall be posted on the Hospital Compare Internet website in an easily understandable format.

(7) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

(A) The criteria described in paragraph (2)(A).

(B) The specification of hospital acquired conditions under paragraph (3).

(C) The specification of the applicable period under paragraph (4).

(D) The provision of reports to applicable hospitals under paragraph (5) and the information made available to the public under paragraph (6).

(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 1, 2012, in order to account for excess readmissions in the hospital, the Secretary shall make payments (in addition to the payments described in paragraph (2)(A)(ii)) for such a discharge to such hospital under subsection (d) (or section 1814(b)(3), as the case may be) in an amount equal to the product of—

(A) the base operating DRG payment amount (as defined in paragraph (2)) for the discharge; and

(B) the adjustment factor (described in paragraph (3)(A)) for the hospital for the fiscal year.

(2) BASE OPERATING DRG PAYMENT AMOUNT DEFINED.—

(A) IN GENERAL.—Except as provided in subparagraph (B), in this subsection, the term "base operating DRG payment amount" means, with respect to a hospital for a fiscal year—

(i) the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (o)) for a discharge if this subsection did not apply; reduced by

(ii) any portion of such payment amount that is attributable to payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d).

(B) SPECIAL RULES FOR CERTAIN HOSPITALS.—

(i) SOLE COMMUNITY HOSPITALS AND MEDICARE-DEPENDENT, SMALL RURAL HOSPITALS.—In the case of a medicare-dependent, small rural hospital (with respect to discharges occurring during fiscal years 2012 and 2013) or a sole community hospital, in applying sub-

paragraph (A)(i), the payment amount that would otherwise be made under subsection (d) shall be determined without regard to subparagraphs (I) and (L) of subsection (b)(3) and subparagraphs (D) and (G) of subsection (d)(5).

(ii) HOSPITALS PAID UNDER SECTION 1814.—In the case of a hospital that is paid under section 1814(b)(3), the Secretary may exempt such hospitals provided that States paid under such section submit an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established herein with respect to this section.

(3) ADJUSTMENT FACTOR.—

(A) IN GENERAL.—For purposes of paragraph (1), the adjustment factor under this paragraph for an applicable hospital for a fiscal year is equal to the greater of—

(i) the ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or

(ii) the floor adjustment factor specified in subparagraph (C).

(B) RATIO.—The ratio described in this subparagraph for a hospital for an applicable period is equal to 1 minus the ratio of—

(i) the aggregate payments for excess readmissions (as defined in paragraph (4)(A)) with respect to an applicable hospital for the applicable period; and

(ii) the aggregate payments for all discharges (as defined in paragraph (4)(B)) with respect to such applicable hospital for such applicable period.

(C) FLOOR ADJUSTMENT FACTOR.—For purposes of subparagraph (A), the floor adjustment factor specified in this subparagraph for—

(i) fiscal year 2013 is 0.99;

(ii) fiscal year 2014 is 0.98; or

(iii) fiscal year 2015 and subsequent fiscal years is 0.97.

(4) AGGREGATE PAYMENTS, EXCESS READMISSION RATIO DEFINED.—For purposes of this subsection:

(A) AGGREGATE PAYMENTS FOR EXCESS READMISSIONS.—The term "aggregate payments for excess readmissions" means, for a hospital for an applicable period, the sum, for applicable conditions (as defined in paragraph (5)(A)), of the product, for each applicable condition, of—

(i) the base operating DRG payment amount for such hospital for such applicable period for such condition;

(ii) the number of admissions for such condition for such hospital for such applicable period; and

(iii) the excess readmissions ratio (as defined in subparagraph (C)) for such hospital for such applicable period minus 1.

(B) AGGREGATE PAYMENTS FOR ALL DISCHARGES.—The term "aggregate payments for all discharges" means, for a hospital for an applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period.

(C) EXCESS READMISSION RATIO.—

(i) IN GENERAL.—Subject to clause (ii), the term "excess readmissions ratio" means, with respect to an applicable condition for a hospital for an applicable period, the ratio (but not less than 1.0) of—

(I) the risk adjusted readmissions based on actual readmissions, as determined consistent with a readmission measure methodology that has been endorsed under paragraph (5)(A)(ii)(I), for an applicable hospital for such condition with respect to such applicable period; to

(II) the risk adjusted expected readmissions (as determined consistent with such a methodology) for such hospital for such condition with respect to such applicable period.

(ii) EXCLUSION OF CERTAIN READMISSIONS.—For purposes of clause (i), with respect to a hospital, excess readmissions shall not include readmissions for an applicable condition for which there are fewer than a minimum number (as determined by the Secretary) of discharges for such applicable condition for the applicable period and such hospital.

(5) DEFINITIONS.—For purposes of this subsection:

(A) APPLICABLE CONDITION.—The term "applicable condition" means, subject to subparagraph (B), a condition or procedure selected by the Secretary among conditions and procedures for which—

(i) readmissions (as defined in subparagraph (E)) that represent conditions or procedures that are high volume or high expenditures under this title (or other criteria specified by the Secretary); and

(ii) measures of such readmissions—

(I) have been endorsed by the entity with a contract under section 1890(a); and

(II) such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital).

(B) EXPANSION OF APPLICABLE CONDITIONS.—Beginning with fiscal year 2015, the Secretary shall, to the extent practicable, expand the applicable conditions beyond the 3 conditions for which measures have been endorsed as described in subparagraph (A)(ii)(I) as of the date of the enactment of this subsection to the additional 4 conditions that have been identified by the Medicare Payment Advisory Commission in its report to Congress in June 2007 and to other conditions and procedures as determined appropriate by the Secretary. In expanding such applicable conditions, the Secretary shall seek the endorsement described in subparagraph (A)(ii)(I) but may apply such

measures without such an endorsement in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(C) APPLICABLE HOSPITAL.—The term "applicable hospital" means a subsection (d) hospital or a hospital that is paid under section 1814(b)(3), as the case may be.

(D) APPLICABLE PERIOD.—The term "applicable period" means, with respect to a fiscal year, such period as the Secretary shall specify.

(E) READMISSION.—The term "readmission" means, in the case of an individual who is discharged from an applicable hospital, the admission of the individual to the same or another applicable hospital within a time period specified by the Secretary from the date of such discharge. Insofar as the discharge relates to an applicable condition for which there is an endorsed measure described in subparagraph (A)(ii)(I), such time period (such as 30 days) shall be consistent with the time period specified for such measure.

(6) REPORTING HOSPITAL SPECIFIC INFORMATION.—

(A) IN GENERAL.—The Secretary shall make information available to the public regarding readmission rates of each subsection (d) hospital under the program.

(B) OPPORTUNITY TO REVIEW AND SUBMIT CORRECTIONS.—The Secretary shall ensure that a subsection (d) hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to the hospital under subparagraph (A) prior to such information being made public.

(C) WEBSITE.—Such information shall be posted on the Hospital Compare Internet website in an easily understandable format.

(7) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

(A) The determination of base operating DRG payment amounts.

(B) The methodology for determining the adjustment factor under paragraph (3), including excess readmissions ratio under paragraph (4)(C), aggregate payments for excess readmissions under paragraph (4)(A), and aggregate payments for all discharges under paragraph (4)(B), and applicable periods and applicable conditions under paragraph (5).

(C) The measures of readmissions as described in paragraph (5)(A)(ii).

(8) READMISSION RATES FOR ALL PATIENTS.—

(A) CALCULATION OF READMISSION.—The Secretary shall calculate readmission rates for all patients (as defined in subparagraph (D)) for a specified hospital (as defined in subparagraph (D)(ii)) for an applicable condition (as defined in paragraph (5)(B)) and other conditions deemed ap-

propriate by the Secretary for an applicable period (as defined in paragraph (5)(D)) in the same manner as used to calculate such readmission rates for hospitals with respect to this title and posted on the CMS Hospital Compare website.

(B) POSTING OF HOSPITAL SPECIFIC ALL PATIENT READMISSION RATES.—The Secretary shall make information on all patient readmission rates calculated under subparagraph (A) available on the CMS Hospital Compare website in a form and manner determined appropriate by the Secretary. The Secretary may also make other information determined appropriate by the Secretary available on such website.

(C) HOSPITAL SUBMISSION OF ALL PATIENT DATA.—

(i) Except as provided for in clause (ii), each specified hospital (as defined in subparagraph (D)(ii)) shall submit to the Secretary, in a form, manner and time specified by the Secretary, data and information determined necessary by the Secretary for the Secretary to calculate the all patient readmission rates described in subparagraph (A).

(ii) Instead of a specified hospital submitting to the Secretary the data and information described in clause (i), such data and information may be submitted to the Secretary, on behalf of such a specified hospital, by a state or an entity determined appropriate by the Secretary.

(D) DEFINITIONS.—For purposes of this paragraph:

(i) The term "all patients" means patients who are treated on an inpatient basis and discharged from a specified hospital (as defined in clause (ii)).

(ii) The term "specified hospital" means a subsection (d) hospital, hospitals described in clauses (i) through (v) of subsection (d)(1)(B) and, as determined feasible and appropriate by the Secretary, other hospitals not otherwise described in this subparagraph.

(r) ADJUSTMENTS TO MEDICARE DSH PAYMENTS.—

(1) EMPIRICALLY JUSTIFIED DSH PAYMENTS.—For fiscal year 2014 and each subsequent fiscal year, instead of the amount of disproportionate share hospital payment that would otherwise be made under subsection (d)(5)(F) to a subsection (d) hospital for the fiscal year, the Secretary shall pay to the subsection (d) hospital 25 percent of such amount (which represents the empirically justified amount for such payment, as determined by the Medicare Payment Advisory Commission in its March 2007 Report to the Congress).

(2) ADDITIONAL PAYMENT.—In addition to the payment made to a subsection (d) hospital under paragraph (1), for fiscal year 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospitals an additional amount equal to the product of the following factors:

(A) FACTOR ONE.—A factor equal to the difference between—

(i) the aggregate amount of payments that would be made to subsection (d) hospitals under subsection

(d)(5)(F) if this subsection did not apply for such fiscal year (as estimated by the Secretary); and

(ii) the aggregate amount of payments that are made to subsection (d) hospitals under paragraph (1) for such fiscal year (as so estimated).

(B) FACTOR TWO.—

(i) FISCAL YEARS 2014, 2015, 2016, AND 2017.—For each of fiscal years 2014, 2015, 2016, and 2017, a factor equal to 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, as determined by comparing the percent of such individuals—

(I) who are uninsured in 2013, the last year before coverage expansion under the Patient Protection and Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment); and

(II) who are uninsured in the most recent period for which data is available (as so calculated),

minus 0.1 percentage points for fiscal year 2014 and minus 0.2 percentage points for each of fiscal years 2015, 2016, and 2017.

(ii) 2018 AND SUBSEQUENT YEARS.—For fiscal year 2018 and each subsequent fiscal year, a factor equal to 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals—

(I) who are uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of the Centers for Medicare & Medicaid Services); and

(II) who are uninsured in the most recent period for which data is available (as so estimated and certified),

minus 0.2 percentage points for each of fiscal years 2018 and 2019.

(C) FACTOR THREE.—A factor equal to the percent, for each subsection (d) hospital, that represents the quotient of—

(i) the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines that alternative data is available which is a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and

(ii) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment

under this subsection for such period (as so estimated, based on such data).

(3) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

(A) Any estimate of the Secretary for purposes of determining the factors described in paragraph (2).

(B) Any period selected by the Secretary for such purposes.

(s) PROSPECTIVE PAYMENT FOR PSYCHIATRIC HOSPITALS.—

(1) REFERENCE TO ESTABLISHMENT AND IMPLEMENTATION OF SYSTEM.—For provisions related to the establishment and implementation of a prospective payment system for payments under this title for inpatient hospital services furnished by psychiatric hospitals (as described in clause (i) of subsection (d)(1)(B)) and psychiatric units (as described in the matter following clause (v) of such subsection), see section 124 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999.

(2) IMPLEMENTATION FOR RATE YEAR BEGINNING IN 2010 AND SUBSEQUENT RATE YEARS.—

(A) IN GENERAL.—In implementing the system described in paragraph (1) for the rate year beginning in 2010 and any subsequent rate year, any update to a base rate for days during the rate year for a psychiatric hospital or unit, respectively, shall be reduced—

(i) for the rate year beginning in 2012 and each subsequent rate year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(ii) for each of the rate years beginning in 2010 through 2019, by the other adjustment described in paragraph (3).

(B) SPECIAL RULE.—The application of this paragraph may result in such update being less than 0.0 for a rate year, and may result in payment rates under the system described in paragraph (1) for a rate year being less than such payment rates for the preceding rate year.

(3) OTHER ADJUSTMENT.—For purposes of paragraph (2)(A)(ii), the other adjustment described in this paragraph is—

(A) for each of the rate years beginning in 2010 and 2011, 0.25 percentage point;

(B) for each of the rate years beginning in 2012 and 2013, 0.1 percentage point;

(C) for the rate year beginning in 2014, 0.3 percentage point;

(D) for each of the rate years beginning in 2015 and 2016, 0.2 percentage point; and

(E) for each of the rate years beginning in 2017, 2018, and 2019, 0.75 percentage point.

(4) QUALITY REPORTING.—

(A) REDUCTION IN UPDATE FOR FAILURE TO REPORT.—

(i) IN GENERAL.—Under the system described in paragraph (1), for rate year 2014 and each subsequent rate year, in the case of a psychiatric hospital or psychiatric unit that does not submit data to the Sec-

retary in accordance with subparagraph (C) with respect to such a rate year, any annual update to a standard Federal rate for discharges for the hospital during the rate year, and after application of paragraph (2), shall be reduced by 2 percentage points.

(ii) SPECIAL RULE.—The application of this subparagraph may result in such annual update being less than 0.0 for a rate year, and may result in payment rates under the system described in paragraph (1) for a rate year being less than such payment rates for the preceding rate year.

(B) NONCUMULATIVE APPLICATION.—Any reduction under subparagraph (A) shall apply only with respect to the rate year involved and the Secretary shall not take into account such reduction in computing the payment amount under the system described in paragraph (1) for a subsequent rate year.

(C) SUBMISSION OF QUALITY DATA.—For rate year 2014 and each subsequent rate year, each psychiatric hospital and psychiatric unit shall submit to the Secretary data on quality measures specified under subparagraph (D). Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(D) QUALITY MEASURES.—

(i) IN GENERAL.—Subject to clause (ii), any measure specified by the Secretary under this subparagraph must have been endorsed by the entity with a contract under section 1890(a).

(ii) EXCEPTION.—In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(iii) TIME FRAME.—Not later than October 1, 2012, the Secretary shall publish the measures selected under this subparagraph that will be applicable with respect to rate year 2014.

(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.

* * * * * * *

MEDICARE INTEGRITY PROGRAM

SEC. 1893. (a) ESTABLISHMENT OF PROGRAM.—There is hereby established the Medicare Integrity Program (in this section referred to as the "Program") under which the Secretary shall promote the integrity of the medicare program by entering into contracts in accordance with this section with eligible entities, or otherwise, to carry out the activities described in subsection (b).

(b) ACTIVITIES DESCRIBED.—The activities described in this subsection are as follows:

(1) Review of activities of providers of services or other individuals and entities furnishing items and services for which payment may be made under this title (including skilled nursing facilities and home health agencies), including medical and utilization review and fraud review (employing similar standards, processes, and technologies used by private health plans, including equipment and software technologies which surpass the capability of the equipment and technologies used in the review of claims under this title as of the date of the enactment of this section).

(2) Audit of cost reports.

(3) Determinations as to whether payment should not be, or should not have been, made under this title by reason of section 1862(b), and recovery of payments that should not have been made.

(4) Education of providers of services, beneficiaries, and other persons with respect to payment integrity and benefit quality assurance issues.

(5) Developing (and periodically updating) a list of items of durable medical equipment in accordance with section 1834(a)(15) which are subject to prior authorization under such section.

(6) The Medicare-Medicaid Data Match Program in accordance with subsection (g).

(c) ELIGIBILITY OF ENTITIES.—An entity is eligible to enter into a contract under the Program to carry out any of the activities described in subsection (b) if—

(1) the entity has demonstrated capability to carry out such activities;

(2) in carrying out such activities, the entity agrees to cooperate with the Inspector General of the Department of Health and Human Services, the Attorney General, and other law enforcement agencies, as appropriate, in the investigation and deterrence of fraud and abuse in relation to this title and in other cases arising out of such activities;

(3) the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement;

(4) the entity agrees to provide the Secretary and the Inspector General of the Department of Health and Human Services with such performance statistics (including the number and amount of overpayments recovered, the number of fraud referrals, and the return on investment of such activities by the entity) as the Secretary or the Inspector General may request; and

(5) the entity meets such other requirements as the Secretary may impose.

In the case of the activity described in subsection (b)(5), an entity shall be deemed to be eligible to enter into a contract under the Program to carry out the activity if the entity is a carrier with a contract in effect under section 1842.

(d) PROCESS FOR ENTERING INTO CONTRACTS.—The Secretary shall enter into contracts under the Program in accordance with such procedures as the Secretary shall by regulation establish, except that such procedures shall include the following:

(1) Procedures for identifying, evaluating, and resolving organizational conflicts of interest that are generally applicable to Federal acquisition and procurement.

(2) Competitive procedures to be used—

(A) when entering into new contracts under this section;

(B) when entering into contracts that may result in the elimination of responsibilities of an individual fiscal intermediary or carrier under section 202(b) of the Health Insurance Portability and Accountability Act of 1996; and

(C) at any other time considered appropriate by the Secretary,

except that the Secretary may continue to contract with entities that are carrying out the activities described in this section pursuant to agreements under section 1816 or contracts under section 1842 in effect on the date of the enactment of this section.

(3) Procedures under which a contract under this section may be renewed without regard to any provision of law requiring competition if the contractor has met or exceeded the performance requirements established in the current contract.

The Secretary may enter into such contracts without regard to final rules having been promulgated.

(e) LIMITATION ON CONTRACTOR LIABILITY.—The Secretary shall by regulation provide for the limitation of a contractor's liability for actions taken to carry out a contract under the Program, and such regulation shall, to the extent the Secretary finds appropriate, employ the same or comparable standards and other substantive and procedural provisions as are contained in section 1157.

(f) RECOVERY OF OVERPAYMENTS.—

(1) USE OF REPAYMENT PLANS.—

(A) IN GENERAL.—If the repayment, within 30 days by a provider of services or supplier, of an overpayment under this title would constitute a hardship (as described in subparagraph (B)), subject to subparagraph (C), upon request of the provider of services or supplier the Secretary shall enter into a plan with the provider of services or supplier for the repayment (through offset or otherwise) of such overpayment over a period of at least 6 months but not longer than 3 years (or not longer than 5 years in the case of extreme hardship, as determined by the Secretary). Interest shall accrue on the balance through the period of repayment. Such plan shall meet terms and conditions determined to be appropriate by the Secretary.

(B) HARDSHIP.—

(i) IN GENERAL.—For purposes of subparagraph (A), the repayment of an overpayment (or overpayments) within 30 days is deemed to constitute a hardship if—

(I) in the case of a provider of services that files cost reports, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services for the cost reporting period covered by the most recently submitted cost report; or

(II) in the case of another provider of services or supplier, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services or supplier for the previous calendar year.

(ii) RULE OF APPLICATION.—The Secretary shall establish rules for the application of this subparagraph in the case of a provider of services or supplier that was not paid under this title during the previous year or was paid under this title only during a portion of that year.

(iii) TREATMENT OF PREVIOUS OVERPAYMENTS.—If a provider of services or supplier has entered into a repayment plan under subparagraph (A) with respect to a specific overpayment amount, such payment amount under the repayment plan shall not be taken into account under clause (i) with respect to subsequent overpayment amounts.

(C) EXCEPTIONS.—Subparagraph (A) shall not apply if—

(i) the Secretary has reason to suspect that the provider of services or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in the program under this title; or

(ii) there is an indication of fraud or abuse committed against the program.

(D) IMMEDIATE COLLECTION IF VIOLATION OF REPAYMENT PLAN.—If a provider of services or supplier fails to make a payment in accordance with a repayment plan under this paragraph, the Secretary may immediately seek to offset or otherwise recover the total balance outstanding (including applicable interest) under the repayment plan.

(E) RELATION TO NO FAULT PROVISION.—Nothing in this paragraph shall be construed as affecting the application of section 1870(c) (relating to no adjustment in the cases of certain overpayments).

(2) LIMITATION ON RECOUPMENT.—

(A) IN GENERAL.—In the case of a provider of services or supplier that is determined to have received an overpayment under this title and that seeks a reconsideration by a qualified independent contractor on such determination under section 1869(b)(1), the Secretary may not take any action (or authorize any other person, including any medicare contractor, as defined in subparagraph (C)) to recoup the overpayment until the date the decision on the reconsideration has been rendered. If the provisions of section 1869(b)(1) (providing for such a reconsideration by a quali-

fied independent contractor) are not in effect, in applying the previous sentence any reference to such a reconsideration shall be treated as a reference to a redetermination by the fiscal intermediary or carrier involved.

(B) COLLECTION WITH INTEREST.—Insofar as the determination on such appeal is against the provider of services or supplier, interest on the overpayment shall accrue on and after the date of the original notice of overpayment. Insofar as such determination against the provider of services or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest at the same rate as would apply under the previous sentence for the period in which the amount was recouped.

(C) MEDICARE CONTRACTOR DEFINED.—For purposes of this subsection, the term "medicare contractor" has the meaning given such term in section 1889(g).

(3) LIMITATION ON USE OF EXTRAPOLATION.—A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that—

(A) there is a sustained or high level of payment error; or

(B) documented educational intervention has failed to correct the payment error.

There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph.

(4) PROVISION OF SUPPORTING DOCUMENTATION.—In the case of a provider of services or supplier with respect to which amounts were previously overpaid, a medicare contractor may request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing.

(5) CONSENT SETTLEMENT REFORMS.—

(A) IN GENERAL.—The Secretary may use a consent settlement (as defined in subparagraph (D)) to settle a projected overpayment.

(B) OPPORTUNITY TO SUBMIT ADDITIONAL INFORMATION BEFORE CONSENT SETTLEMENT OFFER.—Before offering a provider of services or supplier a consent settlement, the Secretary shall—

(i) communicate to the provider of services or supplier—

(I) that, based on a review of the medical records requested by the Secretary, a preliminary evaluation of those records indicates that there would be an overpayment;

(II) the nature of the problems identified in such evaluation; and

(III) the steps that the provider of services or supplier should take to address the problems; and

(ii) provide for a 45-day period during which the provider of services or supplier may furnish additional in-

formation concerning the medical records for the claims that had been reviewed.

(C) CONSENT SETTLEMENT OFFER.—The Secretary shall review any additional information furnished by the provider of services or supplier under subparagraph (B)(ii). Taking into consideration such information, the Secretary shall determine if there still appears to be an overpayment. If so, the Secretary—

(i) shall provide notice of such determination to the provider of services or supplier, including an explanation of the reason for such determination; and

(ii) in order to resolve the overpayment, may offer the provider of services or supplier—

(I) the opportunity for a statistically valid random sample; or

(II) a consent settlement.

The opportunity provided under clause (ii)(I) does not waive any appeal rights with respect to the alleged overpayment involved.

(D) CONSENT SETTLEMENT DEFINED.—For purposes of this paragraph, the term "consent settlement" means an agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services or supplier agrees not to appeal the claims involved.

(6) NOTICE OF OVER-UTILIZATION OF CODES.—The Secretary shall establish, in consultation with organizations representing the classes of providers of services and suppliers, a process under which the Secretary provides for notice to classes of providers of services and suppliers served by the contractor in cases in which the contractor has identified that particular billing codes may be overutilized by that class of providers of services or suppliers under the programs under this title (or provisions of title XI insofar as they relate to such programs).

(7) PAYMENT AUDITS.—

(A) WRITTEN NOTICE FOR POST-PAYMENT AUDITS.—Subject to subparagraph (C), if a medicare contractor decides to conduct a post-payment audit of a provider of services or supplier under this title, the contractor shall provide the provider of services or supplier with written notice (which may be in electronic form) of the intent to conduct such an audit.

(B) EXPLANATION OF FINDINGS FOR ALL AUDITS.—Subject to subparagraph (C), if a medicare contractor audits a provider of services or supplier under this title, the contractor shall—

(i) give the provider of services or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider of services or supplier and permits the development of an appropriate corrective action plan;

(ii) inform the provider of services or supplier of the appeal rights under this title as well as consent settle-

ment options (which are at the discretion of the Secretary);

(iii) give the provider of services or supplier an opportunity to provide additional information to the contractor; and

(iv) take into account information provided, on a timely basis, by the provider of services or supplier under clause (iii).

(C) EXCEPTION.—Subparagraphs (A) and (B) shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits.

(8) STANDARD METHODOLOGY FOR PROBE SAMPLING.—The Secretary shall establish a standard methodology for medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.

(g) MEDICARE-MEDICAID DATA MATCH PROGRAM.—

(1) EXPANSION OF PROGRAM.—

(A) IN GENERAL.—The Secretary shall enter into contracts with eligible entities for the purpose of ensuring that, beginning with 2006, the Medicare-Medicaid Data Match Program (commonly referred to as the "Medi-Medi Program") is conducted with respect to the program established under this title and State Medicaid programs under title XIX for the purpose of—

(i) identifying program vulnerabilities in the program established under this title and the Medicaid program established under title XIX through the use of computer algorithms to look for payment anomalies (including billing or billing patterns identified with respect to service, time, or patient that appear to be suspect or otherwise implausible);

(ii) working with States, the Attorney General, and the Inspector General of the Department of Health and Human Services to coordinate appropriate actions to protect the Federal and State share of expenditures under the Medicaid program under title XIX, as well as the program established under this title; and

(iii) increasing the effectiveness and efficiency of both such programs through cost avoidance, savings, and recoupments of fraudulent, wasteful, or abusive expenditures.

(B) REPORTING REQUIREMENTS.—The Secretary shall make available in a timely manner any data and statistical information collected by the Medi-Medi Program to the Attorney General, the Director of the Federal Bureau of Investigation, the Inspector General of the Department of Health and Human Services, and the States (including a Medicaid fraud and abuse control unit described in section 1903(q)). Such information shall be disseminated no less frequently than quarterly.

(2) LIMITED WAIVER AUTHORITY.—The Secretary shall waive only such requirements of this section and of titles XI and XIX as are necessary to carry out paragraph (1).

(3) INCENTIVES FOR STATES.—The Secretary shall study and, as appropriate, may specify incentives for States to work with the Secretary for the purposes described in paragraph (1)(A)(ii). The application of the previous sentence may include use of the waiver authority described in paragraph (2).

(h) USE OF RECOVERY AUDIT CONTRACTORS.—

(1) IN GENERAL.—Under the Program, the Secretary shall enter into contracts with recovery audit contractors in accordance with this subsection for the purpose of identifying underpayments and overpayments and recouping overpayments under this title with respect to all services for which payment is made under this title. Under the contracts—

(A) payment shall be made to such a contractor only from amounts recovered;

(B) from such amounts recovered, payment—

(i) shall be made on a contingent basis for collecting overpayments; and

(ii) may be made in such amounts as the Secretary may specify for identifying underpayments; and

(C) the Secretary shall retain a portion of the amounts recovered which shall be available to the program management account of the Centers for Medicare & Medicaid Services for purposes of activities conducted under the recovery audit program under this subsection.

(2) DISPOSITION OF REMAINING RECOVERIES.—The amounts recovered under such contracts that are not paid to the contractor under paragraph (1) or retained by the Secretary under paragraph (1)(C) or paragraph (10) shall be applied to reduce expenditures under this title.

(3) NATIONWIDE COVERAGE.—The Secretary shall enter into contracts under paragraph (1) in a manner so as to provide for activities in all States under such a contract by not later than January 1, 2010 (not later than December 31, 2010, in the case of contracts relating to payments made under part C or D).

(4) AUDIT AND RECOVERY PERIODS.—Each such contract shall provide that audit and recovery activities may be conducted during a fiscal year with respect to payments made under this title—

(A) during such fiscal year; and

(B) retrospectively (for a period of not more than 4 fiscal years prior to such fiscal year).

(5) WAIVER.—The Secretary shall waive such provisions of this title as may be necessary to provide for payment of recovery audit contractors under this subsection in accordance with paragraph (1).

(6) QUALIFICATIONS OF CONTRACTORS.—

(A) IN GENERAL.—The Secretary may not enter into a contract under paragraph (1) with a recovery audit contractor unless the contractor has staff that has the appropriate clinical knowledge of, and experience with, the payment rules and regulations under this title or the contractor has, or will contract with, another entity that has such knowledgeable and experienced staff.

(B) INELIGIBILITY OF CERTAIN CONTRACTORS.—The Secretary may not enter into a contract under paragraph (1)

with a recovery audit contractor to the extent the contractor is a fiscal intermediary under section 1816, a carrier under section 1842, or a medicare administrative contractor under section 1874A.

(C) PREFERENCE FOR ENTITIES WITH DEMONSTRATED PROFICIENCY.—In awarding contracts to recovery audit contractors under paragraph (1), the Secretary shall give preference to those risk entities that the Secretary determines have demonstrated more than 3 years direct management experience and a proficiency for cost control or recovery audits with private insurers, health care providers, health plans, under the Medicaid program under title XIX, or under this title.

(7) CONSTRUCTION RELATING TO CONDUCT OF INVESTIGATION OF FRAUD.—A recovery of an overpayment to a individual or entity by a recovery audit contractor under this subsection shall not be construed to prohibit the Secretary or the Attorney General from investigating and prosecuting, if appropriate, allegations of fraud or abuse arising from such overpayment.

(8) ANNUAL REPORT.—The Secretary shall annually submit to Congress a report on the use of recovery audit contractors under this subsection. Each such report shall include information on the performance of such contractors in identifying underpayments and overpayments and recouping overpayments, including an evaluation of the comparative performance of such contractors and savings to the program under this title.

(9) SPECIAL RULES RELATING TO PARTS C AND D.—The Secretary shall enter into contracts under paragraph (1) to require recovery audit contractors to—

(A) ensure that each MA plan under part C has an anti-fraud plan in effect and to review the effectiveness of each such anti-fraud plan;

(B) ensure that each prescription drug plan under part D has an anti-fraud plan in effect and to review the effectiveness of each such anti-fraud plan;

(C) examine claims for reinsurance payments under section 1860D–15(b) to determine whether prescription drug plans submitting such claims incurred costs in excess of the allowable reinsurance costs permitted under paragraph (2) of that section; and

(D) review estimates submitted by prescription drug plans by private plans with respect to the enrollment of high cost beneficiaries (as defined by the Secretary) and to compare such estimates with the numbers of such beneficiaries actually enrolled by such plans.

(10) USE OF CERTAIN RECOVERED FUNDS.—

(A) IN GENERAL.—After application of paragraph (1)(C), the Secretary shall retain a portion of the amounts recovered by recovery audit contractors for each year under this section which shall be available to the program management account of the Centers for Medicare & Medicaid Services for purposes of, subject to subparagraph (B), carrying out sections 1833(z), 1834(l)(16), and 1874A(a)(4)(G), carrying out section 514(b) of the Medicare Access and CHIP Reauthorization Act of 2015, and implementing

strategies (such as claims processing edits) to help reduce the error rate of payments under this title. The amounts retained under the preceding sentence shall not exceed an amount equal to 15 percent of the amounts recovered under this subsection, and shall remain available until expended.

(B) LIMITATION.—Except for uses that support claims processing (including edits) or system functionality for detecting fraud, amounts retained under subparagraph (A) may not be used for technological-related infrastructure, capital investments, or information systems.

(C) NO REDUCTION IN PAYMENTS TO RECOVERY AUDIT CONTRACTORS.—Nothing in subparagraph (A) shall reduce amounts available for payments to recovery audit contractors under this subsection.

(i) EVALUATIONS AND ANNUAL REPORT.—

(1) EVALUATIONS.—The Secretary shall conduct evaluations of eligible entities which the Secretary contracts with under the Program not less frequently than every 3 years.

(2) ANNUAL REPORT.—Not later than 180 days after the end of each fiscal year (beginning with fiscal year 2011), the Secretary shall submit a report to Congress which identifies—

(A) the use of funds, including funds transferred from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Insurance Trust Fund under section 1841, to carry out this section; and

(B) the effectiveness of the use of such funds.

(j) EXPANDING ACTIVITIES OF MEDICARE DRUG INTEGRITY CONTRACTORS (MEDICS).—

(1) ACCESS TO INFORMATION.—Under contracts entered into under this section with Medicare drug integrity contractors (including any successor entity to a Medicare drug integrity contractor), the Secretary shall authorize such contractors to directly accept prescription and necessary medical records from entities such as pharmacies, prescription drug plans, MA–PD plans, and physicians with respect to an individual in order for such contractors to provide information relevant to the determination of whether such individual is an at-risk beneficiary for prescription drug abuse, as defined in section 1860D–4(c)(5)(C).

(2) REQUIREMENT FOR ACKNOWLEDGMENT OF REFERRALS.—If a PDP sponsor or MA organization refers information to a contractor described in paragraph (1) in order for such contractor to assist in the determination described in such paragraph, the contractor shall—

(A) acknowledge to the sponsor or organization receipt of the referral; and

(B) in the case that any PDP sponsor or MA organization contacts the contractor requesting to know the determination by the contractor of whether or not an individual has been determined to be an individual described such paragraph, shall inform such sponsor or organization of such determination on a date that is not later than 15 days after the date on which the sponsor or organization contacts the contractor.

(3) MAKING DATA AVAILABLE TO OTHER ENTITIES.—

(A) IN GENERAL.—For purposes of carrying out this subsection, subject to subparagraph (B), the Secretary shall authorize MEDICs to respond to requests for information from PDP sponsors and MA organizations, State prescription drug monitoring programs, and other entities delegated by such sponsors or organizations using available programs and systems in the effort to prevent fraud, waste, and abuse.

(B) HIPAA COMPLIANT INFORMATION ONLY.—Information may only be disclosed by a MEDIC under subparagraph (A) if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

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TITLE XIX—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

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PAYMENT TO STATES

SEC. 1903. (a) From the sums appropriated therefor, the Secretary (except as otherwise provided in this section) shall pay to each State which has a plan approved under this title, for each quarter, beginning with the quarter commencing January 1, 1966—

(1) an amount equal to the Federal medical assistance percentage (as defined in section 1905(b), subject to subsections (g) and (j) of this section and subsection 1923(f)) of the total amount expended during such quarter as medical assistance under the State plan; plus

(2)(A) an amount equal to 75 per centum of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to compensation or training of skilled professional medical personnel, and staff directly supporting such personnel, of the State agency or any other public agency; plus

(B) notwithstanding paragraph (1) or subparagraph (A), with respect to amounts expended for nursing aide training and competency evaluation programs, and competency evaluation programs, described in section 1919(e)(1) (including the costs for nurse aides to complete such competency evaluation programs), regardless of whether the programs are provided in or outside nursing facilities or of the skill of the personnel involved in such programs, an amount equal to 50 percent (or, for calendar quarters beginning on or after July 1, 1988, and before October 1, 1990, the lesser of 90 percent or the Federal medical assistance percentage plus 25 percentage points) of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to such programs; plus

(C) an amount equal to 75 percent of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to preadmission screening and resident review activities conducted by the State under section 1919(e)(7); plus

(D) for each calendar quarter during—

(i) fiscal year 1991, an amount equal to 90 percent,

(ii) fiscal year 1992, an amount equal to 85 percent,

(iii) fiscal year 1993, an amount equal to 80 percent, and

(iv) fiscal year 1994 and thereafter, an amount equal to 75 percent,

of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to State activities under section 1919(g); plus

(E) an amount equal to 75 percent of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to translation or interpretation services in connection with the enrollment of, retention of, and use of services under this title by, children of families for whom English is not the primary language; plus

(3) an amount equal to—

(A)(i) 90 per centum of so much of the sums expended during such quarter as are attributable to the design, development, or installation of such mechanized claims processing and information retrieval systems as the Secretary determines are likely to provide more efficient, economical, and effective administration of the plan and to be compatible with the claims processing and information retrieval systems utilized in the administration of title XVIII, including the State's share of the cost of installing such a system to be used jointly in the administration of such State's plan and the plan of any other State approved under this title,

(ii) 90 per centum of so much of the sums expended during any such quarter in the fiscal year ending June 30, 1972, or the fiscal year ending June 30, 1973, as are attributable to the design, development, or installation of cost determination systems for State-owned general hospitals (except that the total amount paid to all States under this clause for either such fiscal year shall not exceed $150,000), and

(iii) an amount equal to the Federal medical assistance percentage (as defined in section 1905(b)) of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to such developments or modifications of systems of the type described in clause (i) as are necessary for the efficient collection and reporting on child health measures; and

(B) 75 per centum of so much of the sums expended during such quarter as are attributable to the operation of systems (whether such systems are operated directly by

the State or by another person under a contract with the State) of the type described in subparagraph (A)(i) (whether or not designed, developed, or installed with assistance under such subparagraph) which are approved by the Secretary and which include provision for prompt written notice to each individual who is furnished services covered by the plan, or to each individual in a sample group of individuals who are furnished such services, of the specific services (other than confidential services) so covered, the name of the person or persons furnishing the services, the date or dates on which the services were furnished, and the amount of the payment or payments made under the plan on account of the services; and

(C)(i) 75 per centum of the sums expended with respect to costs incurred during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to the performance of medical and utilization review by a utilization and quality control peer review organization or by an entity which meets the requirements of section 1152, as determined by the Secretary, under a contract entered into under section 1902(d); and

(ii) 75 percent of the sums expended with respect to costs incurred during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to the performance of independent external reviews conducted under section 1932(c)(2); and

(D) 75 percent of so much of the sums expended by the State plan during a quarter in 1991, 1992, or 1993, as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of section 1927(g);

(E) 50 percent of the sums expended with respect to costs incurred during such quarter as are attributable to providing—

(i) services to identify and educate individuals who are likely to be eligible for medical assistance under this title and who have Sickle Cell Disease or who are carriers of the sickle cell gene, including education regarding how to identify such individuals; or

(ii) education regarding the risks of stroke and other complications, as well as the prevention of stroke and other complications, in individuals who are likely to be eligible for medical assistance under this title and who have Sickle Cell Disease; and

(F)(i) 100 percent of so much of the sums expended during such quarter as are attributable to payments to Medicaid providers described in subsection (t)(1) to encourage the adoption and use of certified EHR technology; and

(ii) 90 percent of so much of the sums expended during such quarter as are attributable to payments for reasonable administrative expenses related to the administration of payments described in clause (i) if the State meets the condition described in subsection (t)(9); plus

(H)(i) 90 percent of the sums expended during the quarter as are attributable to the design, development, or installation of such mechanized verification and information retrieval systems as the Secretary determines are necessary to implement section 1902(ee) (including a system described in paragraph (2)(B) thereof), and

(ii) 75 percent of the sums expended during the quarter as are attributable to the operation of systems to which clause (i) applies, plus

(4) an amount equal to 100 percent of the sums expended during the quarter which are attributable to the costs of the implementation and operation of the immigration status verification system described in section 1137(d); plus

(5) an amount equal to 90 per centum of the sums expended during such quarter which are attributable to the offering, arranging, and furnishing (directly or on a contract basis) of family planning services and supplies;

(6) subject to subsection (b)(3), an amount equal to—

(A) 90 per centum of the sums expended during such a quarter within the twelve-quarter period beginning with the first quarter in which a payment is made to the State pursuant to this paragraph, and

(B) 75 per centum of the sums expended during each succeeding calendar quarter,

with respect to costs incurred during such quarter (as found necessary by the Secretary for the elimination of fraud in the provision and administration of medical assistance provided under the State plan) which are attributable to the establishment and operation of (including the training of personnel employed by) a State medicaid fraud control unit (described in subsection (q)); plus

(7) subject to section 1919(g)(3)(B), an amount equal to 50 per centum of the remainder of the amounts expended during such quarter as found necessary by the Secretary for the proper and efficient administration of the State plan.

(b)(1) Notwithstanding the preceding provisions of this section, the amount determined under subsection (a)(1) for any State for any quarter beginning after December 31, 1969, shall not take into account any amounts expended as medical assistance with respect to individuals aged 65 or over and disabled individuals entitled to hospital insurance benefits under title XVIII which would not have been so expended if the individuals involved had been enrolled in the insurance program established by part B of title XVIII, other than amounts expended under provisions of the plan of such State required by section 1902(a)(34).

(2) For limitation on Federal participation for capital expenditures which are out of conformity with a comprehensive plan of a State or areawide planning agency, see section 1122.

(3) The amount of funds which the Secretary is otherwise obligated to pay a State during a quarter under subsection (a)(6) may not exceed the higher of—

(A) $125,000, or

(B) one-quarter of 1 per centum of the sums expended by the Federal, State, and local governments during the previous quarter in carrying out the State's plan under this title.

(4) Amounts expended by a State for the use of an enrollment broker in marketing medicaid managed care organizations and other managed care entities to eligible individuals under this title shall be considered, for purposes of subsection (a)(7), to be necessary for the proper and efficient administration of the State plan but only if the following conditions are met with respect to the broker:

(A) The broker is independent of any such entity and of any health care providers (whether or not any such provider participates in the State plan under this title) that provide coverage of services in the same State in which the broker is conducting enrollment activities.

(B) No person who is an owner, employee, consultant, or has a contract with the broker either has any direct or indirect financial interest with such an entity or health care provider or has been excluded from participation in the program under this title or title XVIII or debarred by any Federal agency, or subject to a civil money penalty under this Act.

(5) Notwithstanding the preceding provisions of this section, the amount determined under subsection (a)(1) for any State shall be decreased in a quarter by the amount of any health care related taxes (described in section 1902(w)(3)(A)) that are imposed on a hospital described in subsection (w)(3)(F) in that quarter.

(c) Nothing in this title shall be construed as prohibiting or restricting, or authorizing the Secretary to prohibit or restrict, payment under subsection (a) for medical assistance for covered services furnished to a child with a disability because such services are included in the child's individualized education program established pursuant to part B of the Individuals with Disabilities Education Act or furnished to an infant or toddler with a disability because such services are included in the child's individualized family service plan adopted pursuant to part C of such Act.

(d)(1) Prior to the beginning of each quarter, the Secretary shall estimate the amount to which a State will be entitled under subsections (a) and (b) for such quarter, such estimates to be based on (A) a report filed by the State containing its estimate of the total sum to be expended in such quarter in accordance with the provisions of such subsections, and stating the amount appropriated or made available by the State and its political subdivisions for such expenditures in such quarter, and if such amount is less than the State's proportionate share of the total sum of such estimated expenditures, the source or sources from which the difference is expected to be derived, and (B) such other investigation as the Secretary may find necessary.

(2)(A) The Secretary shall then pay to the State, in such installments as he may determine, the amount so estimated, reduced or increased to the extent of any overpayment or underpayment which the Secretary determines was made under this section to such State for any prior quarter and with respect to which adjustment has not already been made under this subsection.

(B) Expenditures for which payments were made to the State under subsection (a) shall be treated as an overpayment to the extent that the State or local agency administering such plan has been reimbursed for such expenditures by a third party pursuant to the provisions of its plan in compliance with section 1902(a)(25).

(C) For purposes of this subsection, when an overpayment is discovered, which was made by a State to a person or other entity, the State shall have a period of 1 year in which to recover or attempt to recover such overpayment before adjustment is made in the Federal payment to such State on account of such overpayment. Except as otherwise provided in subparagraph (D), the adjustment in the Federal payment shall be made at the end of the 1-year period, whether or not recovery was made.

(D)(i) In any case where the State is unable to recover a debt which represents an overpayment (or any portion thereof) made to a person or other entity on account of such debt having been discharged in bankruptcy or otherwise being uncollectable, no adjustment shall be made in the Federal payment to such State on account of such overpayment (or portion thereof).

(ii) In any case where the State is unable to recover a debt which represents an overpayment (or any portion thereof) made to a person or other entity due to fraud within 1 year of discovery because there is not a final determination of the amount of the overpayment under an administrative or judicial process (as applicable), including as a result of a judgment being under appeal, no adjustment shall be made in the Federal payment to such State on account of such overpayment (or portion thereof) before the date that is 30 days after the date on which a final judgment (including, if applicable, a final determination on an appeal) is made.

(3)(A) The pro rata share to which the United States is equitably entitled, as determined by the Secretary, of the net amount recovered during any quarter by the State or any political subdivision thereof with respect to medical assistance furnished under the State plan shall be considered an overpayment to be adjusted under this subsection.

(B)(i) Subparagraph (A) and paragraph (2)(B) shall not apply to any amount recovered or paid to a State as part of the comprehensive settlement of November 1998 between manufacturers of tobacco products, as defined in section 5702(d) of the Internal Revenue Code of 1986, and State Attorneys General, or as part of any individual State settlement or judgment reached in litigation initiated or pursued by a State against one or more such manufacturers.

(ii) Except as provided in subsection (i)(19), a State may use amounts recovered or paid to the State as part of a comprehensive or individual settlement, or a judgment, described in clause (i) for any expenditures determined appropriate by the State.

(4) Upon the making of any estimate by the Secretary under this subsection, any appropriations available for payments under this section shall be deemed obligated.

(5) In any case in which the Secretary estimates that there has been an overpayment under this section to a State on the basis of a claim by such State that has been disallowed by the Secretary under section 1116(d), and such State disputes such disallowance, the amount of the Federal payment in controversy shall, at the option of the State, be retained by such State or recovered by the Secretary pending a final determination with respect to such payment amount. If such final determination is to the effect that any amount was properly disallowed, and the State chose to retain payment of the amount in controversy, the Secretary shall offset, from

any subsequent payments made to such State under this title, an amount equal to the proper amount of the disallowance plus interest on such amount disallowed for the period beginning on the date such amount was disallowed and ending on the date of such final determination at a rate (determined by the Secretary) based on the average of the bond equivalent of the weekly 90-day treasury bill auction rates during such period.

(6)(A) Each State (as defined in subsection (w)(7)(D)) shall include, in the first report submitted under paragraph (1) after the end of each fiscal year, information related to—

(i) provider-related donations made to the State or units of local government during such fiscal year, and

(ii) health care related taxes collected by the State or such units during such fiscal year.

(B) Each State shall include, in the first report submitted under paragraph (1) after the end of each fiscal year, information related to the total amount of payment adjustments made, and the amount of payment adjustments made to individual providers (by provider), under section 1923(c) during such fiscal year.

(e) A State plan approved under this title may include, as a cost with respect to hospital services under the plan under this title, periodic expenditures made to reflect transitional allowances established with respect to a hospital closure or conversion under section 1884.

(f)(1)(A) Except as provided in paragraph (4), payment under the preceding provisions of this section shall not be made with respect to any amount expended as medical assistance in a calendar quarter, in any State, for any member of a family the annual income of which exceeds the applicable income limitation determined under this paragraph.

(B)(i) Except as provided in clause (ii) of this subparagraph, the applicable income limitation with respect to any family is the amount determined, in accordance with standards prescribed by the Secretary, to be equivalent to 133⅓ percent of the highest amount which would ordinarily be paid to a family of the same size without any income or resources, in the form of money payments, under the plan of the State approved under part A of title IV of this Act.

(ii) If the Secretary finds that the operation of a uniform maximum limits payments to families of more than one size, he may adjust the amount otherwise determined under clause (i) to take account of families of different sizes.

(C) The total amount of any applicable income limitation determined under subparagraph (B) shall, if it is not a multiple of $100 or such other amount as the Secretary may prescribe, be rounded to the next higher multiple of $100 or such other amount, as the case may be.

(2)(A) In computing a family's income for purposes of paragraph (1), there shall be excluded any costs (whether in the form of insurance premiums or otherwise and regardless of whether such costs are reimbursed under another public program of the State or political subdivision thereof) incurred by such family for medical care or for any other type of remedial care recognized under State law or, (B) notwithstanding section 1916 at State option, an amount paid by such family, at the family's option, to the State, provided

that the amount, when combined with costs incurred in prior months, is sufficient when excluded from the family's income to reduce such family's income below the applicable income limitation described in paragraph (1). The amount of State expenditures for which medical assistance is available under subsection (a)(1) will be reduced by amounts paid to the State pursuant to this subparagraph.

(3) For purposes of paragraph (1)(B), in the case of a family consisting of only one individual, the "highest amount which would ordinarily be paid" to such family under the State's plan approved under part A of title IV of this Act shall be the amount determined by the State agency (on the basis of reasonable relationship to the amounts payable under such plan to families consisting of two or more persons) to be the amount of the aid which would ordinarily be payable under such plan to a family (without any income or resources) consisting of one person if such plan provided for aid to such a family.

(4) The limitations on payment imposed by the preceding provisions of this subsection shall not apply with respect to any amount expended by a State as medical assistance for any individual described in section 1902(a)(10)(A)(i)(III), 1902(a)(10)(A)(i)(IV), 1902(a)(10)(A)(i)(V), 1902(a)(10)(A)(i)(VI), 1902(a)(10)(A)(i)(VII), 1902(a)(10)(A)(i)(VIII),1902(a)(10)(A)(i)(IX), 1902(a)(10)(A)(ii)(IX), 1902(a)(10)(A)(ii)(X), 1902(a)(10)(A)(ii)(XIII), 1902(a)(10)(A)(ii)(XIV), or 1902(a)(10)(A)(ii)(XV), 1902(a)(10)(A)(ii)(XVI), 1902(a)(10)(A)(ii)(XVII), 1902(a)(10)(A)(ii)(XVIII), 1902(a)(10)(A)(ii)(XIX), 1902(a)(10)(A)(ii)(XX), 1902(a)(10)(A)(ii)(XXI), 1902(a)(10)(A)(ii)(XXII), 1905(p)(1) or for any individual—

(A) who is receiving aid or assistance under any plan of the State approved under title I, X, XIV or XVI, or part A of title IV, or with respect to whom supplemental security income benefits are being paid under title XVI, or

(B) who is not receiving such aid or assistance, and with respect to whom such benefits are not being paid, but (i) is eligible to receive such aid or assistance, or to have such benefits paid with respect to him, or (ii) would be eligible to receive such aid or assistance, or to have such benefits paid with respect to him if he were not in a medical institution, or

(C) with respect to whom there is being paid, or who is eligible, or would be eligible if he were not in a medical institution, to have paid with respect to him, a State supplementary payment and is eligible for medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in section 1902(a)(10)(A), or who is a PACE program eligible individual enrolled in a PACE program under section 1934, but only if the income of such individual (as determined under section 1612, but without regard to subsection (b) thereof) does not exceed 300 percent of the supplemental security income benefit rate established by section 1611(b)(1),

at the time of the provision of the medical assistance giving rise to such expenditure.

(g)(1) Subject to paragraph (3), with respect to amounts paid for the following services furnished under the State plan after June 30,

1973 (other than services furnished pursuant to a contract with a health maintenance organization as defined in section 1876 or which is a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Service Act)), the Federal medical assistance percentage shall be decreased as follows: After an individual has received inpatient hospital services or services in an intermediate care facility for the mentally retarded for 60 days or inpatient mental hospital services for 90 days (whether or not such days are consecutive), during any fiscal year, the Federal medical assistance percentage with respect to amounts paid for any such care furnished thereafter to such individual shall be decreased by a per centum thereof (determined under paragraph (5)) unless the State agency responsible for the administration of the plan makes a showing satisfactory to the Secretary that, with respect to each calendar quarter for which the State submits a request for payment at the full Federal medical assistance percentage for amounts paid for inpatient hospital services or services in an intermediate care facility for the mentally retarded furnished beyond 60 days (or inpatient mental hospital services furnished beyond 90 days), such State has an effective program of medical review of the care of patients in mental hospitals and intermediate care facilities for the mentally retarded pursuant to paragraphs (26) and (31) of section 1902(a) whereby the professional management of each case is reviewed and evaluated at least annually by independent professional review teams. In determining the number of days on which an individual has received services described in this subsection, there shall not be counted any days with respect to which such individual is entitled to have payments made (in whole or in part) on his behalf under section 1812.

(2) The Secretary shall, as part of his validation procedures under this subsection, conduct timely sample onsite surveys of private and public institutions in which recipients of medical assistance may receive care and services under a State plan approved under this title, and his findings with respect to such surveys (as well as the showings of the State agency required under this subsection) shall be made available for public inspection.

(3)(A) No reduction in the Federal medical assistance percentage of a State otherwise required to be imposed under this subsection shall take effect—

(i) if such reduction is due to the State's unsatisfactory or invalid showing made with respect to a calendar quarter beginning before January 1, 1977;

(ii) before January 1, 1978;

(iii) unless a notice of such reduction has been provided to the State at least 30 days before the date such reduction takes effect; or

(iv) due to the State's unsatisfactory or invalid showing made with respect to a calendar quarter beginning after September 30, 1977, unless notice of such reduction has been provided to the State no later than the first day of the fourth calendar quarter following the calendar quarter with respect to which such showing was made.

(B) The Secretary shall waive application of any reduction in the Federal medical assistance percentage of a State otherwise required to be imposed under paragraph (1) because a showing by the

State, made under such paragraph with respect to a calendar quarter ending after January 1, 1977, and before January 1, 1978, is determined to be either unsatisfactory under such paragraph or invalid under paragraph (2), if the Secretary determines that the State's showing made under paragraph (1) with respect to any calendar quarter ending on or before December 31, 1978, is satisfactory under such paragraph and is valid under paragraph (2).

(4)(A) The Secretary may not find the showing of a State, with respect to a calendar quarter under paragraph (1), to be satisfactory if the showing is submitted to the Secretary later than the 30th day after the last day of the calendar quarter, unless the State demonstrates to the satisfaction of the Secretary good cause for not meeting such deadline.

(B) The Secretary shall find a showing of a State, with respect to a calendar quarter under paragraph (1), to be satisfactory under such paragraph with respect to the requirement that the State conduct annual onsite inspections in mental hospitals and intermediate care facilities for the mentally retarded under paragraphs (26) and (31) of section 1902(a), if the showing demonstrates that the State has conducted such an onsite inspection during the 12-month period ending on the last date of the calendar quarter—

(i) in each of not less than 98 per centum of the number of such hospitals and facilities requiring such inspection, and

(ii) in every such hospital or facility which has 200 or more beds,

and that, with respect to such hospitals and facilities not inspected within such period, the State has exercised good faith and due diligence in attempting to conduct such inspection, or if the State demonstrates to the satisfaction of the Secretary that it would have made such a showing but for failings of a technical nature only.

(5) In the case of a State's unsatisfactory or invalid showing made with respect to a type of facility or institutional services in a calendar quarter, the per centum amount of the reduction of the State's Federal medical assistance percentage for that type of services under paragraph (1) is equal to 33⅓ per centum multiplied by a fraction, the denominator of which is equal to the total number of patients receiving that type of services in that quarter under the State plan in facilities or institutions for which a showing was required to be made under this subsection, and the numerator of which is equal to the number of such patients receiving such type of services in that quarter in those facilities or institutions for which a satisfactory and valid showing was not made for that calendar quarter.

(6)(A) Recertifications required under section 1902(a)(44) shall be conducted at least every 60 days in the case of inpatient hospital services.

(B) Such recertifications in the case of services in an intermediate care facility for the mentally retarded shall be conducted at least—

(i) 60 days after the date of the initial certification,

(ii) 180 days after the date of the initial certification,

(iii) 12 months after the date of the initial certification,

(iv) 18 months after the date of the initial certification,

(v) 24 months after the date of the initial certification, and

(vi) every 12 months thereafter.

(C) For purposes of determining compliance with the schedule established by this paragraph, a recertification shall be considered to have been done on a timely basis if it was performed not later than 10 days after the date the recertification was otherwise required and the State establishes good cause why the physician or other person making such recertification did not meet such schedule.

(i) Payment under the preceding provisions of this section shall not be made—

(1) for organ transplant procedures unless the State plan provides for written standards respecting the coverage of such procedures and unless such standards provide that—

(A) similarly situated individuals are treated alike; and

(B) any restriction, on the facilities or practitioners which may provide such procedures, is consistent with the accessibility of high quality care to individuals eligible for the procedures under the State plan; or

(2) with respect to any amount expended for an item or service (other than an emergency item or service, not including items or services furnished in an emergency room of a hospital) furnished—

(A) under the plan by any individual or entity during any period when the individual or entity is excluded from participation under title V, XVIII, or XX or under this title pursuant to section 1128, 1128A, 1156, or 1842(j)(2),

(B) at the medical direction or on the prescription of a physician, during the period when such physician is excluded from participation under title V, XVIII, or XX or under this title pursuant to section 1128, 1128A, 1156, or 1842(j)(2) and when the person furnishing such item or service knew or had reason to know of the exclusion (after a reasonable time period after reasonable notice has been furnished to the person); or

(C) by any individual or entity to whom the State has failed to suspend payments under the plan during any period when there is pending an investigation of a credible allegation of fraud against the individual or entity, as determined by the State in accordance with regulations promulgated by the Secretary for purposes of section 1862(o) and this subparagraph, unless the State determines in accordance with such regulations there is good cause not to suspend such payments; or

(3) with respect to any amount expended for inpatient hospital services furnished under the plan (other than amounts attributable to the special situation of a hospital which serves a disproportionate number of low income patients with special needs) to the extent that such amount exceeds the hospital's customary charges with respect to such services or (if such services are furnished under the plan by a public institution free of charge or at nominal charges to the public) exceeds an amount determined on the basis of those items (specified in regulations prescribed by the Secretary) included in the determination of such payment which the Secretary finds will provide fair compensation to such institution for such services; or

(4) with respect to any amount expended for care or services furnished under the plan by a hospital unless such hospital

has in effect a utilization review plan which meets the requirements imposed by section 1861(k) for purposes of title XVIII; and if such hospital has in effect such a utilization review plan for purposes of title XVIII, such plan shall serve as the plan required by this subsection (with the same standards and procedures and the same review committee or group) as a condition of payment under this title; the Secretary is authorized to waive the requirements of this paragraph if the State agency demonstrates to his satisfaction that it has in operation utilization review procedures which are superior in their effectiveness to the procedures required under section 1861(k); or

(5) with respect to any amount expended for any drug product for which payment may not be made under part B of title XVIII because of section 1862(c); or

(6) with respect to any amount expended for inpatient hospital tests (other than in emergency situations) not specifically ordered by the attending physician or other responsible practitioner; or

(7) with respect to any amount expended for clinical diagnostic laboratory tests performed by a physician, independent laboratory, or hospital, to the extent such amount exceeds the amount that would be recognized under section 1833(h) for such tests performed for an individual enrolled under part B of title XVIII; or

(8) with respect to any amount expended for medical assistance (A) for nursing facility services to reimburse (or otherwise compensate) a nursing facility for payment of a civil money penalty imposed under section 1919(h) or (B) for home and community care to reimburse (or otherwise compensate) a provider of such care for payment of a civil money penalty imposed under this title or title XI or for legal expenses in defense of an exclusion or civil money penalty under this title or title XI if there is no reasonable legal ground for the provider's case; or

(10)(A) with respect to covered outpatient drugs unless there is a rebate agreement in effect under section 1927 with respect to such drugs or unless section 1927(a)(3) applies,

(B) with respect to any amount expended for an innovator multiple source drug (as defined in section 1927(k)) dispensed on or after July 1, 1991, if, under applicable State law, a less expensive multiple source drug could have been dispensed, but only to the extent that such amount exceeds the upper payment limit for such multiple source drug;

(C) with respect to covered outpatient drugs described in section 1927(a)(7), unless information respecting utilization data and coding on such drugs that is required to be submitted under such section is submitted in accordance with such section, and

(D) with respect to any amount expended for reimbursement to a pharmacy under this title for the ingredient cost of a covered outpatient drug for which the pharmacy has already received payment under this title (other than with respect to a reasonable restocking fee for such drug); or

(11) with respect to any amount expended for physicians' services furnished on or after the first day of the first quarter

beginning more than 60 days after the date of establishment of the physician identifier system under section 1902(x), unless the claim for the services includes the unique physician identifier provided under such system; or

(13) with respect to any amount expended to reimburse (or otherwise compensate) a nursing facility for payment of legal expenses associated with any action initiated by the facility that is dismissed on the basis that no reasonable legal ground existed for the institution of such action; or

(14) with respect to any amount expended on administrative costs to carry out the program under section 1928; or

(15) with respect to any amount expended for a single-antigen vaccine and its administration in any case in which the administration of a combined-antigen vaccine was medically appropriate (as determined by the Secretary); or

(16) with respect to any amount expended for which funds may not be used under the Assisted Suicide Funding Restriction Act of 1997; or

(17) with respect to any amount expended for roads, bridges, stadiums, or any other item or service not covered under a State plan under this title; or

(18) with respect to any amount expended for home health care services provided by an agency or organization unless the agency or organization provides the State agency on a continuing basis a surety bond in a form specified by the Secretary under paragraph (7) of section 1861(o) and in an amount that is not less than $50,000 or such comparable surety bond as the Secretary may permit under the last sentence of such section; or

(19) with respect to any amount expended on administrative costs to initiate or pursue litigation described in subsection (d)(3)(B);

(20) with respect to amounts expended for medical assistance provided to an individual described in subclause (XV) or (XVI) of section 1902(a)(10)(A)(ii) for a fiscal year unless the State demonstrates to the satisfaction of the Secretary that the level of State funds expended for such fiscal year for programs to enable working individuals with disabilities to work (other than for such medical assistance) is not less than the level expended for such programs during the most recent State fiscal year ending before the date of the enactment of this paragraph;

(21) with respect to amounts expended for covered outpatient drugs described in section 1927(d)(2)(K) (relating to drugs when used for treatment of sexual or erectile dysfunction);

(22) with respect to amounts expended for medical assistance for an individual who declares under section 1137(d)(1)(A) to be a citizen or national of the United States for purposes of establishing eligibility for benefits under this title, unless the requirement of section 1902(a)(46)(B) is met;

(23) with respect to amounts expended for medical assistance for covered outpatient drugs (as defined in section 1927(k)(2)) for which the prescription was executed in written (and nonelectronic) form unless the prescription was executed on a tamper-resistant pad;

(24) if a State is required to implement an asset verification program under section 1940 and fails to implement such program in accordance with such section, with respect to amounts expended by such State for medical assistance for individuals subject to asset verification under such section, unless—

(A) the State demonstrates to the Secretary's satisfaction that the State made a good faith effort to comply;

(B) not later than 60 days after the date of a finding that the State is in noncompliance, the State submits to the Secretary (and the Secretary approves) a corrective action plan to remedy such noncompliance; and

(C) not later than 12 months after the date of such submission (and approval), the State fulfills the terms of such corrective action plan;

(25) with respect to any amounts expended for medical assistance for individuals for whom the State does not report enrollee encounter data (as defined by the Secretary) to the Medicaid Statistical Information System (MSIS) in a timely manner (as determined by the Secretary); **[**or**]**

(26) with respect to any amounts expended for medical assistance for individuals described in subclause (VIII) of subsection (a)(10)(A)(i) other than medical assistance provided through benchmark coverage described in section 1937(b)(1) or benchmark equivalent coverage described in section 1937(b)(2)**[**.**]***; or*

(27) with respect to any amounts expended by the State on the basis of a fee schedule for items described in section 1861(n), as determined in the aggregate with respect to each class of such items as defined by the Secretary, in excess of the aggregate amount, if any, that would be paid for such items within such class on a fee-for-service basis under the program under part B of title XVIII, including, as applicable, under a competitive acquisition program under section 1847 in an area of the State.

Nothing in paragraph (1) shall be construed as permitting a State to provide services under its plan under this title that are not reasonable in amount, duration, and scope to achieve their purpose. Paragraphs (1), (2), (16), (17), and (18) shall apply with respect to items or services furnished and amounts expended by or through a managed care entity (as defined in section 1932(a)(1)(B)) in the same manner as such paragraphs apply to items or services furnished and amounts expended directly by the State.

(j) Notwithstanding the preceding provisions of this section, the amount determined under subsection (a)(1) for any State for any quarter shall be adjusted in accordance with section 1914.

(k) The Secretary is authorized to provide at the request of any State (and without cost to such State) such technical and actuarial assistance as may be necessary to assist such State to contract with any medicaid managed care organization which meets the requirements of subsection (m) of this section for the purpose of providing medical care and services to individuals who are entitled to medical assistance under this title.

(m)(1)(A) The term "medicaid managed care organization" means a health maintenance organization, an eligible organization with a contract under section 1876 or a Medicare+Choice organization with a contract under part C of title XVIII, a provider sponsored

organization, or any other public or private organization, which meets the requirement of section 1902(w) and—

(i) makes services it provides to individuals eligible for benefits under this title accessible to such individuals, within the area served by the organization, to the same extent as such services are made accessible to individuals (eligible for medical assistance under the State plan) not enrolled with the organization, and

(ii) has made adequate provision against the risk of insolvency, which provision is satisfactory to the State, meets the requirements of subparagraph (C)(i) (if applicable), and which assures that individuals eligible for benefits under this title are in no case held liable for debts of the organization in case of the organization's insolvency.

An organization that is a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Service Act) is deemed to meet the requirements of clauses (i) and (ii).

(B) The duties and functions of the Secretary, insofar as they involve making determinations as to whether an organization is a medicaid managed care organization within the meaning of subparagraph (A), shall be integrated with the administration of section 1312 (a) and (b) of the Public Health Service Act.

(C)(i) Subject to clause (ii), a provision meets the requirements of this subparagraph for an organization if the organization meets solvency standards established by the State for private health maintenance organizations or is licensed or certified by the State as a risk-bearing entity.

(ii) Clause (i) shall not apply to an organization if—

(I) the organization is not responsible for the provision (directly or through arrangements with providers of services) of inpatient hospital services and physicians' services;

(II) the organization is a public entity;

(III) the solvency of the organization is guaranteed by the State; or

(IV) the organization is (or is controlled by) one or more Federally-qualified health centers and meets solvency standards established by the State for such an organization.

For purposes of subclause (IV), the term "control" means the possession, whether direct or indirect, of the power to direct or cause the direction of the management and policies of the organization through membership, board representation, or an ownership interest equal to or greater than 50.1 percent.

(2)(A) Except as provided in subparagraphs (B), (C), and (G), no payment shall be made under this title to a State with respect to expenditures incurred by it for payment (determined under a prepaid capitation basis or under any other risk basis) for services provided by any entity (including a health insuring organization) which is responsible for the provision (directly or through arrangements with providers of services) of inpatient hospital services and any other service described in paragraph (2), (3), (4), (5), or (7) of section 1905(a) or for the provision of any three or more of the services described in such paragraphs unless—

(i) the Secretary has determined that the entity is a medicaid managed care organization organization as defined in paragraph (1);

(iii) such services are provided for the benefit of individuals eligible for benefits under this title in accordance with a contract between the State and the entity under which prepaid payments to the entity are made on an actuarially sound basis and under which the Secretary must provide prior approval for contracts providing for expenditures in excess of $1,000,000 for 1998 and, for a subsequent year, the amount established under this clause for the previous year increased by the percentage increase in the consumer price index for all urban consumers over the previous year;

(iv) such contract provides that the Secretary and the State (or any person or organization designated by either) shall have the right to audit and inspect any books and records of the entity (and of any subcontractor) that pertain (I) to the ability of the entity to bear the risk of potential financial losses, or (II) to services performed or determinations of amounts payable under the contract;

(v) such contract provides that in the entity's enrollment, reenrollment, or disenrollment of individuals who are eligible for benefits under this title and eligible to enroll, reenroll, or disenroll with the entity pursuant to the contract, the entity will not discriminate among such individuals on the basis of their health status or requirements for health care services;

(vi) such contract (I) permits individuals who have elected under the plan to enroll with the entity for provision of such benefits to terminate such enrollment in accordance with section 1932(a)(4), and (II) provides for notification in accordance with such section of each such individual, at the time of the individual's enrollment, of such right to terminate such enrollment;

(vii) such contract provides that, in the case of medically necessary services which were provided (I) to an individual enrolled with the entity under the contract and entitled to benefits with respect to such services under the State's plan and (II) other than through the organization because the services were immediately required due to an unforeseen illness, injury, or condition, either the entity or the State provides for reimbursement with respect to those services,

(viii) such contract provides for disclosure of information in accordance with section 1124 and paragraph (4) of this subsection;

(ix) such contract provides, in the case of an entity that has entered into a contract for the provision of services with a Federally-qualified health center or a rural health clinic, that the entity shall provide payment that is not less than the level and amount of payment which the entity would make for the services if the services were furnished by a provider which is not a Federally-qualified health center or a rural health clinic;

(x) any physician incentive plan that it operates meets the requirements described in section 1876(i)(8);

(xi) such contract provides for maintenance of sufficient patient encounter data to identify the physician who delivers services to patients and for the provision of such data to the State at a frequency and level of detail to be specified by the Secretary;

(xii) such contract, and the entity complies with the applicable requirements of section 1932; and

(xiii) such contract provides that (I) covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the entity shall be subject to the same rebate required by the agreement entered into under section 1927 as the State is subject to and that the State shall collect such rebates from manufacturers, (II) capitation rates paid to the entity shall be based on actual cost experience related to rebates and subject to the Federal regulations requiring actuarially sound rates, and (III) the entity shall report to the State, on such timely and periodic basis as specified by the Secretary in order to include in the information submitted by the State to a manufacturer and the Secretary under section 1927(b)(2)(A), information on the total number of units of each dosage form and strength and package size by National Drug Code of each covered outpatient drug dispensed to individuals eligible for medical assistance who are enrolled with the entity and for which the entity is responsible for coverage of such drug under this subsection (other than covered outpatient drugs that under subsection (j)(1) of section 1927 are not subject to the requirements of that section) and such other data as the Secretary determines necessary to carry out this subsection.

(B) Subparagraph (A) except with respect to clause (ix) of subparagraph (A), does not apply with respect to payments under this title to a State with respect to expenditures incurred by it for payment for services provided by an entity which—

(i)(I) received a grant of at least $100,000 in the fiscal year ending June 30, 1976, under section 329(d)(1)(A) or 330(d)(1) of the Public Health Service Act, and for the period beginning July 1, 1976, and ending on the expiration of the period for which payments are to be made under this title has been the recipient of a grant under either such section; and

(II) provides to its enrollees, on a prepaid capitation risk basis or on any other risk basis, all of the services and benefits described in paragraphs (1), (2), (3), (4)(C), and (5) of section 1905(a) and, to the extent required by section 1902(a)(10)(D) to be provided under a State plan for medical assistance, the services and benefits described in paragraph (7) of section 1905(a); or

(ii) is a nonprofit primary health care entity located in a rural area (as defined by the Appalachian Regional Commission)—

(I) which received in the fiscal year ending June 30, 1976, at least $100,000 (by grant, subgrant, or subcontract) under the Appalachian Regional Development Act of 1965, and

(II) for the period beginning July 1, 1976, and ending on the expiration of the period for which payments are to be made under this title either has been the recipient of a grant, subgrant, or subcontract under such Act or has provided services under a contract (initially entered into during a year in which the entity was the recipient of such a

grant, subgrant, or subcontract) with a State agency under this title on a prepaid capitation risk basis or on any other risk basis; or

(iii) which has contracted with the single State agency for the provision of services (but not including inpatient hospital services) to persons eligible under this title on a prepaid risk basis prior to 1970.

(G) In the case of an entity which is receiving (and has received during the previous two years) a grant of at least $100,000 under section 329(d)(1)(A) or 330(d)(1) of the Public Health Service Act or is receiving (and has received during the previous two years) at least $100,000 (by grant, subgrant, or subcontract) under the Appalachian Regional Development Act of 1965, clause (i) of subparagraph (A) shall not apply.

(H) In the case of an individual who—

(i) in a month is eligible for benefits under this title and enrolled with a medicaid managed care organization with a contract under this paragraph or with a primary care case manager with a contract described in section 1905(t)(3),

(ii) in the next month (or in the next 2 months) is not eligible for such benefits, but

(iii) in the succeeding month is again eligible for such benefits,

the State plan, subject to subparagraph (A)(vi), may enroll the individual for that succeeding month with the organization described in clause (i) if the organization continues to have a contract under this paragraph with the State or with the manager described in such clause if the manager continues to have a contract described in section 1905(t)(3) with the State.

(4)(A) Each medicaid managed care organization which is not a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Service Act) must report to the State and, upon request, to the Secretary, the Inspector General of the Department of Health and Human Services, and the Comptroller General a description of transactions between the organization and a party in interest (as defined in section 1318(b) of such Act), including the following transactions:

(i) Any sale or exchange, or leasing of any property between the organization and such a party.

(ii) Any furnishing for consideration of goods, services (including management services), or facilities between the organization and such a party, but not including salaries paid to employees for services provided in the normal course of their employment.

(iii) Any lending of money or other extension of credit between the organization and such a party.

The State or Secretary may require that information reported respecting an organization which controls, or is controlled by, or is under common control with, another entity be in the form of a consolidated financial statement for the organization and such entity.

(B) Each organization shall make the information reported pursuant to subparagraph (A) available to its enrollees upon reasonable request.

(5)(A) If the Secretary determines that an entity with a contract under this subsection—

(i) fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(ii) imposes premiums on individuals enrolled under this subsection in excess of the premiums permitted under this title;

(iii) acts to discriminate among individuals in violation of the provision of paragraph (2)(A)(v), including expulsion or refusal to re-enroll an individual or engaging in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this subsection) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services;

(iv) misrepresents or falsifies information that is furnished—

(I) to the Secretary or the State under this subsection, or

(II) to an individual or to any other entity under this subsection, or

(v) fails to comply with the requirements of section 1876(i)(8),

the Secretary may provide, in addition to any other remedies available under law, for any of the remedies described in subparagraph (B).

(B) The remedies described in this subparagraph are—

(i) civil money penalties of not more than $25,000 for each determination under subparagraph (A), or, with respect to a determination under clause (iii) or (iv)(I) of such subparagraph, of not more than $100,000 for each such determination, plus, with respect to a determination under subparagraph (A)(ii), double the excess amount charged in violation of such subparagraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and plus, with respect to a determination under subparagraph (A)(iii), $15,000 for each individual not enrolled as a result of a practice described in such subparagraph, or

(ii) denial of payment to the State for medical assistance furnished under the contract under this subsection for individuals enrolled after the date the Secretary notifies the organization of a determination under subparagraph (A) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur.

The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (i) in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(6)(A) For purposes of this subsection and section 1902(e)(2)(A), in the case of the State of New Jersey, the term "contract" shall be deemed to include an undertaking by the State agency, in the State plan under this title, to operate a program meeting all requirements of this subsection.

(B) The undertaking described in subparagraph (A) must provide—

(i) for the establishment of a separate entity responsible for the operation of a program meeting the requirements of this subsection, which entity may be a subdivision of the State agency administering the State plan under this title;

(ii) for separate accounting for the funds used to operate such program; and

(iii) for setting the capitation rates and any other payment rates for services provided in accordance with this subsection using a methodology satisfactory to the Secretary designed to ensure that total Federal matching payments under this title for such services will be lower than the matching payments that would be made for the same services, if provided under the State plan on a fee for service basis to an actuarially equivalent population.

(C) The undertaking described in subparagraph (A) shall be subject to approval (and annual re-approval) by the Secretary in the same manner as a contract under this subsection.

(D) The undertaking described in subparagraph (A) shall not be eligible for a waiver under section 1915(b).

(o) Notwithstanding the preceding provisions of this section, no payment shall be made to a State under the preceding provisions of this section for expenditures for medical assistance provided for an individual under its State plan approved under this title to the extent that a private insurer (as defined by the Secretary by regulation and including a group health plan (as defined in section 607(1) of the Employee Retirement Income Security Act of 1974), a service benefit plan, and a health maintenance organization) would have been obligated to provide such assistance but for a provision of its insurance contract which has the effect of limiting or excluding such obligation because the individual is eligible for or is provided medical assistance under the plan.

(p)(1) When a political subdivision of a State makes, for the State of which it is a political subdivision, or one State makes, for another State, the enforcement and collection of rights of support or payment assigned under section 1912, pursuant to a cooperative arrangement under such section (either within or outside of such State), there shall be paid to such political subdivision or such other State from amounts which would otherwise represent the Federal share of payments for medical assistance provided to the eligible individuals on whose behalf such enforcement and collection was made, an amount equal to 15 percent of any amount collected which is attributable to such rights of support or payment.

(2) Where more than one jurisdiction is involved in such enforcement or collection, the amount of the incentive payment determined under paragraph (1) shall be allocated among the jurisdictions in a manner to be prescribed by the Secretary.

(q) For the purposes of this section, the term "State medicaid fraud control unit" means a single identifiable entity of the State government which the Secretary certifies (and annually recertifies) as meeting the following requirements:

(1) The entity (A) is a unit of the office of the State Attorney General or of another department of State government which possesses statewide authority to prosecute individuals for criminal violations, (B) is in a State the constitution of which does not provide for the criminal prosecution of individuals by

a statewide authority and has formal procedures, approved by the Secretary, that (i) assure its referral of suspected criminal violations relating to the program under this title to the appropriate authority or authorities in the State for prosecution and (ii) assure its assistance of, and coordination with, such authority or authorities in such prosecutions, or (C) has a formal working relationship with the office of the State Attorney General and has formal procedures (including procedures for its referral of suspected criminal violations to such office) which are approved by the Secretary and which provide effective coordination of activities between the entity and such office with respect to the detection, investigation, and prosecution of suspected criminal violations relating to the program under this title.

(2) The entity is separate and distinct from the single State agency that administers or supervises the administration of the State plan under this title.

(3) The entity's function is conducting a statewide program for the investigation and prosecution of violations of all applicable State laws regarding any and all aspects of fraud in connection with (A) any aspect of the provision of medical assistance and the activities of providers of such assistance under the State plan under this title; and (B) upon the approval of the Inspector General of the relevant Federal agency, any aspect of the provision of health care services and activities of providers of such services under any Federal health care program (as defined in section 1128B(f)(1)), if the suspected fraud or violation of law in such case or investigation is primarily related to the State plan under this title.

(4)(A) The entity has—

(i) procedures for reviewing complaints of abuse or neglect of patients in health care facilities which receive payments under the State plan under this title;

(ii) at the option of the entity, procedures for reviewing complaints of abuse or neglect of patients residing in board and care facilities; and

(iii) procedures for acting upon such complaints under the criminal laws of the State or for referring such complaints to other State agencies for action.

(B) For purposes of this paragraph, the term "board and care facility" means a residential setting which receives payment (regardless of whether such payment is made under the State plan under this title) from or on behalf of two or more unrelated adults who reside in such facility, and for whom one or both of the following is provided:

(i) Nursing care services provided by, or under the supervision of, a registered nurse, licensed practical nurse, or licensed nursing assistant.

(ii) A substantial amount of personal care services that assist residents with the activities of daily living, including personal hygiene, dressing, bathing, eating, toileting, ambulation, transfer, positioning, self-medication, body care, travel to medical services, essential shopping, meal preparation, laundry, and housework.

(5) The entity provides for the collection, or referral for collection to a single State agency, of overpayments that are made under the State plan or under any Federal health care program (as so defined) to health care facilities and that are discovered by the entity in carrying out its activities. All funds collected in accordance with this paragraph shall be credited exclusively to, and available for expenditure under, the Federal health care program (including the State plan under this title) that was subject to the activity that was the basis for the collection.

(6) The entity employs such auditors, attorneys, investigators, and other necessary personnel and is organized in such a manner as is necessary to promote the effective and efficient conduct of the entity's activities.

(7) The entity submits to the Secretary an application and annual reports containing such information as the Secretary determines, by regulation, to be necessary to determine whether the entity meets the other requirements of this subsection.

(r)(1) In order to receive payments under subsection (a) for use of automated data systems in administration of the State plan under this title, a State must, in addition to meeting the requirements of paragraph (3), have in operation mechanized claims processing and information retrieval systems that meet the requirements of this subsection and that the Secretary has found—

(A) are adequate to provide efficient, economical, and effective administration of such State plan;

(B) are compatible with the claims processing and information retrieval systems used in the administration of title XVIII, and for this purpose—

(i) have a uniform identification coding system for providers, other payees, and beneficiaries under this title or title XVIII;

(ii) provide liaison between States and carriers and intermediaries with agreements under title XVIII to facilitate timely exchange of appropriate data;

(iii) provide for exchange of data between the States and the Secretary with respect to persons sanctioned under this title or title XVIII; and

(iv) effective for claims filed on or after October 1, 2010, incorporate compatible methodologies of the National Correct Coding Initiative administered by the Secretary (or any successor initiative to promote correct coding and to control improper coding leading to inappropriate payment) and such other methodologies of that Initiative (or such other national correct coding methodologies) as the Secretary identifies in accordance with paragraph (4);

(C) are capable of providing accurate and timely data;

(D) are complying with the applicable provisions of part C of title XI;

(E) are designed to receive provider claims in standard formats to the extent specified by the Secretary; and

(F) effective for claims filed on or after January 1, 1999, provide for electronic transmission of claims data in the format specified by the Secretary and consistent with the Medicaid Statistical Information System (MSIS) (including detailed indi-

vidual enrollee encounter data and other information that the Secretary may find necessary and including, for data submitted to the Secretary on or after January 1, 2010, data elements from the automated data system that the Secretary determines to be necessary for program integrity, program oversight, and administration, at such frequency as the Secretary shall determine).

(2) In order to meet the requirements of this paragraph, mechanized claims processing and information retrieval systems must meet the following requirements:

(A) The systems must be capable of developing provider, physician, and patient profiles which are sufficient to provide specific information as to the use of covered types of services and items, including prescribed drugs.

(B) The State must provide that information on probable fraud or abuse which is obtained from, or developed by, the systems, is made available to the State's medicaid fraud control unit (if any) certified under subsection (q) of this section.

(C) The systems must meet all performance standards and other requirements for initial approval developed by the Secretary.

(3) In order to meet the requirements of this paragraph, a State must have in operation an eligibility determination system which provides for data matching through the Public Assistance Reporting Information System (PARIS) facilitated by the Secretary (or any successor system), including matching with medical assistance programs operated by other States.

(4) For purposes of paragraph (1)(B)(iv), the Secretary shall do the following:

(A) Not later than September 1, 2010:

(i) Identify those methodologies of the National Correct Coding Initiative administered by the Secretary (or any successor initiative to promote correct coding and to control improper coding leading to inappropriate payment) which are compatible to claims filed under this title.

(ii) Identify those methodologies of such Initiative (or such other national correct coding methodologies) that should be incorporated into claims filed under this title with respect to items or services for which States provide medical assistance under this title and no national correct coding methodologies have been established under such Initiative with respect to title XVIII.

(iii) Notify States of—

(I) the methodologies identified under subparagraphs (A) and (B) (and of any other national correct coding methodologies identified under subparagraph (B)); and

(II) how States are to incorporate such methodologies into claims filed under this title.

(B) Not later than March 1, 2011, submit a report to Congress that includes the notice to States under clause (iii) of subparagraph (A) and an analysis supporting the identification of the methodologies made under clauses (i) and (ii) of subparagraph (A).

(s) Notwithstanding the preceding provisions of this section, no payment shall be made to a State under this section for expenditures for medical assistance under the State plan consisting of a designated health service (as defined in subsection (h)(6) of section 1877) furnished to an individual on the basis of a referral that would result in the denial of payment for the service under title XVIII if such title provided for coverage of such service to the same extent and under the same terms and conditions as under the State plan, and subsections (f) and (g)(5) of such section shall apply to a provider of such a designated health service for which payment may be made under this title in the same manner as such subsections apply to a provider of such a service for which payment may be made under such title.

(t)(1) For purposes of subsection (a)(3)(F), the payments described in this paragraph to encourage the adoption and use of certified EHR technology are payments made by the State in accordance with this subsection —

(A) to Medicaid providers described in paragraph (2)(A) not in excess of 85 percent of net average allowable costs (as defined in paragraph (3)(E)) for certified EHR technology (and support services including maintenance and training that is for, or is necessary for the adoption and operation of, such technology) with respect to such providers; and

(B) to Medicaid providers described in paragraph (2)(B) not in excess of the maximum amount permitted under paragraph (5) for the provider involved.

(2) In this subsection and subsection (a)(3)(F), the term "Medicaid provider" means—

(A) an eligible professional (as defined in paragraph (3)(B))—

(i) who is not hospital-based and has at least 30 percent of the professional's patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under this title;

(ii) who is not described in clause (i), who is a pediatrician, who is not hospital-based, and who has at least 20 percent of the professional's patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under this title; and

(iii) who practices predominantly in a Federally qualified health center or rural health clinic and has at least 30 percent of the professional's patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to needy individuals (as defined in paragraph (3)(F)); and

(B)(i) a children's hospital, or

(ii) an acute-care hospital that is not described in clause (i) and that has at least 10 percent of the hospital's patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under this title.

An eligible professional shall not qualify as a Medicaid provider under this subsection unless any right to payment under sections 1848(o) and 1853(l) with respect to the eligible professional has

been waived in a manner specified by the Secretary. For purposes of calculating patient volume under subparagraph (A)(iii), insofar as it is related to uncompensated care, the Secretary may require the adjustment of such uncompensated care data so that it would be an appropriate proxy for charity care, including a downward adjustment to eliminate bad debt data from uncompensated care. In applying subparagraphs (A) and (B)(ii), the methodology established by the Secretary for patient volume shall include individuals enrolled in a Medicaid managed care plan (under section 1903(m) or section 1932). *An eligible professional shall not qualify as a Medicaid provider under this subsection, with respect to a year beginning with 2018, unless such provider demonstrates to the Secretary, through means such as an attestation, that the provider has not taken any action described in subsection (a)(2) of section 3010A of the Public Health Service Act with respect to which the provider knows or should know (as defined in section 1128A(i)(7) of the Social Security Act) about, with respect to the use of any certified EHR technology.*

(3) In this subsection and subsection (a)(3)(F):

(A) The term "certified EHR technology" means a qualified electronic health record (as defined in 3000(13) of the Public Health Service Act) that is certified pursuant to section 3001(c)(5) of such Act as meeting standards adopted under section 3004 of such Act that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).

(B) The term "eligible professional" means a—

(i) physician;

(ii) dentist;

(iii) certified nurse mid-wife;

(iv) nurse practitioner; and

(v) physician assistant insofar as the assistant is practicing in a rural health clinic that is led by a physician assistant or is practicing in a Federally qualified health center that is so led.

(C) The term "average allowable costs" means, with respect to certified EHR technology of Medicaid providers described in paragraph (2)(A) for—

(i) the first year of payment with respect to such a provider, the average costs for the purchase and initial implementation or upgrade of such technology (and support services including training that is for, or is necessary for the adoption and initial operation of, such technology) for such providers, as determined by the Secretary based upon studies conducted under paragraph (4)(C); and

(ii) a subsequent year of payment with respect to such a provider, the average costs not described in clause (i) relating to the operation, maintenance, and use of such technology for such providers, as determined by the Secretary based upon studies conducted under paragraph (4)(C).

(D) The term "hospital-based" means, with respect to an eligible professional, a professional (such as a pathologist, anesthesiologist, or emergency physician) who furnishes substantially all of the individual's professional services in a hospital

inpatient or emergency room setting and through the use of the facilities and equipment, including qualified electronic health records, of the hospital. The determination of whether an eligible professional is a hospital-based eligible professional shall be made on the basis of the site of service (as defined by the Secretary) and without regard to any employment or billing arrangement between the eligible professional and any other provider.

(E) The term "net average allowable costs" means, with respect to a Medicaid provider described in paragraph (2)(A), average allowable costs reduced by the average payment the Secretary estimates will be made to such Medicaid providers (determined on a percentage or other basis for such classes or types of providers as the Secretary may specify) from other sources (other than under this subsection, or by the Federal government or a State or local government) that is directly attributable to payment for certified EHR technology or support services described in subparagraph (C).

(F) The term "needy individual" means, with respect to a Medicaid provider, an individual—

(i) who is receiving assistance under this title;

(ii) who is receiving assistance under title XXI;

(iii) who is furnished uncompensated care by the provider; or

(iv) for whom charges are reduced by the provider on a sliding scale basis based on an individual's ability to pay.

(4)(A) With respect to a Medicaid provider described in paragraph (2)(A), subject to subparagraph (B), in no case shall—

(i) the net average allowable costs under this subsection for the first year of payment (which may not be later than 2016), which is intended to cover the costs described in paragraph (3)(C)(i), exceed $25,000 (or such lesser amount as the Secretary determines based on studies conducted under subparagraph (C));

(ii) the net average allowable costs under this subsection for a subsequent year of payment, which is intended to cover costs described in paragraph (3)(C)(ii), exceed $10,000; and

(iii) payments be made for costs described in clause (ii) after 2021 or over a period of longer than 5 years.

(B) In the case of Medicaid provider described in paragraph (2)(A)(ii), the dollar amounts specified in subparagraph (A) shall be ⅔ of the dollar amounts otherwise specified.

(C) For the purposes of determining average allowable costs under this subsection, the Secretary shall study the average costs to Medicaid providers described in paragraph (2)(A) of purchase and initial implementation and upgrade of certified EHR technology described in paragraph (3)(C)(i) and the average costs to such providers of operations, maintenance, and use of such technology described in paragraph (3)(C)(ii). In determining such costs for such providers, the Secretary may utilize studies of such amounts submitted by States.

(5)(A) In no case shall the payments described in paragraph (1)(B) with respect to a Medicaid provider described in paragraph (2)(B) exceed—

(i) in the aggregate the product of—

(I) the overall hospital EHR amount for the provider computed under subparagraph (B); and

(II) the Medicaid share for such provider computed under subparagraph (C);

(ii) in any year 50 percent of the product described in clause (i); and

(iii) in any 2-year period 90 percent of such product.

(B) For purposes of this paragraph, the overall hospital EHR amount, with respect to a Medicaid provider, is the sum of the applicable amounts specified in section 1886(n)(2)(A) for such provider for the first 4 payment years (as estimated by the Secretary) determined as if the Medicare share specified in clause (ii) of such section were 1. The Secretary shall establish, in consultation with the State, the overall hospital EHR amount for each such Medicaid provider eligible for payments under paragraph (1)(B). For purposes of this subparagraph in computing the amounts under section 1886(n)(2)(C) for payment years after the first payment year, the Secretary shall assume that in subsequent payment years discharges increase at the average annual rate of growth of the most recent 3 years for which discharge data are available per year.

(C) The Medicaid share computed under this subparagraph, for a Medicaid provider for a period specified by the Secretary, shall be calculated in the same manner as the Medicare share under section 1886(n)(2)(D) for such a hospital and period, except that there shall be substituted for the numerator under clause (i) of such section the amount that is equal to the number of inpatient-bed-days (as established by the Secretary) which are attributable to individuals who are receiving medical assistance under this title and who are not described in section 1886(n)(2)(D)(i). In computing inpatient-bed-days under the previous sentence, the Secretary shall take into account inpatient-bed-days attributable to inpatient-bed-days that are paid for individuals enrolled in a Medicaid managed care plan (under section 1903(m) or section 1932).

(D) In no case may the payments described in paragraph (1)(B) with respect to a Medicaid provider described in paragraph (2)(B) be paid—

(i) for any year beginning after 2016 unless the provider has been provided payment under paragraph (1)(B) for the previous year; and

(ii) over a period of more than 6 years of payment.

(6) Payments described in paragraph (1) are not in accordance with this subsection unless the following requirements are met:

(A)(i) The State provides assurances satisfactory to the Secretary that amounts received under subsection (a)(3)(F) with respect to payments to a Medicaid provider are paid, subject to clause (ii), directly to such provider (or to an employer or facility to which such provider has assigned payments) without any deduction or rebate.

(ii) Amounts described in clause (i) may also be paid to an entity promoting the adoption of certified EHR technology, as designated by the State, if participation in such a payment arrangement is voluntary for the eligible professional involved and if such entity does not retain more than 5 percent of such payments for costs not related to certified EHR technology (and

support services including maintenance and training) that is for, or is necessary for the operation of, such technology.

(B) A Medicaid provider described in paragraph (2)(A) is responsible for payment of the remaining 15 percent of the net average allowable cost and shall be determined to have met such responsibility to the extent that the payment to the Medicaid provider is not in excess of 85 percent of the net average allowable cost.

(C)(i) Subject to clause (ii), with respect to payments to a Medicaid provider—

(I) for the first year of payment to the Medicaid provider under this subsection, the Medicaid provider demonstrates that it is engaged in efforts to adopt, implement, or upgrade certified EHR technology; and

(II) for a year of payment, other than the first year of payment to the Medicaid provider under this subsection, the Medicaid provider demonstrates meaningful use of certified EHR technology through a means that is approved by the State and acceptable to the Secretary, and that may be based upon the methodologies applied under section 1848(o) or 1886(n).

(ii) In the case of a Medicaid provider who has completed adopting, implementing, or upgrading such technology prior to the first year of payment to the Medicaid provider under this subsection, clause (i)(I) shall not apply and clause (i)(II) shall apply to each year of payment to the Medicaid provider under this subsection, including the first year of payment.

(D) To the extent specified by the Secretary, the certified EHR technology is compatible with State or Federal administrative management systems.

For purposes of subparagraph (B), a Medicaid provider described in paragraph (2)(A) may accept payments for the costs described in such subparagraph from a State or local government. For purposes of subparagraph (C), in establishing the means described in such subparagraph, which may include clinical quality reporting to the State, the State shall ensure that populations with unique needs, such as children, are appropriately addressed.

(7) With respect to Medicaid providers described in paragraph (2)(A), the Secretary shall ensure coordination of payment with respect to such providers under sections 1848(o) and 1853(l) and under this subsection to assure no duplication of funding. Such coordination shall include, to the extent practicable, a data matching process between State Medicaid agencies and the Centers for Medicare & Medicaid Services using national provider identifiers. For such purposes, the Secretary may require the submission of such data relating to payments to such Medicaid providers as the Secretary may specify.

(8) In carrying out paragraph (6)(C), the State and Secretary shall seek, to the maximum extent practicable, to avoid duplicative requirements from Federal and State governments to demonstrate meaningful use of certified EHR technology under this title and title XVIII. In doing so, the Secretary may deem satisfaction of requirements for such meaningful use for a payment year under title XVIII to be sufficient to qualify as meaningful use under this sub-

section. The Secretary may also specify the reporting periods under this subsection in order to carry out this paragraph.

(9) In order to be provided Federal financial participation under subsection (a)(3)(F)(ii), a State must demonstrate to the satisfaction of the Secretary, that the State—

(A) is using the funds provided for the purposes of administering payments under this subsection, including tracking of meaningful use by Medicaid providers;

(B) is conducting adequate oversight of the program under this subsection, including routine tracking of meaningful use attestations and reporting mechanisms; and

(C) is pursuing initiatives to encourage the adoption of certified EHR technology to promote health care quality and the exchange of health care information under this title, subject to applicable laws and regulations governing such exchange.

(10) The Secretary shall periodically submit reports to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate on status, progress, and oversight of payments described in paragraph (1), including steps taken to carry out paragraph (7). Such reports shall also describe the extent of adoption of certified EHR technology among Medicaid providers resulting from the provisions of this subsection and any improvements in health outcomes, clinical quality, or efficiency resulting from such adoption.

(u)(1)(A) Notwithstanding subsection (a)(1), if the ratio of a State's erroneous excess payments for medical assistance (as defined in subparagraph (D)) to its total expenditures for medical assistance under the State plan approved under this title exceeds 0.03, for the period consisting of the third and fourth quarters of fiscal year 1983, or for any full fiscal year thereafter, then the Secretary shall make no payment for such period or fiscal year with respect to so much of such erroneous excess payments as exceeds such allowable error rate of 0.03.

(B) The Secretary may waive, in certain limited cases, all or part of the reduction required under subparagraph (A) with respect to any State if such State is unable to reach the allowable error rate for a period or fiscal year despite a good faith effort by such State.

(C) In estimating the amount to be paid to a State under subsection (d), the Secretary shall take into consideration the limitation on Federal financial participation imposed by subparagraph (A) and shall reduce the estimate he makes under subsection (d)(1), for purposes of payment to the State under subsection (d)(3), in light of any expected erroneous excess payments for medical assistance (estimated in accordance with such criteria, including sampling procedures, as he may prescribe and subject to subsequent adjustment, if necessary, under subsection (d)(2)).

(D)(i) For purposes of this subsection, the term "erroneous excess payments for medical assistance" means the total of—

(I) payments under the State plan with respect to ineligible individuals and families, and

(II) overpayments on behalf of eligible individuals and families by reason of error in determining the amount of expenditures for medical care required of an individual or family as a condition of eligibility.

(ii) In determining the amount of erroneous excess payments for medical assistance to an ineligible individual or family under clause (i)(I), if such ineligibility is the result of an error in determining the amount of the resources of such individual or family, the amount of the erroneous excess payment shall be the smaller of (I) the amount of the payment with respect to such individual or family, or (II) the difference between the actual amount of such resources and the allowable resource level established under the State plan.

(iii) In determining the amount of erroneous excess payments for medical assistance to an individual or family under clause (i)(II), the amount of the erroneous excess payment shall be the smaller of (I) the amount of the payment on behalf of the individual or family, or (II) the difference between the actual amount incurred for medical care by the individual or family and the amount which should have been incurred in order to establish eligibility for medical assistance.

(iv) In determining the amount of erroneous excess payments, there shall not be included any error resulting from a failure of an individual to cooperate or give correct information with respect to third-party liability as required under section 1912(a)(1)(C) or 402(a)(26)(C) or with respect to payments made in violation of section 1906.

(v) In determining the amount of erroneous excess payments, there shall not be included any erroneous payments made for ambulatory prenatal care provided during a presumptive eligibility period (as defined in section 1920(b)(1)), for items and services described in subsection (a) of section 1920A provided to a child during a presumptive eligibility period under such section, for medical assistance provided to an individual described in subsection (a) of section 1920B during a presumptive eligibility period under such section, or for medical assistance provided to an individual during a presumptive eligibility period resulting from a determination of presumptive eligibility made by a hospital that elects under section 1902(a)(47)(B) to be a qualified entity for such purpose.

(E) For purposes of subparagraph (D), there shall be excluded, in determining both erroneous excess payments for medical assistance and total expenditures for medical assistance—

(i) payments with respect to any individual whose eligibility therefor was determined exclusively by the Secretary under an agreement pursuant to section 1634 and such other classes of individuals as the Secretary may by regulation prescribe whose eligibility was determined in part under such an agreement; and

(ii) payments made as the result of a technical error.

(2) The State agency administering the plan approved under this title shall, at such times and in such form as the Secretary may specify, provide information on the rates of erroneous excess payments made (or expected, with respect to future periods specified by the Secretary) in connection with its administration of such plan, together with any other data he requests that are reasonably necessary for him to carry out the provisions of this subsection.

(3)(A) If a State fails to cooperate with the Secretary in providing information necessary to carry out this subsection, the Secretary, directly or through contractual or such other arrangements as he

may find appropriate, shall establish the error rates for that State on the basis of the best data reasonably available to him and in accordance with such techniques for sampling and estimating as he finds appropriate.

(B) In any case in which it is necessary for the Secretary to exercise his authority under subparagraph (A) to determine a State's error rates for a fiscal year, the amount that would otherwise be payable to such State under this title for quarters in such year shall be reduced by the costs incurred by the Secretary in making (directly or otherwise) such determination.

(4) This subsection shall not apply with respect to Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, or American Samoa.

(v)(1) Notwithstanding the preceding provisions of this section, except as provided in paragraphs (2) and (4), no payment may be made to a State under this section for medical assistance furnished to an alien who is not lawfully admitted for permanent residence or otherwise permanently residing in the United States under color of law.

(2) Payment shall be made under this section for care and services that are furnished to an alien described in paragraph (1) only if—

(A) such care and services are necessary for the treatment of an emergency medical condition of the alien,

(B) such alien otherwise meets the eligibility requirements for medical assistance under the State plan approved under this title (other than the requirement of the receipt of aid or assistance under title IV, supplemental security income benefits under title XVI, or a State supplementary payment), and

(C) such care and services are not related to an organ transplant procedure.

(3) For purposes of this subsection, the term "emergency medical condition" means a medical condition (including emergency labor and delivery) manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—

(A) placing the patient's health in serious jeopardy,

(B) serious impairment to bodily functions, or

(C) serious dysfunction of any bodily organ or part.

(4)(A) A State may elect (in a plan amendment under this title) to provide medical assistance under this title, notwithstanding sections 401(a), 402(b), 403, and 421 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, to children and pregnant women who are lawfully residing in the United States (including battered individuals described in section 431(c) of such Act) and who are otherwise eligible for such assistance, within either or both of the following eligibility categories:

(i) PREGNANT WOMEN.—Women during pregnancy (and during the 60-day period beginning on the last day of the pregnancy).

(ii) CHILDREN.—Individuals under 21 years of age, including optional targeted low-income children described in section 1905(u)(2)(B).

(B) In the case of a State that has elected to provide medical assistance to a category of aliens under subparagraph (A), no debt

shall accrue under an affidavit of support against any sponsor of such an alien on the basis of provision of assistance to such category and the cost of such assistance shall not be considered as an unreimbursed cost.

(C) As part of the State's ongoing eligibility redetermination requirements and procedures for an individual provided medical assistance as a result of an election by the State under subparagraph (A), a State shall verify that the individual continues to lawfully reside in the United States using the documentation presented to the State by the individual on initial enrollment. If the State cannot successfully verify that the individual is lawfully residing in the United States in this manner, it shall require that the individual provide the State with further documentation or other evidence to verify that the individual is lawfully residing in the United States.

(w)(1)(A) Notwithstanding the previous provisions of this section, for purposes of determining the amount to be paid to a State (as defined in paragraph (7)(D)) under subsection (a)(1) for quarters in any fiscal year, the total amount expended during such fiscal year as medical assistance under the State plan (as determined without regard to this subsection) shall be reduced by the sum of any revenues received by the State (or by a unit of local government in the State) during the fiscal year—

(i) from provider-related donations (as defined in paragraph (2)(A)), other than—

(I) bona fide provider-related donations (as defined in paragraph (2)(B)), and

(II) donations described in paragraph (2)(C);

(ii) from health care related taxes (as defined in paragraph (3)(A)), other than broad-based health care related taxes (as defined in paragraph (3)(B));

(iii) from a broad-based health care related tax, if there is in effect a hold harmless provision (described in paragraph (4)) with respect to the tax; or

(iv) only with respect to State fiscal years (or portions thereof) occurring on or after January 1, 1992, and before October 1, 1995, from broad-based health care related taxes to the extent the amount of such taxes collected exceeds the limit established under paragraph (5).

(B) Notwithstanding the previous provisions of this section, for purposes of determining the amount to be paid to a State under subsection (a)(7) for all quarters in a Federal fiscal year (beginning with fiscal year 1993), the total amount expended during the fiscal year for administrative expenditures under the State plan (as determined without regard to this subsection) shall be reduced by the sum of any revenues received by the State (or by a unit of local government in the State) during such quarters from donations described in paragraph (2)(C), to the extent the amount of such donations exceeds 10 percent of the amounts expended under the State plan under this title during the fiscal year for purposes described in paragraphs (2), (3), (4), (6), and (7) of subsection (a).

(C)(i) Except as otherwise provided in clause (ii), subparagraph (A)(i) shall apply to donations received on or after January 1, 1992.

(ii) Subject to the limits described in clause (iii) and subparagraph (E), subparagraph (A)(i) shall not apply to donations received

before the effective date specified in subparagraph (F) if such donations are received under programs in effect or as described in State plan amendments or related documents submitted to the Secretary by September 30, 1991, and applicable to State fiscal year 1992, as demonstrated by State plan amendments, written agreements, State budget documentation, or other documentary evidence in existence on that date.

(iii) In applying clause (ii) in the case of donations received in State fiscal year 1993, the maximum amount of such donations to which such clause may be applied may not exceed the total amount of such donations received in the corresponding period in State fiscal year 1992 (or not later than 5 days after the last day of the corresponding period).

(D)(i) Except as otherwise provided in clause (ii), subparagraphs (A)(ii) and (A)(iii) shall apply to taxes received on or after January 1, 1992.

(ii) Subparagraphs (A)(ii) and (A)(iii) shall not apply to impermissible taxes (as defined in clause (iii)) received before the effective date specified in subparagraph (F) to the extent the taxes (including the tax rate or base) were in effect, or the legislation or regulations imposing such taxes were enacted or adopted, as of November 22, 1991.

(iii) In this subparagraph and subparagraph (E), the term "impermissible tax" means a health care related tax for which a reduction may be made under clause (ii) or (iii) of subparagraph (A).

(E)(i) In no case may the total amount of donations and taxes permitted under the exception provided in subparagraphs (C)(ii) and (D)(ii) for the portion of State fiscal year 1992 occurring during calendar year 1992 exceed the limit under paragraph (5) minus the total amount of broad-based health care related taxes received in the portion of that fiscal year.

(ii) In no case may the total amount of donations and taxes permitted under the exception provided in subparagraphs (C)(ii) and (D)(ii) for State fiscal year 1993 exceed the limit under paragraph (5) minus the total amount of broad-based health care related taxes received in that fiscal year.

(F) In this paragraph in the case of a State—

(i) except as provided in clause (iii), with a State fiscal year beginning on or before July 1, the effective date is October 1, 1992,

(ii) except as provided in clause (iii), with a State fiscal year that begins after July 1, the effective date is January 1, 1993, or

(iii) with a State legislature which is not scheduled to have a regular legislative session in 1992, with a State legislature which is not scheduled to have a regular legislative session in 1993, or with a provider-specific tax enacted on November 4, 1991, the effective date is July 1, 1993.

(2)(A) In this subsection (except as provided in paragraph (6)), the term "provider-related donation" means any donation or other voluntary payment (whether in cash or in kind) made (directly or indirectly) to a State or unit of local government by—

(i) a health care provider (as defined in paragraph (7)(B)),

(ii) an entity related to a health care provider (as defined in paragraph (7)(C)), or

(iii) an entity providing goods or services under the State plan for which payment is made to the State under paragraph (2), (3), (4), (6), or (7) of subsection (a).

(B) For purposes of paragraph (1)(A)(i)(I), the term "bona fide provider-related donation" means a provider-related donation that has no direct or indirect relationship (as determined by the Secretary) to payments made under this title to that provider, to providers furnishing the same class of items and services as that provider, or to any related entity, as established by the State to the satisfaction of the Secretary. The Secretary may by regulation specify types of provider-related donations described in the previous sentence that will be considered to be bona fide provider-related donations.

(C) For purposes of paragraph (1)(A)(i)(II), donations described in this subparagraph are funds expended by a hospital, clinic, or similar entity for the direct cost (including costs of training and of preparing and distributing outreach materials) of State or local agency personnel who are stationed at the hospital, clinic, or entity to determine the eligibility of individuals for medical assistance under this title and to provide outreach services to eligible or potentially eligible individuals.

(3)(A) In this subsection (except as provided in paragraph (6)), the term "health care related tax" means a tax (as defined in paragraph (7)(F)) that—

(i) is related to health care items or services, or to the provision of, the authority to provide, or payment for, such items or services, or

(ii) is not limited to such items or services but provides for treatment of individuals or entities that are providing or paying for such items or services that is different from the treatment provided to other individuals or entities.

In applying clause (i), a tax is considered to relate to health care items or services if at least 85 percent of the burden of such tax falls on health care providers.

(B) In this subsection, the term "broad-based health care related tax" means a health care related tax which is imposed with respect to a class of health care items or services (as described in paragraph (7)(A)) or with respect to providers of such items or services and which, except as provided in subparagraphs (D), (E), and (F)—

(i) is imposed at least with respect to all items or services in the class furnished by all non-Federal, nonpublic providers in the State (or, in the case of a tax imposed by a unit of local government, the area over which the unit has jurisdiction) or is imposed with respect to all non-Federal, nonpublic providers in the class; and

(ii) is imposed uniformly (in accordance with subparagraph (C)).

(C)(i) Subject to clause (ii), for purposes of subparagraph (B)(ii), a tax is considered to be imposed uniformly if—

(I) in the case of a tax consisting of a licensing fee or similar tax on a class of health care items or services (or providers of such items or services), the amount of the tax imposed is the same for every provider providing items or services within the class;

(II) in the case of a tax consisting of a licensing fee or similar tax imposed on a class of health care items or services (or providers of such services) on the basis of the number of beds (licensed or otherwise) of the provider, the amount of the tax is the same for each bed of each provider of such items or services in the class;

(III) in the case of a tax based on revenues or receipts with respect to a class of items or services (or providers of items or services) the tax is imposed at a uniform rate for all items and services (or providers of such items of services) in the class on all the gross revenues or receipts, or net operating revenues, relating to the provision of all such items or services (or all such providers) in the State (or, in the case of a tax imposed by a unit of local government within the State, in the area over which the unit has jurisdiction); or

(IV) in the case of any other tax, the State establishes to the satisfaction of the Secretary that the tax is imposed uniformly.

(ii) Subject to subparagraphs (D) and (E), a tax imposed with respect to a class of health care items and services is not considered to be imposed uniformly if the tax provides for any credits, exclusions, or deductions which have as their purpose or effect the return to providers of all or a portion of the tax paid in a manner that is inconsistent with subclauses (I) and (II) of subparagraph (E)(ii) or provides for a hold harmless provision described in paragraph (4).

(D) A tax imposed with respect to a class of health care items and services is considered to be imposed uniformly—

(i) notwithstanding that the tax is not imposed with respect to items or services (or the providers thereof) for which payment is made under a State plan under this title or title XVIII, or

(ii) in the case of a tax described in subparagraph (C)(i)(III), notwithstanding that the tax provides for exclusion (in whole or in part) of revenues or receipts from a State plan under this title or title XVIII.

(E)(i) A State may submit an application to the Secretary requesting that the Secretary treat a tax as a broad-based health care related tax, notwithstanding that the tax does not apply to all health care items or services in class (or all providers of such items and services), provides for a credit, deduction, or exclusion, is not applied uniformly, or otherwise does not meet the requirements of subparagraph (B) or (C). Permissible waivers may include exemptions for rural or sole-community providers.

(ii) The Secretary shall approve such an application if the State establishes to the satisfaction of the Secretary that—

(I) the net impact of the tax and associated expenditures under this title as proposed by the State is generally redistributive in nature, and

(II) the amount of the tax is not directly correlated to payments under this title for items or services with respect to which the tax is imposed.

The Secretary shall by regulation specify types of credits, exclusions, and deductions that will be considered to meet the requirements of this subparagraph.

(F) In no case shall a tax not qualify as a broad-based health care related tax under this paragraph because it does not apply to a hospital that is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a) of such Code and that does not accept payment under the State plan under this title or under title XVIII.

(4) For purposes of paragraph (1)(A)(iii), there is in effect a hold harmless provision with respect to a broad-based health care related tax imposed with respect to a class of items or services if the Secretary determines that any of the following applies:

(A) The State or other unit of government imposing the tax provides (directly or indirectly) for a payment (other than under this title) to taxpayers and the amount of such payment is positively correlated either to the amount of such tax or to the difference between the amount of the tax and the amount of payment under the State plan.

(B) All or any portion of the payment made under this title to the taxpayer varies based only upon the amount of the total tax paid.

(C)(i) The State or other unit of government imposing the tax provides (directly or indirectly) for any payment, offset, or waiver that guarantees to hold taxpayers harmless for any portion of the costs of the tax.

(ii) For purposes of clause (i), a determination of the existence of an indirect guarantee shall be made under paragraph (3)(i) of section 433.68(f) of title 42, Code of Federal Regulations, as in effect on November 1, 2006, except that for portions of fiscal years beginning on or after January 1, 2008, and before October 1, 2011, "5.5 percent" shall be substituted for "6 percent" each place it appears.

The provisions of this paragraph shall not prevent use of the tax to reimburse health care providers in a class for expenditures under this title nor preclude States from relying on such reimbursement to justify or explain the tax in the legislative process.

(5)(A) For purposes of this subsection, the limit under this subparagraph with respect to a State is an amount equal to 25 percent (or, if greater, the State base percentage, as defined in subparagraph (B)) of the non-Federal share of the total amount expended under the State plan during a State fiscal year (or portion thereof), as it would be determined pursuant to paragraph (1)(A) without regard to paragraph (1)(A)(iv).

(B)(i) In subparagraph (A), the term "State base percentage" means, with respect to a State, an amount (expressed as a percentage) equal to—

(I) the total of the amount of health care related taxes (whether or not broad-based) and the amount of provider-related donations (whether or not bona fide) projected to be collected (in accordance with clause (ii)) during State fiscal year 1992, divided by

(II) the non-Federal share of the total amount estimated to be expended under the State plan during such State fiscal year.

(ii) For purposes of clause (i)(I), in the case of a tax that is not in effect throughout State fiscal year 1992 or the rate (or base) of which is increased during such fiscal year, the Secretary shall

project the amount to be collected during such fiscal year as if the tax (or increase) were in effect during the entire State fiscal year.

(C)(i) The total amount of health care related taxes under subparagraph (B)(i)(I) shall be determined by the Secretary based on only those taxes (including the tax rate or base) which were in effect, or for which legislation or regulations imposing such taxes were enacted or adopted, as of November 22, 1991.

(ii) The amount of provider-related donations under subparagraph (B)(i)(I) shall be determined by the Secretary based on programs in effect on September 30, 1991, and applicable to State fiscal year 1992, as demonstrated by State plan amendments, written agreements, State budget documentation, or other documentary evidence in existence on that date.

(iii) The amount of expenditures described in subparagraph (B)(i)(II) shall be determined by the Secretary based on the best data available as of the date of the enactment of this subsection.

(6)(A) Notwithstanding the provisions of this subsection, the Secretary may not restrict States' use of funds where such funds are derived from State or local taxes (or funds appropriated to State university teaching hospitals) transferred from or certified by units of government within a State as the non-Federal share of expenditures under this title, regardless of whether the unit of government is also a health care provider, except as provided in section 1902(a)(2), unless the transferred funds are derived by the unit of government from donations or taxes that would not otherwise be recognized as the non-Federal share under this section.

(B) For purposes of this subsection, funds the use of which the Secretary may not restrict under subparagraph (A) shall not be considered to be a provider-related donation or a health care related tax.

(7) For purposes of this subsection:

(A) Each of the following shall be considered a separate class of health care items and services:

(i) Inpatient hospital services.

(ii) Outpatient hospital services.

(iii) Nursing facility services (other than services of intermediate care facilities for the mentally retarded).

(iv) Services of intermediate care facilities for the mentally retarded.

(v) Physicians' services.

(vi) Home health care services.

(vii) Outpatient prescription drugs.

(viii) Services of managed care organizations (including health maintenance organizations, preferred provider organizations, and such other similar organizations as the Secretary may specify by regulation).

(ix) Such other classification of health care items and services consistent with this subparagraph as the Secretary may establish by regulation.

(B) The term "health care provider" means an individual or person that receives payments for the provision of health care items or services.

(C) An entity is considered to be "related" to a health care provider if the entity—

(i) is an organization, association, corporation or partnership formed by or on behalf of health care providers;

(ii) is a person with an ownership or control interest (as defined in section 1124(a)(3)) in the provider;

(iii) is the employee, spouse, parent, child, or sibling of the provider (or of a person described in clause (ii)); or

(iv) has a similar, close relationship (as defined in regulations) to the provider.

(D) The term "State" means only the 50 States and the District of Columbia but does not include any State whose entire program under this title is operated under a waiver granted under section 1115.

(E) The "State fiscal year" means, with respect to a specified year, a State fiscal year ending in that specified year.

(F) The term "tax" includes any licensing fee, assessment, or other mandatory payment, but does not include payment of a criminal or civil fine or penalty (other than a fine or penalty imposed in lieu of or instead of a fee, assessment, or other mandatory payment).

(G) The term "unit of local government" means, with respect to a State, a city, county, special purpose district, or other governmental unit in the State.

(x)(1) For purposes of section 1902(a)(46)(B)(i), the requirement of this subsection is, with respect to an individual declaring to be a citizen or national of the United States, that, subject to paragraph (2), there is presented satisfactory documentary evidence of citizenship or nationality (as defined in paragraph (3)) of the individual.

(2) The requirement of paragraph (1) shall not apply to an individual declaring to be a citizen or national of the United States who is eligible for medical assistance under this title—

(A) and is entitled to or enrolled for benefits under any part of title XVIII;

(B) and is receiving—

(i) disability insurance benefits under section 223 or monthly insurance benefits under section 202 based on such individual's disability (as defined in section 223(d)); or

(ii) supplemental security income benefits under title XVI;

(C) and with respect to whom—

(i) child welfare services are made available under part B of title IV on the basis of being a child in foster care; or

(ii) adoption or foster care assistance is made available under part E of title IV;

(D) pursuant to the application of section 1902(e)(4) (and, in the case of an individual who is eligible for medical assistance on such basis, the individual shall be deemed to have provided satisfactory documentary evidence of citizenship or nationality and shall not be required to provide further documentary evidence on any date that occurs during or after the period in which the individual is eligible for medical assistance on such basis); or

(E) on such basis as the Secretary may specify under which satisfactory documentary evidence of citizenship or nationality has been previously presented.

(3)(A) For purposes of this subsection, the term "satisfactory documentary evidence of citizenship or nationality" means—

(i) any document described in subparagraph (B); or

(ii) a document described in subparagraph (C) and a document described in subparagraph (D).

(B) The following are documents described in this subparagraph:

(i) A United States passport.

(ii) Form N–550 or N–570 (Certificate of Naturalization).

(iii) Form N–560 or N–561 (Certificate of United States Citizenship).

(iv) A valid State-issued driver's license or other identity document described in section 274A(b)(1)(D) of the Immigration and Nationality Act, but only if the State issuing the license or such document requires proof of United States citizenship before issuance of such license or document or obtains a social security number from the applicant and verifies before certification that such number is valid and assigned to the applicant who is a citizen.

(v)(I) Except as provided in subclause (II), a document issued by a federally recognized Indian tribe evidencing membership or enrollment in, or affiliation with, such tribe (such as a tribal enrollment card or certificate of degree of Indian blood).

(II) With respect to those federally recognized Indian tribes located within States having an international border whose membership includes individuals who are not citizens of the United States, the Secretary shall, after consulting with such tribes, issue regulations authorizing the presentation of such other forms of documentation (including tribal documentation, if appropriate) that the Secretary determines to be satisfactory documentary evidence of citizenship or nationality for purposes of satisfying the requirement of this subsection.

(vi) Such other document as the Secretary may specify, by regulation, that provides proof of United States citizenship or nationality and that provides a reliable means of documentation of personal identity.

(C) The following are documents described in this subparagraph:

(i) A certificate of birth in the United States.

(ii) Form FS–545 or Form DS–1350 (Certification of Birth Abroad).

(iii) Form I–197 (United States Citizen Identification Card).

(iv) Form FS–240 (Report of Birth Abroad of a Citizen of the United States).

(v) Such other document (not described in subparagraph (B)(iv)) as the Secretary may specify that provides proof of United States citizenship or nationality.

(D) The following are documents described in this subparagraph:

(i) Any identity document described in section 274A(b)(1)(D) of the Immigration and Nationality Act.

(ii) Any other documentation of personal identity of such other type as the Secretary finds, by regulation, provides a reliable means of identification.

(E) A reference in this paragraph to a form includes a reference to any successor form.

(4) In the case of an individual declaring to be a citizen or national of the United States with respect to whom a State requires the presentation of satisfactory documentary evidence of citizenship or nationality under section 1902(a)(46)(B)(i), the individual shall be provided at least the reasonable opportunity to present satisfactory documentary evidence of citizenship or nationality under this subsection as is provided under clauses (i) and (ii) of section 1137(d)(4)(A) to an individual for the submittal to the State of evidence indicating a satisfactory immigration status.

(5) Nothing in subparagraph (A) or (B) of section 1902(a)(46), the preceding paragraphs of this subsection, or the Deficit Reduction Act of 2005, including section 6036 of such Act, shall be construed as changing the requirement of section 1902(e)(4) that a child born in the United States to an alien mother for whom medical assistance for the delivery of such child is available as treatment of an emergency medical condition pursuant to subsection (v) shall be deemed eligible for medical assistance during the first year of such child's life.

(y) PAYMENTS FOR ESTABLISHMENT OF ALTERNATE NON-EMERGENCY SERVICES PROVIDERS.—

(1) PAYMENTS.—In addition to the payments otherwise provided under subsection (a), subject to paragraph (2), the Secretary shall provide for payments to States under such subsection for the establishment of alternate non-emergency service providers (as defined in section 1916A(e)(5)(B)), or networks of such providers.

(2) LIMITATION.—The total amount of payments under this subsection shall not exceed $50,000,000 during the 4-year period beginning with 2006. This subsection constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this subsection.

(3) PREFERENCE.—In providing for payments to States under this subsection, the Secretary shall provide preference to States that establish, or provide for, alternate non-emergency services providers or networks of such providers that—

(A) serve rural or underserved areas where beneficiaries under this title may not have regular access to providers of primary care services; or

(B) are in partnership with local community hospitals.

(4) FORM AND MANNER OF PAYMENT.—Payment to a State under this subsection shall be made only upon the filing of such application in such form and in such manner as the Secretary shall specify. Payment to a State under this subsection shall be made in the same manner as other payments under section 1903(a).

(z) MEDICAID TRANSFORMATION PAYMENTS.—

(1) IN GENERAL.—In addition to the payments provided under subsection (a), subject to paragraph (4), the Secretary shall provide for payments to States for the adoption of innovative methods to improve the effectiveness and efficiency in providing medical assistance under this title.

(2) PERMISSIBLE USES OF FUNDS.—The following are examples of innovative methods for which funds provided under this subsection may be used:

(A) Methods for reducing patient error rates through the implementation and use of electronic health records, electronic clinical decision support tools, or e-prescribing programs.

(B) Methods for improving rates of collection from estates of amounts owed under this title.

(C) Methods for reducing waste, fraud, and abuse under the program under this title, such as reducing improper payment rates as measured by annual payment error rate measurement (PERM) project rates.

(D) Implementation of a medication risk management program as part of a drug use review program under section 1927(g).

(E) Methods in reducing, in clinically appropriate ways, expenditures under this title for covered outpatient drugs, particularly in the categories of greatest drug utilization, by increasing the utilization of generic drugs through the use of education programs and other incentives to promote greater use of generic drugs.

(F) Methods for improving access to primary and specialty physician care for the uninsured using integrated university-based hospital and clinic systems.

(3) APPLICATION; TERMS AND CONDITIONS.—

(A) IN GENERAL.—No payments shall be made to a State under this subsection unless the State applies to the Secretary for such payments in a form, manner, and time specified by the Secretary.

(B) TERMS AND CONDITIONS.—Such payments are made under such terms and conditions consistent with this subsection as the Secretary prescribes.

(C) ANNUAL REPORT.—Payment to a State under this subsection is conditioned on the State submitting to the Secretary an annual report on the programs supported by such payment. Such report shall include information on—

(i) the specific uses of such payment;

(ii) an assessment of quality improvements and clinical outcomes under such programs; and

(iii) estimates of cost savings resulting from such programs.

(4) FUNDING.—

(A) LIMITATION ON FUNDS.—The total amount of payments under this subsection shall be equal to, and shall not exceed—

(i) $75,000,000 for fiscal year 2007; and

(ii) $75,000,000 for fiscal year 2008.

This subsection constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this subsection.

(B) ALLOCATION OF FUNDS.—The Secretary shall specify a method for allocating the funds made available under this subsection among States. Such method shall provide

preference for States that design programs that target health providers that treat significant numbers of Medicaid beneficiaries. Such method shall provide that not less than 25 percent of such funds shall be allocated among States the population of which (as determined according to data collected by the United States Census Bureau) as of July 1, 2004, was more than 105 percent of the population of the respective State (as so determined) as of April 1, 2000.

(C) FORM AND MANNER OF PAYMENT.—Payment to a State under this subsection shall be made in the same manner as other payments under section 1903(a). There is no requirement for State matching funds to receive payments under this subsection.

(5) MEDICATION RISK MANAGEMENT PROGRAM.—

(A) IN GENERAL.—For purposes of this subsection, the term "medication risk management program" means a program for targeted beneficiaries that ensures that covered outpatient drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events.

(B) ELEMENTS.—Such program may include the following elements:

(i) The use of established principles and standards for drug utilization review and best practices to analyze prescription drug claims of targeted beneficiaries and identify outlier physicians.

(ii) On an ongoing basis provide outlier physicians—

(I) a comprehensive pharmacy claims history for each targeted beneficiary under their care;

(II) information regarding the frequency and cost of relapses and hospitalizations of targeted beneficiaries under the physician's care; and

(III) applicable best practice guidelines and empirical references.

(iii) Monitor outlier physician's prescribing, such as failure to refill, dosage strengths, and provide incentives and information to encourage the adoption of best clinical practices.

(C) TARGETED BENEFICIARIES.—For purposes of this paragraph, the term "targeted beneficiaries" means Medicaid eligible beneficiaries who are identified as having high prescription drug costs and medical costs, such as individuals with behavioral disorders or multiple chronic diseases who are taking multiple medications.

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PAYMENT FOR COVERED OUTPATIENT DRUGS

SEC. 1927. (a) REQUIREMENT FOR REBATE AGREEMENT.—

(1) IN GENERAL.—In order for payment to be available under section 1903(a) or under part B of title XVIII for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except

that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of title VI of the Veterans Health Care Act of 1992) and paragraph (6). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter on or before the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(2) EFFECTIVE DATE.—Paragraph (1) shall first apply to drugs dispensed under this title on or after January 1, 1991.

(3) AUTHORIZING PAYMENT FOR DRUGS NOT COVERED UNDER REBATE AGREEMENTS.—Paragraph (1), and section 1903(i)(10)(A), shall not apply to the dispensing of a single source drug or innovator multiple source drug if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1-A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d), or (II) the Secretary has reviewed and approved the State's determination under subparagraph (A); or (B) the Secretary determines that in the first calendar quarter of 1991, there were extenuating circumstances.

(4) EFFECT ON EXISTING AGREEMENTS.—In the case of a rebate agreement in effect between a State and a manufacturer on the date of the enactment of this section, such agreement, for the initial agreement period specified therein, shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State agrees to report to the Secretary any rebates paid pursuant to the agreement and such agreement provides for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs under this title. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement in effect on the date of the enactment of this section provides for rebates that are at least as large as the rebates otherwise required under this section, and the State agrees to report any rebates under the agreement to the Secretary, the agreement shall be considered to be a rebate agreement in compliance with the section for the renewal periods of such agreement.

(5) LIMITATION ON PRICES OF DRUGS PURCHASED BY COVERED ENTITIES.—

(A) AGREEMENT WITH SECRETARY.—A manufacturer meets the requirements of this paragraph if the manufacturer has entered into an agreement with the Secretary that meets the requirements of section 340B of the Public Health Service Act with respect to covered outpatient drugs purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of this paragraph.

(B) COVERED ENTITY DEFINED.—In this subsection, the term "covered entity" means an entity described in section 340B(a)(4) of the Public Health Service Act.

(C) ESTABLISHMENT OF ALTERNATIVE MECHANISM TO ENSURE AGAINST DUPLICATE DISCOUNTS OR REBATES.—If the Secretary does not establish a mechanism under section 340B(a)(5)(A) of the Public Health Service Act within 12 months of the date of the enactment of such section, the following requirements shall apply:

(i) ENTITIES.—Each covered entity shall inform the single State agency under section 1902(a)(5) when it is seeking reimbursement from the State plan for medical assistance described in section 1905(a)(12) with respect to a unit of any covered outpatient drug which is subject to an agreement under section 340B(a) of such Act.

(ii) STATE AGENCY.—Each such single State agency shall provide a means by which a covered entity shall indicate on any drug reimbursement claims form (or format, where electronic claims management is used) that a unit of the drug that is the subject of the form is subject to an agreement under section 340B of such Act, and not submit to any manufacturer a claim for a rebate payment under subsection (b) with respect to such a drug.

(D) EFFECT OF SUBSEQUENT AMENDMENTS.—In determining whether an agreement under subparagraph (A) meets the requirements of section 340B of the Public Health Service Act, the Secretary shall not take into account any amendments to such section that are enacted after the enactment of title VI of the Veterans Health Care Act of 1992.

(E) DETERMINATION OF COMPLIANCE.—A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 340B of the Public Health Service Act (as in effect immediately after the enactment of this paragraph, and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after the date of the enactment of this paragraph.

(6) REQUIREMENTS RELATING TO MASTER AGREEMENTS FOR DRUGS PROCURED BY DEPARTMENT OF VETERANS AFFAIRS AND CERTAIN OTHER FEDERAL AGENCIES.—

(A) IN GENERAL.—A manufacturer meets the requirements of this paragraph if the manufacturer com-

plies with the provisions of section 8126 of title 38, United States Code, including the requirement of entering into a master agreement with the Secretary of Veterans Affairs under such section.

(B) EFFECT OF SUBSEQUENT AMENDMENTS.—In determining whether a master agreement described in subparagraph (A) meets the requirements of section 8126 of title 38, United States Code, the Secretary shall not take into account any amendments to such section that are enacted after the enactment of title VI of the Veterans Health Care Act of 1992.

(C) DETERMINATION OF COMPLIANCE.—A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 8126 of title 38, United States Code (as in effect immediately after the enactment of this paragraph) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after the date of the enactment of this paragraph.

(7) REQUIREMENT FOR SUBMISSION OF UTILIZATION DATA FOR CERTAIN PHYSICIAN ADMINISTERED DRUGS.—

(A) SINGLE SOURCE DRUGS.—In order for payment to be available under section 1903(a) for a covered outpatient drug that is a single source drug that is physician administered under this title (as determined by the Secretary), and that is administered on or after January 1, 2006, the State shall provide for the collection and submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section for drugs administered for which payment is made under this title.

(B) MULTIPLE SOURCE DRUGS.—

(i) IDENTIFICATION OF MOST FREQUENTLY PHYSICIAN ADMINISTERED MULTIPLE SOURCE DRUGS.—Not later than January 1, 2007, the Secretary shall publish a list of the 20 physician administered multiple source drugs that the Secretary determines have the highest dollar volume of physician administered drugs dispensed under this title. The Secretary may modify such list from year to year to reflect changes in such volume.

(ii) REQUIREMENT.—In order for payment to be available under section 1903(a) for a covered outpatient drug that is a multiple source drug that is physician administered (as determined by the Secretary), that is on the list published under clause (i), and that is administered on or after January 1, 2008, the State shall provide for the submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Sec-

retary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section.

(C) USE OF NDC CODES.—Not later than January 1, 2007, the information shall be submitted under subparagraphs (A) and (B)(ii) using National Drug Code codes unless the Secretary specifies that an alternative coding system should be used.

(D) HARDSHIP WAIVER.—The Secretary may delay the application of subparagraph (A) or (B)(ii), or both, in the case of a State to prevent hardship to States which require additional time to implement the reporting system required under the respective subparagraph.

(b) TERMS OF REBATE AGREEMENT.—

(1) PERIODIC REBATES.—

(A) IN GENERAL.—A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this title, a rebate for a rebate period in an amount specified in subsection (c) for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period, including such drugs dispensed to individuals enrolled with a medicaid managed care organization if the organization is responsible for coverage of such drugs. Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

(B) OFFSET AGAINST MEDICAL ASSISTANCE.—Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) or an agreement described in subsection (a)(4)) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1903(a)(1).

(C) SPECIAL RULE FOR INCREASED MINIMUM REBATE PERCENTAGE.—

(i) IN GENERAL.—In addition to the amounts applied as a reduction under subparagraph (B), for rebate periods beginning on or after January 1, 2010, during a fiscal year, the Secretary shall reduce payments to a State under section 1903(a) in the manner specified in clause (ii), in an amount equal to the product of—

(I) 100 percent minus the Federal medical assistance percentage applicable to the rebate period for the State; and

(II) the amounts received by the State under such subparagraph that are attributable (as estimated by the Secretary based on utilization and other data) to the increase in the minimum rebate percentage effected by the amendments made by subsections (a)(1), (b), and (d) of section 2501 of the Patient Protection and Affordable Care Act, taking into account the additional drugs included under the amendments made by subsection (c) of section 2501 of such Act.

The Secretary shall adjust such payment reduction for a calendar quarter to the extent the Secretary determines, based upon subsequent utilization and other data, that the reduction for such quarter was greater or less than the amount of payment reduction that should have been made.

(ii) MANNER OF PAYMENT REDUCTION.—The amount of the payment reduction under clause (i) for a State for a quarter shall be deemed an overpayment to the State under this title to be disallowed against the State's regular quarterly draw for all Medicaid spending under section 1903(d)(2). Such a disallowance is not subject to a reconsideration under section 1116(d).

(2) STATE PROVISION OF INFORMATION.—

(A) STATE RESPONSIBILITY.—Each State agency under this title shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, including such information reported by each medicaid managed care organization, and shall promptly transmit a copy of such report to the Secretary.

(B) AUDITS.—A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

(3) MANUFACTURER PROVISION OF PRICE INFORMATION.—

(A) IN GENERAL.—Each manufacturer with an agreement in effect under this section shall report to the Secretary—

(i) not later than 30 days after the last day of each rebate period under the agreement—

(I) on the average manufacturer price (as defined in subsection (k)(1)) for covered outpatient drugs for the rebate period under the agreement (including for all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act); and

(II) for single source drugs and innovator multiple source drugs (including all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), on the manufacturer's best price (as defined in subsection (c)(1)(C)) for such drugs for the rebate period under the agreement;

(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1)) as of October 1, 1990 for each of the manufacturer's covered outpatient drugs (including for such drugs that are sold under a new drug application approved under

section 505(c) of the Federal Food, Drug, and Cosmetic Act); and

(iii) for calendar quarters beginning on or after January 1, 2004, in conjunction with reporting required under clause (i) and by National Drug Code (including package size)—

(I) the manufacturer's average sales price (as defined in section 1847A(c)) and the total number of units specified under section 1847A(b)(2)(A);

(II) if required to make payment under section 1847A, *or under section 1886(d) pursuant to paragraph (5)(M) of such section,* the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and

(III) information on those sales that were made at a nominal price or otherwise described in section 1847A(c)(2)(B);

for a drug or biological described in subparagraph (C), (D), (E), or (G) of section 1842(o)(1) or section 1881(b)(13)(A)(ii) *or section 1886(d)(5)(M)*, and, for calendar quarters beginning on or after January 1, 2007 and only with respect to the information described in subclause (III), for covered outpatient drugs.

(iv) not later than 30 days after the last day of each month of a rebate period under the agreement, on the manufacturer's total number of units that are used to calculate the monthly average manufacturer price for each covered outpatient drug;

Information reported under this subparagraph is subject to audit by the Inspector General of the Department of Health and Human Services. Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States under subparagraph (D)(iv) the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website under subparagraph (D)(v) (relating to the weighted average of the most recently reported monthly average manufacturer prices).

(B) VERIFICATION SURVEYS OF AVERAGE MANUFACTURER PRICE AND MANUFACTURER'S AVERAGE SALES PRICE.—The Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments)

and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(C) PENALTIES.—

(i) FAILURE TO PROVIDE TIMELY INFORMATION.—In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) on a timely basis, the amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of such 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).

(ii) FALSE INFORMATION.—Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(D) CONFIDENTIALITY OF INFORMATION.—Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) (other than the wholesale acquisition cost for purposes of carrying out section 1847A) is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except—

(i) as the Secretary determines to be necessary to carry out this section, to carry out section 1847A (including the determination and implementation of the payment amount), or to carry out section 1847B,

(ii) to permit the Comptroller General to review the information provided,

(iii) to permit the Director of the Congressional Budget Office to review the information provided,

(iv) to States to carry out this title, and

(v) to the Secretary to disclose (through a website accessible to the public) the weighted average of the most recently reported monthly average manufacturer prices and the average retail survey price determined for each multiple source drug in accordance with subsection (f).

The previous sentence shall also apply to information disclosed under section 1860D–2(d)(2) or 1860D–4(c)(2)(E) and drug pricing data reported under the first sentence of section 1860D–31(i)(1).

(4) LENGTH OF AGREEMENT.—

(A) IN GENERAL.—A rebate agreement shall be effective for an initial period of not less than 1 year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

(B) TERMINATION.—

(i) BY THE SECRETARY.—The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(ii) BY A MANUFACTURER.—A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until the calendar quarter beginning at least 60 days after the date the manufacturer provides notice to the Secretary.

(iii) EFFECTIVENESS OF TERMINATION.—Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

(iv) NOTICE TO STATES.—In the case of a termination under this subparagraph, the Secretary shall provide notice of such termination to the States within not less than 30 days before the effective date of such termination.

(v) APPLICATION TO TERMINATIONS OF OTHER AGREEMENTS.—The provisions of this subparagraph shall apply to the terminations of agreements described in section 340B(a)(1) of the Public Health Service Act and master agreements described in section 8126(a) of title 38, United States Code.

(C) DELAY BEFORE REENTRY.—In the case of any rebate agreement with a manufacturer under this section which is terminated, another such agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed since the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

(c) DETERMINATION OF AMOUNT OF REBATE.—

(1) BASIC REBATE FOR SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS.—

(A) IN GENERAL.—Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8)) with respect to each dosage form and strength of a single source drug

or an innovator multiple source drug shall be equal to the product of—

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of—

(I) the difference between the average manufacturer price and the best price (as defined in subparagraph (C)) for the dosage form and strength of the drug, or

(II) the minimum rebate percentage (specified in subparagraph (B)(i)) of such average manufacturer price,

of or the rebate period.

(B) RANGE OF REBATES REQUIRED.—

(i) MINIMUM REBATE PERCENTAGE.—For purposes of subparagraph (A)(ii)(II), the "minimum rebate percentage" for rebate periods beginning—

(I) after December 31, 1990, and before October 1, 1992, is 12.5 percent;

(II) after September 30, 1992, and before January 1, 1994, is 15.7 percent;

(III) after December 31, 1993, and before January 1, 1995, is 15.4 percent;

(IV) after December 31, 1994, and before January 1, 1996, is 15.2 percent;

(V) after December 31, 1995, and before January 1, 2010 is 15.1 percent;and

(VI) except as provided in clause (iii), after December 31, 2009, 23.1 percent.

(ii) TEMPORARY LIMITATION ON MAXIMUM REBATE AMOUNT.—In no case shall the amount applied under subparagraph (A)(ii) for a rebate period beginning—

(I) before January 1, 1992, exceed 25 percent of the average manufacturer price; or

(II) after December 31, 1991, and before January 1, 1993, exceed 50 percent of the average manufacturer price.

(iii) MINIMUM REBATE PERCENTAGE FOR CERTAIN DRUGS.—

(I) IN GENERAL.—In the case of a single source drug or an innovator multiple source drug described in subclause (II), the minimum rebate percentage for rebate periods specified in clause (i)(VI) is 17.1 percent.

(II) DRUG DESCRIBED.—For purposes of subclause (I), a single source drug or an innovator multiple source drug described in this subclause is any of the following drugs:

(aa) A clotting factor for which a separate furnishing payment is made under section 1842(o)(5) and which is included on a list of such factors specified and updated regularly by the Secretary.

(bb) A drug approved by the Food and Drug Administration exclusively for pediatric indications.

(C) BEST PRICE DEFINED.—For purposes of this section—

(i) IN GENERAL.—The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding—

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, United States Code, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the Public Health Service Act);

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State pharmaceutical assistance program;

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(V) the prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under section 1860D–31; and

(VI) any prices charged which are negotiated by a prescription drug plan under part D of title XVIII, by an MA–PD plan under part C of such title with respect to covered part D drugs or by a qualified retiree prescription drug plan (as defined in section 1860D–22(a)(2)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D–14A.

(ii) SPECIAL RULES.—The term "best price"—

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package;

(III) shall not take into account prices that are merely nominal in amount; and

(IV) in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding those prices described in subclauses (I) through (IV) of clause (i).

(iii) APPLICATION OF AUDITING AND RECORDKEEPING REQUIREMENTS.—With respect to a covered entity described in section 340B(a)(4)(L) of the Public Health Service Act, any drug purchased for inpatient use shall be subject to the auditing and recordkeeping requirements described in section 340B(a)(5)(C) of the Public Health Service Act.

(D) LIMITATION ON SALES AT A NOMINAL PRICE.—

(i) IN GENERAL.—For purposes of subparagraph (C)(ii)(III) and subsection (b)(3)(A)(iii)(III), only sales by a manufacturer of covered outpatient drugs at nominal prices to the following shall be considered to be sales at a nominal price or merely nominal in amount:

(I) A covered entity described in section 340B(a)(4) of the Public Health Service Act.

(II) An intermediate care facility for the mentally retarded.

(III) A State-owned or operated nursing facility.

(IV) An entity that—

(aa) is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Act or is State-owned or operated; and

(bb) would be a covered entity described in section 340(B)(a)(4) of the Public Health Service Act insofar as the entity provides the same type of services to the same type of populations as a covered entity described in such section provides, but does not receive funding under a provision of law referred to in such section;

(V) A public or nonprofit entity, or an entity based at an institution of higher learning whose primary purpose is to provide health care services to students of that institution, that provides a service or services described under section 1001(a) of the Public Health Service Act, 42 U.S.C. 300.

(VI) Any other facility or entity that the Secretary determines is a safety net provider to which sales of such drugs at a nominal price

would be appropriate based on the factors described in clause (ii).

(ii) FACTORS.—The factors described in this clause with respect to a facility or entity are the following:

(I) The type of facility or entity.

(II) The services provided by the facility or entity.

(III) The patient population served by the facility or entity.

(IV) The number of other facilities or entities eligible to purchase at nominal prices in the same service area.

(iii) NONAPPLICATION.—Clause (i) shall not apply with respect to sales by a manufacturer at a nominal price of covered outpatient drugs pursuant to a master agreement under section 8126 of title 38, United States Code.

(iv) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed to alter any existing statutory or regulatory prohibition on services with respect to an entity described in clause (i)(IV), including the prohibition set forth in section 1008 of the Public Health Service Act.

(2) ADDITIONAL REBATE FOR SINGLE SOURCE AND INNOVATOR MULTIPLE SOURCE DRUGS.—

(A) IN GENERAL.—The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of—

(i) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period; and

(ii) the amount (if any) by which—

(I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds

(II) the average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

(B) TREATMENT OF SUBSEQUENTLY APPROVED DRUGS.—In the case of a covered outpatient drug approved by the Food and Drug Administration after October 1, 1990, clause (ii)(II) of subparagraph (A) shall be applied by substituting "the first full calendar quarter after the day on which the drug was first marketed" for "the calendar quarter begin-

ning July 1, 1990" and "the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed" for "September 1990".

(C) TREATMENT OF NEW FORMULATIONS.—In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation with respect to such drug under this section shall be the amount computed under this section for such new drug or, if greater, the product of—

(i) the average manufacturer price of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form;

(ii) the highest additional rebate (calculated as a percentage of average manufacturer price) under this section for any strength of the original single source drug or innovator multiple source drug; and

(iii) the total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

In this subparagraph, the term "line extension" means, with respect to a drug, a new formulation of the drug, such as an extended release formulation.

(D) MAXIMUM REBATE AMOUNT.—In no case shall the sum of the amounts applied under paragraph (1)(A)(ii) and this paragraph with respect to each dosage form and strength of a single source drug or an innovator multiple source drug for a rebate period beginning after December 31, 2009, exceed 100 percent of the average manufacturer price of the drug.

(3) REBATE FOR OTHER DRUGS.—

(A) IN GENERAL.—The amount of the rebate paid to a State for a rebate period with respect to each dosage form and strength of covered outpatient drugs (other than single source drugs and innovator multiple source drugs) shall be equal to the product of—

(i) the applicable percentage (as described in subparagraph (B)) of the average manufacturer price for the dosage form and strength for the rebate period, and

(ii) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period.

(B) APPLICABLE PERCENTAGE DEFINED.—For purposes of subparagraph (A)(i), the "applicable percentage" for rebate periods beginning—

(i) before January 1, 1994, is 10 percent,

(ii) after December 31, 1993, and before January 1, 2010, is 11 percent; and

(iii) after December 31, 2009, is 13 percent.

(d) LIMITATIONS ON COVERAGE OF DRUGS.—

(1) PERMISSIBLE RESTRICTIONS.—(A) A State may subject to prior authorization any covered outpatient drug. Any such

prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if—

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6));

(ii) the drug is contained in the list referred to in paragraph (2);

(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4); or

(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

(2) LIST OF DRUGS SUBJECT TO RESTRICTION.—The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(F) Nonprescription drugs, except, in the case of pregnant women when recommended in accordance with the Guideline referred to in section 1905(bb)(2)(A), agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

(G) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(H) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

(3) UPDATE OF DRUG LISTINGS.—The Secretary shall, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

(4) REQUIREMENTS FOR FORMULARIES.—A State may establish a formulary if the formulary meets the following requirements:

(A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at

the option of the State, the State's drug use review board established under subsection (g)(3)).

(B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6)), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) REQUIREMENTS OF PRIOR AUTHORIZATION PROGRAMS.—A State plan under this title may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) only if the system providing for such approval—

(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(6) OTHER PERMISSIBLE RESTRICTIONS.—A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this Act.

(7) NON-EXCLUDABLE DRUGS.—The following drugs or classes of drugs, or their medical uses, shall not be excluded from coverage:

(A) Agents when used to promote smoking cessation, including agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

(B) Barbiturates.

(C) Benzodiazepines.

(e) TREATMENT OF PHARMACY REIMBURSEMENT LIMITS.—

(1) IN GENERAL.—During the period beginning on January 1, 1991, and ending on December 31, 1994—

(A) a State may not reduce the payment limits established by regulation under this title or any limitation described in paragraph (3) with respect to the ingredient cost of a covered outpatient drug or the dispensing fee for such a drug below the limits in effect as of January 1, 1991, and

(B) except as provided in paragraph (2), the Secretary may not modify by regulation the formula established under sections 447.331 through 447.334 of title 42, Code of Federal Regulations, in effect on November 5, 1990, to reduce the limits described in subparagraph (A).

(2) SPECIAL RULE.—If a State is not in compliance with the regulations described in paragraph (1)(B), paragraph (1)(A) shall not apply to such State until such State is in compliance with such regulations.

(3) EFFECT ON STATE MAXIMUM ALLOWABLE COST LIMITATIONS.—This section shall not supersede or affect provisions in effect prior to January 1, 1991, or after December 31, 1994, relating to any maximum allowable cost limitation established by a State for payment by the State for covered outpatient drugs, and rebates shall be made under this section without regard to whether or not payment by the State for such drugs is subject to such a limitation or the amount of such a limitation.

(4) ESTABLISHMENT OF UPPER PAYMENT LIMITS.—Subject to paragraph (5), the Secretary shall establish a Federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such and shall use only such formulations when determining any such upper limit.

(5) USE OF AMP IN UPPER PAYMENT LIMITS.—The Secretary shall calculate the Federal upper reimbursement limit established under paragraph (4) as no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly average manufacturer prices for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. The Secretary shall implement a smoothing process for average manufacturer prices. Such process shall be similar to the smoothing process used in determining the average sales price of a drug or biological under section 1847A.

(f) SURVEY OF RETAIL PRICES; STATE PAYMENT AND UTILIZATION RATES; AND PERFORMANCE RANKINGS.—

(1) SURVEY OF RETAIL PRICES.—

(A) USE OF VENDOR.—The Secretary may contract services for—

(i) with respect to a retail community pharmacy, the determination on a monthly basis of retail survey prices for covered outpatient drugs that represent a nationwide average of consumer purchase prices for such drugs, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available); and

(ii) the notification of the Secretary when a drug product that is therapeutically and pharmaceutically equivalent and bioequivalent becomes generally available.

(B) SECRETARY RESPONSE TO NOTIFICATION OF AVAILABILITY OF MULTIPLE SOURCE PRODUCTS.—If contractor notifies the Secretary under subparagraph (A)(ii) that a drug product described in such subparagraph has become generally available, the Secretary shall make a determination, within 7 days after receiving such notification, as to whether the product is now described in subsection (e)(4).

(C) USE OF COMPETITIVE BIDDING.—In contracting for such services, the Secretary shall competitively bid for an outside vendor that has a demonstrated history in—

(i) surveying and determining, on a representative nationwide basis, retail prices for ingredient costs of prescription drugs;

(ii) working with retail community pharmacies, commercial payers, and States in obtaining and disseminating such price information; and

(iii) collecting and reporting such price information on at least a monthly basis.

In contracting for such services, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this subsection, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(D) ADDITIONAL PROVISIONS.—A contract with a vendor under this paragraph shall include such terms and conditions as the Secretary shall specify, including the following:

(i) The vendor must monitor the marketplace and report to the Secretary each time there is a new covered outpatient drug generally available.

(ii) The vendor must update the Secretary no less often than monthly on the retail survey prices for covered outpatient drugs.

(iii) The contract shall be effective for a term of 2 years.

(E) AVAILABILITY OF INFORMATION TO STATES.—Information on retail survey prices obtained under this paragraph, including applicable information on single source drugs,

shall be provided to States on at least a monthly basis. The Secretary shall devise and implement a means for providing access to each State agency designated under section 1902(a)(5) with responsibility for the administration or supervision of the administration of the State plan under this title of the retail survey price determined under this paragraph.

(2) ANNUAL STATE REPORT.—Each State shall annually report to the Secretary information on—

(A) the payment rates under the State plan under this title for covered outpatient drugs;

(B) the dispensing fees paid under such plan for such drugs; and

(C) utilization rates for noninnovator multiple source drugs under such plan.

(3) ANNUAL STATE PERFORMANCE RANKINGS.—

(A) COMPARATIVE ANALYSIS.—The Secretary annually shall compare, for the 50 most widely prescribed drugs identified by the Secretary, the national retail sales price data (collected under paragraph (1)) for such drugs with data on prices under this title for each such drug for each State.

(B) AVAILABILITY OF INFORMATION.—The Secretary shall submit to Congress and the States full information regarding the annual rankings made under subparagraph (A).

(4) APPROPRIATION.—Out of any funds in the Treasury not otherwise appropriated, there is appropriated to the Secretary of Health and Human Services $5,000,000 for each of fiscal years 2006 through 2010 to carry out this subsection.

(g) DRUG USE REVIEW.—

(1) IN GENERAL.—

(A) In order to meet the requirement of section 1903(i)(10)(B), a State shall provide, by not later than January 1, 1993, for a drug use review program described in paragraph (2) for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

(i) compendia which shall consist of the following:

(I) American Hospital Formulary Service Drug Information;

(II) United States Pharmacopeia-Drug Information (or its successor publications); and

(III) the DRUGDEX Information System; and

(ii) the peer-reviewed medical literature.

(C) The Secretary, under the procedures established in section 1903, shall pay to each State an amount equal to 75 per centum of so much of the sums expended by the State plan during calendar years 1991 through 1993 as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of this subsection.

(D) States shall not be required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with the drug regimen review procedures prescribed by the Secretary for such facilities in regulations implementing section 1919, currently at section 483.60 of title 42, Code of Federal Regulations.

(2) DESCRIPTION OF PROGRAM.—Each drug use review program shall meet the following requirements for covered outpatient drugs:

(A) PROSPECTIVE DRUG REVIEW.—(i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this title, typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

(ii) As part of the State's prospective drug use review program under this subparagraph applicable State law shall establish standards for counseling of individuals receiving benefits under this title by pharmacists which includes at least the following:

(I) The pharmacist must offer to discuss with each individual receiving benefits under this title or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:

(aa) The name and description of the medication.

(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

(cc) Special directions and precautions for preparation, administration and use by the patient.

(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(ee) Techniques for self-monitoring drug therapy.

(ff) Proper storage.

(gg) Prescription refill information.

(hh) Action to be taken in the event of a missed dose.

(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this title:

(aa) Name, address, telephone number, date of birth (or age) and gender.

(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

(cc) Pharmacist comments relevant to the individual's drug therapy.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual receiving benefits under this title or caregiver of such individual refuses such consultation, or to require verification of the offer to provide consultation or a refusal of such offer.

(B) RETROSPECTIVE DRUG USE REVIEW.—The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1903(r)) or otherwise, for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits under this title, or associated with specific drugs or groups of drugs.

(C) APPLICATION OF STANDARDS.—The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using the compendia and literature referred to in subsection (1)(B) as the source of standards for such assessment) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

(D) EDUCATIONAL PROGRAM.—The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with accredited health care educational institutions, State medical

societies or State pharmacists associations/societies or other organizations as specified by the State, and using data provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities described in paragraph (3)(C)(iii) of this subsection) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

(3) STATE DRUG USE REVIEW BOARD.—

(A) ESTABLISHMENT.—Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the "DUR Board") either directly or through a contract with a private organization.

(B) MEMBERSHIP.—The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

(i) The clinically appropriate prescribing of covered outpatient drugs.

(ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.

(iii) Drug use review, evaluation, and intervention.

(iv) Medical quality assurance.

The membership of the DUR Board shall be made up at least ⅓ but no more than 51 percent licensed and actively practicing physicians and at least ⅓ licensed and actively practicing pharmacists.

(C) ACTIVITIES.—The activities of the DUR Board shall include but not be limited to the following:

(i) Retrospective DUR as defined in section (2)(B).

(ii) Application of standards as defined in section (2)(C).

(iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:

(I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of information concerning its duties, powers, and basis for its standards;

(II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;

(III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care

practices, and follow-up face-to-face discussions; and

(IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

(D) ANNUAL REPORT.—Each State shall require the DUR Board to prepare a report on an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

(h) ELECTRONIC CLAIMS MANAGEMENT.—

(1) IN GENERAL.—In accordance with chapter 35 of title 44, United States Code (relating to coordination of Federal information policy), the Secretary shall encourage each State agency to establish, as its principal means of processing claims for covered outpatient drugs under this title, a point-of-sale electronic claims management system, for the purpose of performing on-line, real time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment.

(2) ENCOURAGEMENT.—In order to carry out paragraph (1)—

(A) for calendar quarters during fiscal years 1991 and 1992, expenditures under the State plan attributable to development of a system described in paragraph (1) shall receive Federal financial participation under section 1903(a)(3)(A)(i) (at a matching rate of 90 percent) if the State acquires, through applicable competitive procurement process in the State, the most cost-effective telecommunications network and automatic data processing services and equipment; and

(B) the Secretary may permit, in the procurement described in subparagraph (A) in the application of part 433 of title 42, Code of Federal Regulations, and parts 95, 205, and 307 of title 45, Code of Federal Regulations, the substitution of the State's request for proposal in competitive procurement for advance planning and implementation documents otherwise required.

(i) ANNUAL REPORT.—

(1) IN GENERAL.—Not later than May 1 of each year the Secretary shall transmit to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives a report on the operation of this section in the preceding fiscal year.

(2) DETAILS.—Each report shall include information on—

(A) ingredient costs paid under this title for single source drugs, multiple source drugs, and nonprescription covered outpatient drugs;

(B) the total value of rebates received and number of manufacturers providing such rebates;

(C) how the size of such rebates compare with the size or rebates offered to other purchasers of covered outpatient drugs;

(D) the effect of inflation on the value of rebates required under this section;

(E) trends in prices paid under this title for covered outpatient drugs; and

(F) Federal and State administrative costs associated with compliance with the provisions of this title.

(j) EXEMPTION OF ORGANIZED HEALTH CARE SETTINGS.—

(1) Covered outpatient drugs are not subject to the requirements of this section if such drugs are—

(A) dispensed by health maintenance organizations, including Medicaid managed care organizations that contract under section 1903(m); and

(B) subject to discounts under section 340B of the Public Health Service Act.

(2) The State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject to the requirements of this section.

(3) Nothing in this subsection shall be construed as providing that amounts for covered outpatient drugs paid by the institutions described in this subsection should not be taken into account for purposes of determining the best price as described in subsection (c).

(k) DEFINITIONS.—In the section—

(1) AVERAGE MANUFACTURER PRICE.—

(A) IN GENERAL.—Subject to subparagraph (B), the term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by—

(i) wholesalers for drugs distributed to retail community pharmacies; and

(ii) retail community pharmacies that purchase drugs directly from the manufacturer.

(B) EXCLUSION OF CUSTOMARY PROMPT PAY DISCOUNTS AND OTHER PAYMENTS.—

(i) IN GENERAL.—The average manufacturer price for a covered outpatient drug shall exclude—

(I) customary prompt pay discounts extended to wholesalers;

(II) bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking

allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);

(III) reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction;

(IV) payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy, unless the drug is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy; and

(V) discounts provided by manufacturers under section 1860D–14A.

(ii) INCLUSION OF OTHER DISCOUNTS AND PAYMENTS.—Notwithstanding clause (i), any other discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies shall be included in the average manufacturer price for a covered outpatient drug.

(C) INCLUSION OF SECTION 505(c) DRUGS.—In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, such term shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies.

(2) COVERED OUTPATIENT DRUG.—Subject to the exceptions in paragraph (3), the term "covered outpatient drug" means—

(A) of those drugs which are treated as prescribed drugs for purposes of section 1905(a)(12), a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and—

(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act;

(ii)(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the

subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or

(iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

(B) a biological product, other than a vaccine which—

(i) may only be dispensed upon prescription,

(ii) is licensed under section 351 of the Public Health Service Act, and

(iii) is produced at an establishment licensed under such section to produce such product; and

(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.

(3) LIMITING DEFINITION.—The term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug):

(A) Inpatient hospital services.

(B) Hospice services.

(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

(D) Physicians' services.

(E) Outpatient hospital services.

(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

(G) Other laboratory and x-ray services.

(H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological used for a medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C)) for such drug, biological product, or insulin.

(4) NONPRESCRIPTION DRUGS.—If a State plan for medical assistance under this title includes coverage of prescribed drugs as described in section 1905(a)(12) and permits coverage of drugs which may be sold without a prescription (commonly referred to as "over-the-counter" drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug shall be regarded as a covered outpatient drug.

(5) MANUFACTURER.—The term "manufacturer" means any entity which is engaged in—

(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(6) MEDICALLY ACCEPTED INDICATION.—The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).

(7) MULTIPLE SOURCE DRUG; INNOVATOR MULTIPLE SOURCE DRUG; NONINNOVATOR MULTIPLE SOURCE DRUG; SINGLE SOURCE DRUG.—

(A) DEFINED.—

(i) MULTIPLE SOURCE DRUG.—The term "multiple source drug" means, with respect to a rebate period, a covered outpatient drug (not including any drug described in paragraph (5)) for which there at least 1 other drug product which—

(I) is rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations"),

(II) except as provided in subparagraph (B), is pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

(III) is sold or marketed in the United States during the period.

(ii) INNOVATOR MULTIPLE SOURCE DRUG.—The term "innovator multiple source drug" means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

(iii) NONINNOVATOR MULTIPLE SOURCE DRUG.—The term "noninnovator multiple source drug" means a multiple source drug that is not an innovator multiple source drug.

(iv) SINGLE SOURCE DRUG.—The term "single source drug" means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(B) EXCEPTION.—Subparagraph (A)(i)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (A)(i)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

(C) DEFINITIONS.—For purposes of this paragraph—

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

(8) REBATE PERIOD.—The term "rebate period" means, with respect to an agreement under subsection (a), a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under such agreement.

(9) STATE AGENCY.—The term "State agency" means the agency designated under section 1902(a)(5) to administer or supervise the administration of the State plan for medical assistance.

(10) RETAIL COMMUNITY PHARMACY.—The term "retail community pharmacy" means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

(11) WHOLESALER.—The term "wholesaler" means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including (but not limited to) manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer's and distributor's warehouses, chain drug warehouses, and wholesale drug warehouses) independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

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CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT

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TITLE III—IMPORTATION AND EXPORTATION; AMENDMENTS AND REPEALS OF REVENUE LAWS

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PART A—IMPORTATION AND EXPORTATION

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EXPORTATION OF CONTROLLED SUBSTANCES

SEC. 1003. (a) It shall be unlawful to export from the United States any narcotic drug in schedule I, II, III, or IV unless—

(1) it is exported to a country which is a party to—

(A) the International Opium Convention of 1912 for the Suppression of the Abuses of Opium, Morphine, Cocaine, and Derivative Drugs, or to the International Opium Convention signed at Geneva on February 19, 1925; or

(B) the Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs concluded at Geneva, July 13, 1931, as amended by the protocol signed at Lake Success on December 11, 1946, and the protocol bringing under international control drugs outside the scope of the convention of July 13, 1931, for limiting the manufacture and regulating the distribution of narcotic drugs (as amended by the protocol signed at Lake Success on December 11, 1946), signed at Paris, November 19, 1948; or

(C) the Single Convention on Narcotic Drugs, 1961, signed at New York, March 30, 1961;

(2) such country has instituted and maintains, in conformity with the conventions to which it is a party, a system for the control of imports of narcotic drugs which the Attorney General deems adequate;

(3) the narcotic drug is consigned to a holder of such permits or licenses as may be required under the laws of the country of import, and a permit or license to import such drug has been issued by the country of import;

(4) substantial evidence is furnished to the Attorney General by the exporter that (A) the narcotic drug is to be applied exclusively to medical or scientific uses within the country of import, and (B) there is an actual need for the narcotic drug for medical or scientific uses within such country; and

(5) a permit to export the narcotic drug in each instance has been issued by the Attorney General.

(b) Notwithstanding subsection (a), the Attorney General may authorize any narcotic drug (including crude opium and coca leaves) in schedule I, II, III, or IV to be exported from the United States to a country which is a party to any of the international instruments mentioned in subsection (a) if the particular drug is to be applied to a special scientific purpose in the country of destination and the authorities of such country will permit the importation of the particular drug for such purpose.

(c) It shall be unlawful to export from the United States any nonnarcotic controlled substance in schedule I or II unless—

(1) it is exported to a country which has instituted and maintains a system which the Attorney General deems adequate for the control of imports of such substances;

(2) the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of the country of import;

(3) substantial evidence is furnished to the Attorney General that (A) the controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country to which exported, (B) it will not be exported from such country, and (C) there is an actual need for the controlled substance for medical, scientific, or other legitimate uses within the country; and

(4) a permit to export the controlled substance in each instance has been issued by the Attorney General.

(d) Notwithstanding subsection (c), the Attorney General may authorize any nonnarcotic controlled substance in schedule I or II to be exported from the United States if the particular substance is to be applied to a special scientific purpose in the country of destination and the authorities of such country will permit the importation of the particular drug for such purpose.

(e) It shall be unlawful to export from the United States to any other country any nonnarcotic controlled substances in schedule III or IV or any controlled substances in schedule V unless—

(1) there is furnished (before export) to the Attorney General documentary proof that importation is not contrary to the laws or regulations of the country of destination for consumption for medical, scientific, or other legitimate purposes;

(2) it is exported pursuant to such notification or declaration, or in the case of any nonnarcotic controlled substance in schedule III, such export permit, notification, or declaration as the Attorney General may by regulation prescribe; and

(3) in the case of a nonnarcotic controlled substance in schedule IV or V which is also listed in schedule I or II of the Convention on Psychotropic Substances, it is exported pursuant to such export permit requirements, prescribed by regulation of the Attorney General, as are required by the Convention.

(f) Notwithstanding subsections (a)(4) and (c)(3), the Attorney General may authorize any controlled substance that is in schedule I or II, or is a narcotic drug in schedule III or IV, to be exported from the United States to a country for subsequent export from that country to another country, if each of the following conditions is met:

(1) Both the country to which the controlled substance is exported from the United States (referred to in this subsection as the "first country") and the country to which the controlled substance is exported from the first country (referred to in this subsection as the "second country") are parties to the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971.

(2) The first country and the second country have each instituted and maintain, in conformity with such Conventions, a

system of controls of imports of controlled substances which the Attorney General deems adequate.

(3) With respect to the first country, the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance has been issued by the country.

(4) With respect to the second country, substantial evidence is furnished to the Attorney General by the person who will export the controlled substance from the United States that—

(A) the controlled substance is to be consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance is to be issued by the country; and

(B) the controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country.

(5)*(A)* The controlled substance will not be exported from the second country*, except that the controlled substance may be exported from the second country to another country that is a member of the European Economic Area*.

(B) Subsequent to any re-exportation described in subparagraph (A), a controlled substance may continue to be exported from any country that is a member of the European Economic Area to any other such country, provided that—

(i) the conditions applicable with respect to the first country under paragraphs (1), (2), (3), (4), (6), and (7) are met by each subsequent country from which the controlled substance is exported pursuant to this paragraph; and

(ii) the conditions applicable with respect to the second country under such paragraphs are met by each subsequent country to which the controlled substance is exported pursuant to this paragraph.

(6)*(A)* Within 30 days after the controlled substance is exported from the first country to the second country, the person who exported the controlled substance from the United States delivers to the Attorney General documentation certifying that such export from the first country has occurred.

(B) In the case of re-exportation among members of the European Economic Area, within 30 days after each re-exportation, the person who exported the controlled substance from the United States delivers to the Attorney General—

(i) documentation certifying that such re-exportation has occurred; and

(ii) information concerning the consignee, country, and product.

(7) A permit to export the controlled substance from the United States has been issued by the Attorney General.

(g) LIMITATION.—The Attorney General shall not promulgate nor enforce any regulation, subregulatory guidance, or enforcement policy which impedes re-exportation among European Economic Area countries (as provided in subsection (f)(5)), including by promulgating or enforcing any requirement that—

(1) re-exportation from the first country to the second country or re-exportation from the second country to another country (as

such terms are used in subsection (f)) occur within a specified period of time; or

(2) information concerning the consignee, country, and product be provided prior to exportation of the controlled substance from the United States or prior to each re-exportation among members of the European Economic Area.

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BALANCED BUDGET AND EMERGENCY DEFICIT CONTROL ACT OF 1985

PART C—EMERGENCY POWERS TO ELIMINATE DEFICITS IN EXCESS OF MAXIMUM DEFICIT AMOUNT

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SEC. 255. EXEMPT PROGRAMS AND ACTIVITIES.

(a) SOCIAL SECURITY BENEFITS AND TIER I RAILROAD RETIREMENT BENEFITS.—Benefits payable under the old-age, survivors, and disability insurance program established under title II of the Social Security Act (42 U.S.C. 401 et seq.), and benefits payable under sections 3 and 4 of the Railroad Retirement Act of 1937 (45 U.S.C. 231 et seq.), shall be exempt from reduction under any order issued under this part.

(b) VETERANS PROGRAMS.—The following programs shall be exempt from reduction under any order issued under this part:

All programs administered by the Department of Veterans Affairs.

Special Benefits for Certain World War II Veterans (28–0401–0–1–701).

(c) NET INTEREST.—No reduction of payments for net interest (all of major functional category 900) shall be made under any order issued under this part.

(d) REFUNDABLE INCOME TAX CREDITS.—Payments to individuals made pursuant to provisions of the Internal Revenue Code of 1986 establishing refundable tax credits shall be exempt from reduction under any order issued under this part.

(e) NON-DEFENSE UNOBLIGATED BALANCES.—Unobligated balances of budget authority carried over from prior fiscal years, except balances in the defense category, shall be exempt from reduction under any order issued under this part.

(f) OPTIONAL EXEMPTION OF MILITARY PERSONNEL.—

(1) IN GENERAL.—The President may, with respect to any military personnel account, exempt that account from sequestration or provide for a lower uniform percentage reduction than would otherwise apply.

(2) LIMITATION.—The President may not use the authority provided by paragraph (1) unless the President notifies the Congress of the manner in which such authority will be exercised on or before the date specified in section 254(a) for the budget year.

(g) OTHER PROGRAMS AND ACTIVITIES.—

(1)(A) The following budget accounts and activities shall be exempt from reduction under any order issued under this part:

Activities resulting from private donations, bequests, or voluntary contributions to the Government.

Activities financed by voluntary payments to the Government for goods or services to be provided for such payments.

Administration of Territories, Northern Mariana Islands Covenant grants (14–0412–0–1–808).

Advances to the Unemployment Trust Fund and Other Funds (16–0327–0–1–600).

Black Lung Disability Trust Fund Refinancing (16–0329–0–1–601).

Bonneville Power Administration Fund and borrowing authority established pursuant to section 13 of Public Law 93–454 (1974), as amended (89–4045–0–3–271).

Claims, Judgments, and Relief Acts (20–1895–0–1–808).

Compact of Free Association (14–0415–0–1–808).

Compensation of the President (11–0209–01–1–802).

Comptroller of the Currency, Assessment Funds (20–8413–0–8–373).

Continuing Fund, Southeastern Power Administration (89–5653–0–2–271).

Continuing Fund, Southwestern Power Administration (89–5649–0–2–271).

Dual Benefits Payments Account (60–0111–0–1–601).

Emergency Fund, Western Area Power Administration (89–5069–0–2–271).

Exchange Stabilization Fund (20–4444–0–3–155).

Farm Credit Administration Operating Expenses Fund (78–4131–0–3–351).

Farm Credit System Insurance Corporation, Farm Credit Insurance Fund (78–4171–0–3–351).

Federal Deposit Insurance Corporation, Deposit Insurance Fund (51–4596–0–4–373).

Federal Deposit Insurance Corporation, FSLIC Resolution Fund (51–4065–0–3–373).

Federal Deposit Insurance Corporation, Noninterest Bearing Transaction Account Guarantee (51–4458–0–3–373).

Federal Deposit Insurance Corporation, Senior Unsecured Debt Guarantee (51–4457–0–3–373).

Federal Home Loan Mortgage Corporation (Freddie Mac).

Federal Housing Finance Agency, Administrative Expenses (95–5532–0–2–371).

Federal National Mortgage Corporation (Fannie Mae).

Federal Payment to the District of Columbia Judicial Retirement and Survivors Annuity Fund (20–1713–0–1–752).

Federal Payment to the District of Columbia Pension Fund (20–1714–0–1–601).

Federal Payments to the Railroad Retirement Accounts (60–0113–0–1–601).

Federal Reserve Bank Reimbursement Fund (20–1884–0–1–803).

Financial Agent Services (20–1802–0–1–803).

Food and Drug Administration, Salaries and Expenses, but only the portion of appropriations under such account corresponding to fees collected under sections 736, 738, 740, 741, 744B, and 744H of the Federal Food, Drug, and Cosmetic Act (75–9911–0–1–554).

Foreign Military Sales Trust Fund (11–8242–0–7–155).

Hazardous Waste Management, Conservation Reserve Program (12–4336–0–3–999).

Host Nation Support Fund for Relocation (97–8337–0–7–051).

Internal Revenue Collections for Puerto Rico (20–5737–0–2–806).

Intragovernmental funds, including those from which the outlays are derived primarily from resources paid in from other government accounts, except to the extent such funds are augmented by direct appropriations for the fiscal year during which an order is in effect.

Medical Facilities Guarantee and Loan Fund (75–9931–0–3–551).

National Credit Union Administration, Central Liquidity Facility (25–4470–0–3–373).

National Credit Union Administration, Corporate Credit Union Share Guarantee Program (25–4476–0–3–376).

National Credit Union Administration, Credit Union Homeowners Affordability Relief Program (25–4473–0–3–371).

National Credit Union Administration, Credit Union Share Insurance Fund (25–4468–0–3–373).

National Credit Union Administration, Credit Union System Investment Program (25–4474–0–3–376).

National Credit Union Administration, Operating fund (25–4056–0–3–373).

National Credit Union Administration, Share Insurance Fund Corporate Debt Guarantee Program (25–4469–0–3–376).

National Credit Union Administration, U.S. Central Federal Credit Union Capital Program (25–4475–0–3–376).

Office of Thrift Supervision (20–4108–0–3–373).

Panama Canal Commission Compensation Fund (16–5155–0–2–602).

Payment of Vietnam and USS Pueblo prisoner-of-war claims within the Salaries and Expenses, Foreign Claims Settlement account (15–0100–0–1–153).

Payment to Civil Service Retirement and Disability Fund (24–0200–0–1–805).

Payment to Department of Defense Medicare-Eligible Retiree Health Care Fund (97–0850–0–1–054).

Payment to Judiciary Trust Funds (10–0941–0–1–752).

Payment to Military Retirement Fund (97–0040–0–1–054).

Payment to the Foreign Service Retirement and Disability Fund (19–0540–0–1–153).

Payments to Copyright Owners (03–5175–0–2–376).

Payments to Health Care Trust Funds (75–0580–0–1–571).

Payment to Radiation Exposure Compensation Trust Fund (15–0333–0–1–054).

Payments to Social Security Trust Funds (28–0404–0–1–651).

Payments to the United States Territories, Fiscal Assistance (14–0418–0–1–806).

Payments to trust funds from excise taxes or other receipts properly creditable to such trust funds.

Payments to widows and heirs of deceased Members of Congress (00–0215–0–1–801).

Postal Service Fund (18–4020–0–3–372).

Radiation Exposure Compensation Trust Fund (15–8116–0–1–054).

Reimbursement to Federal Reserve Banks (20–0562–0–1–803).

Salaries of Article III judges.

Soldiers and Airmen's Home, payment of claims (84–8930–0–7–705).

Tennessee Valley Authority Fund, except nonpower programs and activities (64–4110–0–3–999).

Tribal and Indian trust accounts within the Department of the Interior which fund prior legal obligations of the Government or which are established pursuant to Acts of Congress regarding Federal management of tribal real property or other fiduciary responsibilities, including but not limited to Tribal Special Fund (14–5265–0–2–452), Tribal Trust Fund (14–8030–0–7–452), White Earth Settlement (14–2204–0–1–452), and Indian Water Rights and Habitat Acquisition (14–5505–0–2–303).

United Mine Workers of America 1992 Benefit Plan (95–8260–0–7–551).

United Mine Workers of America 1993 Benefit Plan (95–8535–0–7–551).

United Mine Workers of America Combined Benefit Fund (95–8295–0–7–551).

United States Enrichment Corporation Fund (95–4054–0–3–271).

Universal Service Fund (27–5183–0–2–376).

Vaccine Injury Compensation (75–0320–0–1–551).

Vaccine Injury Compensation Program Trust Fund (20–8175–0–7–551).

(B) The following Federal retirement and disability accounts and activities shall be exempt from reduction under any order issued under this part:

Black Lung Disability Trust Fund (20–8144–0–7–601).

Central Intelligence Agency Retirement and Disability System Fund (56–3400–0–1–054).

Civil Service Retirement and Disability Fund (24–8135–0–7–602).

Comptrollers general retirement system (05–0107–0–1–801).

Contributions to U.S. Park Police annuity benefits, Other Permanent Appropriations (14–9924–0–2–303).

Court of Appeals for Veterans Claims Retirement Fund (95–8290–0–7–705).

Department of Defense Medicare-Eligible Retiree Health Care Fund (97–5472–0–2–551).

District of Columbia Federal Pension Fund (20–5511–0–2–601).

District of Columbia Judicial Retirement and Survivors Annuity Fund (20–8212–0–7–602).

Energy Employees Occupational Illness Compensation Fund (16–1523–0–1–053).

Foreign National Employees Separation Pay (97–8165–0–7–051).

Foreign Service National Defined Contributions Retirement Fund (19–5497–0–2–602).

Foreign Service National Separation Liability Trust Fund (19–8340–0–7–602).

Foreign Service Retirement and Disability Fund (19–8186–0–7–602).

Government Payment for Annuitants, Employees Health Benefits (24–0206–0–1–551).

Government Payment for Annuitants, Employee Life Insurance (24–0500–0–1–602).

Judicial Officers' Retirement Fund (10–8122–0–7–602).

Judicial Survivors' Annuities Fund (10–8110–0–7–602).

Military Retirement Fund (97–8097–0–7–602).

National Railroad Retirement Investment Trust (60–8118–0–7–601).

National Oceanic and Atmospheric Administration retirement (13–1450–0–1–306).

Pensions for former Presidents (47–0105–0–1–802).

Postal Service Retiree Health Benefits Fund (24–5391–0–2–551).

Public Safety Officer Benefits (15–0403–0–1–754).

Rail Industry Pension Fund (60–8011–0–7–601).

Retired Pay, Coast Guard (70–0602–0–1–403).

Retirement Pay and Medical Benefits for Commissioned Officers, Public Health Service (75–0379–0–1–551).

Special Benefits for Disabled Coal Miners (16–0169–0–1–601).

Special Benefits, Federal Employees' Compensation Act (16–1521–0–1–600).

Special Workers Compensation Expenses (16–9971–0–7–601).

Tax Court Judges Survivors Annuity Fund (23–8115–0–7–602).

United States Court of Federal Claims Judges' Retirement Fund (10–8124–0–7–602).

United States Secret Service, DC Annuity (70–0400–0–1–751).

Voluntary Separation Incentive Fund (97–8335–0–7–051).

(2) Prior legal obligations of the Government in the following budget accounts and activities shall be exempt from any order issued under this part:

Biomass Energy Development (20–0114–0–1–271).

Check Forgery Insurance Fund (20–4109–0–3–803).

Credit liquidating accounts.

Credit reestimates.

Employees Life Insurance Fund (24–8424–0–8–602).

Federal Aviation Insurance Revolving Fund (69–4120–0–3–402).

Federal Crop Insurance Corporation Fund (12–4085–0–3–351).

Federal Emergency Management Agency, National Flood Insurance Fund (58–4236–0–3–453).

Geothermal resources development fund (89–0206–0–1–271).

Low-Rent Public Housing—Loans and Other Expenses (86–4098–0–3–604).

Maritime Administration, War Risk Insurance Revolving Fund (69–4302–0–3–403).

Natural Resource Damage Assessment Fund (14–1618–0–1–302).

Overseas Private Investment Corporation, Noncredit Account (71–4184–0–3–151).

Pension Benefit Guaranty Corporation Fund (16–4204–0–3–601).

San Joaquin Restoration Fund (14–5537–0–2–301).

Servicemembers' Group Life Insurance Fund (36–4009–0–3–701).

Terrorism Insurance Program (20–0123–0–1–376).

(h) LOW-INCOME PROGRAMS.—The following programs shall be exempt from reduction under any order issued under this part:

Academic Competitiveness/Smart Grant Program (91–0205–0–1–502).

Child Care Entitlement to States (75–1550–0–1–609).

Child Enrollment Contingency Fund (75–5551–0–2–551).

Child Nutrition Programs (with the exception of special milk programs) (12–3539–0–1–605).

Children's Health Insurance Fund (75–0515–0–1–551).

Commodity Supplemental Food Program (12–3507–0–1–605).

Contingency Fund (75–1522–0–1–609).

Family Support Programs (75–1501–0–1–609).

Federal Pell Grants under section 401 of title IV of the Higher Education Act.

Grants to States for Medicaid (75–0512–0–1–551).

Payments for Foster Care and Permanency (75–1545–0–1–609).

Supplemental Nutrition Assistance Program (12–3505–0–1–605).

Supplemental Security Income Program (28–0406–0–1–609).

Temporary Assistance for Needy Families (75–1552–0–1–609).

(i) ECONOMIC RECOVERY PROGRAMS.—The following programs shall be exempt from reduction under any order issued under this part:

GSE Preferred Stock Purchase Agreements (20–0125–0–1–371).

Office of Financial Stability (20–0128–0–1–376).

Special Inspector General for the Troubled Asset Relief Program (20–0133–0–1–376).

(j) SPLIT TREATMENT PROGRAMS.—Each of the following programs shall be exempt from any order under this part to the extent that the budgetary resources of such programs are subject to obligation limitations in appropriations bills:

Federal-Aid Highways (69–8083–0–7–401).

Highway Traffic Safety Grants (69–8020–0–7–401).

Operations and Research NHTSA and National Driver Register (69–8016–0–7–401).

Motor Carrier Safety Operations and Programs (69–8159–0–7–401).

Motor Carrier Safety Grants (69–8158–0–7–401).

Formula and Bus Grants (69–8350–0–7–401).

Grants-In-Aid for Airports (69–8106–0–7–402).

(k) IDENTIFICATION OF PROGRAMS.—For purposes of subsections (b), (g), and (h), each account is identified by the designated budget account identification code number set forth in the Budget of the United States Government 2010–Appendix, and an activity within an account is designated by the name of the activity and the identification code number of the account.

SEC. 256. GENERAL AND SPECIAL SEQUESTRATION RULES.

(b) STUDENT LOANS.—For all student loans under part B or D of title IV of the Higher Education Act of 1965 made during the period when a sequestration order under section 254 is in effect as required by section 252 or 253, origination fees under sections 438(c)(2) and (6) and 455(c) and loan processing and issuance fees under section 428(f)(1)(A)(ii) of that Act shall each be increased by the uniform percentage specified in that sequestration order, and, for student loans originated during the period of the sequestration, special allowance payments under section 438(b) of that Act accruing during the period of the sequestration shall be reduced by the uniform percentage specified in that sequestration order.

(d) SPECIAL RULES FOR MEDICARE PROGRAM.—

(1) CALCULATION OF REDUCTION IN PAYMENT AMOUNTS.—To achieve the total percentage reduction in those programs required by section 252 or 253, subject to paragraph (2), and notwithstanding section 710 of the Social Security Act, OMB shall determine, and the applicable Presidential order under section 254 shall implement, the percentage reduction that shall apply, with respect to the health insurance programs under title XVIII of the Social Security Act—

(A) in the case of parts A and B of such title, to individual payments for services furnished during the one-year period beginning on the first day of the first month beginning after the date the order is issued (or, if later, the date specified in paragraph (4)); and

(B) in the case of parts C and D, to monthly payments under contracts under such parts for the same one-year period;

such that the reduction made in payments under that order shall achieve the required total percentage reduction in those payments for that period.

(2) UNIFORM REDUCTION RATE; MAXIMUM PERMISSIBLE REDUCTION.—Reductions in payments for programs and activities under such title XVIII pursuant to a sequestration order under section 254 shall be at a uniform rate, which shall not exceed

4 percent, across all such programs and activities subject to such order.

(3) TIMING OF APPLICATION OF REDUCTIONS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), if a reduction is made under paragraph (1) in payment amounts pursuant to a sequestration order, the reduction shall be applied to payment for services furnished during the effective period of the order. For purposes of the previous sentence, in the case of inpatient services furnished for an individual, the services shall be considered to be furnished on the date of the individual's discharge from the inpatient facility.

(B) PAYMENT ON THE BASIS OF COST REPORTING PERIODS.—In the case in which payment for services of a provider of services is made under title XVIII of the Social Security Act on a basis relating to the reasonable cost incurred for the services during a cost reporting period of the provider, if a reduction is made under paragraph (1) in payment amounts pursuant to a sequestration order, the reduction shall be applied to payment for costs for such services incurred at any time during each cost reporting period of the provider any part of which occurs during the effective period of the order, but only (for each such cost reporting period) in the same proportion as the fraction of the cost reporting period that occurs during the effective period of the order.

(4) TIMING OF SUBSEQUENT SEQUESTRATION ORDER.—A sequestration order required by section 252 or 253 with respect to programs under such title XVIII shall not take effect until the first month beginning after the end of the effective period of any prior sequestration order with respect to such programs, as determined in accordance with paragraph (1).

(5) NO INCREASE IN BENEFICIARY CHARGES IN ASSIGNMENT-RELATED CASES.—If a reduction in payment amounts is made under paragraph (1) for services for which payment under part B of title XVIII of the Social Security Act is made on the basis of an assignment described in section 1842(b)(3)(B)(ii), in accordance with section 1842(b)(6)(B), or under the procedure described in section 1870(f)(1), of such Act, the person furnishing the services shall be considered to have accepted payment of the reasonable charge for the services, less any reduction in payment amount made pursuant to a sequestration order, as payment in full.

(6) SEQUESTRATION DISREGARDED IN COMPUTING PAYMENT AMOUNTS.—The Secretary of Health and Human Services shall not take into account any reductions in payment amounts which have been or may be effected under this part, for purposes of computing any adjustments to payment rates under such title XVIII, specifically including—

(A) the part C growth percentage under section 1853(c)(6);

(B) the part D annual growth rate under section 1860D–2(b)(6); and

(C) application of risk corridors to part D payment rates under section 1860D–15(e).

(7) EXEMPTIONS FROM SEQUESTRATION.—In addition to the programs and activities specified in section 255, the following shall be exempt from sequestration under this part:

(A) PART D LOW-INCOME SUBSIDIES.—Premium and cost-sharing subsidies under section 1860D–14 of the Social Security Act.

(B) PART D CATASTROPHIC SUBSIDY.—Payments under section 1860D–15(b) and (e)(2)(B) of the Social Security Act.

(C) QUALIFIED INDIVIDUAL (QI) PREMIUMS.—Payments to States for coverage of Medicare cost-sharing for certain low-income Medicare beneficiaries under section 1933 of the Social Security Act.

(e) COMMUNITY AND MIGRANT HEALTH CENTERS, INDIAN HEALTH SERVICES AND FACILITIES, AND VETERANS' MEDICAL CARE.—

(1) The maximum permissible reduction in budget authority for any account listed in paragraph (2) for any fiscal year, pursuant to an order issued under section 254, shall be 2 percent.

(2) The accounts referred to in paragraph (1) are as follows:

(A) Community health centers (75–0350–0–1–550).

(B) Migrant health centers (75–0350–0–1–550).

(C) Indian health facilities (75–0391–0–1–551).

(D) Indian health services (75–0390–0–1–551).

(E) Veterans' medical care (36–0160–0–1–703).

For purposes of the preceding provisions of this paragraph, programs are identified by the designated budget account identification code numbers set forth in the Budget of the United States Government—Appendix.

(f) TREATMENT OF CHILD SUPPORT ENFORCEMENT PROGRAM.—Notwithstanding any change in the display of budget accounts, any order issued by the President under section 254 shall accomplish the full amount of any required reduction in expenditures under sections 455 and 458 of the Social Security Act by reducing the Federal matching rate for State administrative costs under such program, as specified (for the fiscal year involved) in section 455(a) of such Act, to the extent necessary to reduce such expenditures by that amount.

(g) FEDERAL PAY.—

(1) IN GENERAL.—For purposes of any order issued under section 254—

(A) Federal pay under a statutory pay system, and

(B) elements of military pay,

shall be subject to reduction under an order in the same manner as other administrative expense components of the Federal budget; except that no such order may reduce or have the effect of reducing the rate of pay to which any individual is entitled under any such statutory pay system (as increased by any amount payable under section 5304 of title 5, United States Code, or section 302 of the Federal Employees Pay Comparability Act of 1990) or the rate of any element of military pay to which any individual is entitled under title 37, United States Code, or any increase in rates of pay which is scheduled to take effect under section 5303 of title 5, United States Code, section 1009 of title 37, United States Code, or any other provision of law.

(2) DEFINITIONS.—For purposes of this subsection:

(A) The term "statutory pay system" shall have the meaning given that term in section 5302(1) of title 5, United States Code.

(B) The term "elements of military pay" means—

(i) the elements of compensation of members of the uniformed services specified in section 1009 of title 37, United States Code,

(ii) allowances provided members of the uniformed services under sections 403a and 405 of such title, and

(iii) cadet pay and midshipman pay under section 203(c) of such title.

(C) The term "uniformed services" shall have the meaning given that term in section 101(3) of title 37, United States Code.

(h) TREATMENT OF FEDERAL ADMINISTRATIVE EXPENSES.—

(1) Notwithstanding any other provision of this title, administrative expenses incurred by the departments and agencies, including independent agencies, of the Federal Government in connection with any program, project, activity, or account shall be subject to reduction pursuant to an order issued under section 254, without regard to any exemption, exception, limitation, or special rule which is otherwise applicable with respect to such program, project, activity, or account under this part.

(2) Notwithstanding any other provision of law, administrative expenses of any program, project, activity, or account which is self-supporting and does not receive appropriations shall be subject to reduction under a sequester order, unless specifically exempted in this part.

(3) Payments made by the Federal Government to reimburse or match administrative costs incurred by a State or political subdivision under or in connection with any program, project, activity, or account shall not be considered administrative expenses of the Federal Government for purposes of this section, and shall be subject to reduction or sequestration under this part to the extent (and only to the extent) that other payments made by the Federal Government under or in connection with that program, project, activity, or account are subject to such reduction or sequestration; except that Federal payments made to a State as reimbursement of administrative costs incurred by such State under or in connection with the unemployment compensation programs specified in subsection (h)(1) shall be subject to reduction or sequestration under this part notwithstanding the exemption otherwise granted to such programs under that subsection.

(4) Notwithstanding any other provision of law, this subsection shall not apply with respect to the following:

(A) Comptroller of the Currency.

(B) Federal Deposit Insurance Corporation.

(C) National Credit Union Administration.

(D) National Credit Union Administration, central liquidity facility.

(E) Federal Retirement Thrift Investment Board.

(F) Farm Credit Administration.

(5) Notwithstanding any other provision of law, this subsection shall not apply with respect to the portion of administrative expenses incurred by the Food and Drug Administration that are funded through fees collected under sections 736, 738, 740, 741, 744B, and 744H of the Federal Food, Drug, and Cosmetic Act.

(i) TREATMENT OF PAYMENTS AND ADVANCES MADE WITH RESPECT TO UNEMPLOYMENT COMPENSATION PROGRAMS.—(1) For purposes of section 254—

(A) any amount paid as regular unemployment compensation by a State from its account in the Unemployment Trust Fund (established by section 904(a) of the Social Security Act),

(B) any advance made to a State from the Federal unemployment account (established by section 904(g) of such Act) under title XII of such Act and any advance appropriated to the Federal unemployment account pursuant to section 1203 of such Act, and

(C) any payment made from the Federal Employees Compensation Account (as established under section 909 of such Act) for the purpose of carrying out chapter 85 of title 5, United States Code, and funds appropriated or transferred to or otherwise deposited in such Account,

shall not be subject to reduction.

(2)(A) A State may reduce each weekly benefit payment made under the Federal-State Extended Unemployment Compensation Act of 1970 for any week of unemployment occurring during any period with respect to which payments are reduced under an order issued under section 254 by a percentage not to exceed the percentage by which the Federal payment to the State under section 204 of such Act is to be reduced for such week as a result of such order.

(B) A reduction by a State in accordance with subparagraph (A) shall not be considered as a failure to fulfill the requirements of section 3304(a)(11) of the Internal Revenue Code of 1954.

(j) COMMODITY CREDIT CORPORATION.—

(1) POWERS AND AUTHORITIES OF THE COMMODITY CREDIT CORPORATION.—This title shall not restrict the Commodity Credit Corporation in the discharge of its authority and responsibility as a corporation to buy and sell commodities in world trade, to use the proceeds as a revolving fund to meet other obligations and otherwise operate as a corporation, the purpose for which it was created.

(2) REDUCTION IN PAYMENTS MADE UNDER CONTRACTS.—(A) Loan eligibility under any contract entered into with a person by the Commodity Credit Corporation prior to the time an order has been issued under section 254 shall not be reduced by an order subsequently issued. Subject to subparagraph (B), after an order is issued under such section for a fiscal year, any cash payments for loans or loan deficiencies made by the Commodity Credit Corporation shall be subject to reduction under the order.

(B) Each loan contract entered into with producers or producer cooperatives with respect to a particular crop of a commodity and subject to reduction under subparagraph (A) shall be reduced in accordance with the same terms and conditions. If some, but not all, contracts applicable to a crop of a com-

modity have been entered into prior to the issuance of an order under section 254, the order shall provide that the necessary reduction in payments under contracts applicable to the commodity be uniformly applied to all contracts for the next succeeding crop of the commodity, under the authority provided in paragraph (3).

(3) DELAYED REDUCTION IN OUTLAYS PERMISSIBLE.—Notwithstanding any other provision of this title, if an order under section 254 is issued with respect to a fiscal year, any reduction under the order applicable to contracts described in paragraph (1) may provide for reductions in outlays for the account involved to occur in the fiscal year following the fiscal year to which the order applies.

(4) UNIFORM PERCENTAGE RATE OF REDUCTION AND OTHER LIMITATIONS.—All reductions described in paragraph (2) which are required to be made in connection with an order issued under section 254 with respect to a fiscal year shall be made so as to ensure that outlays for each program, project, activity, or account involved are reduced by a percentage rate that is uniform for all such programs, projects, activities, and accounts, and may not be made so as to achieve a percentage rate of reduction in any such item exceeding the rate specified in the order.

(5) DAIRY PROGRAM.—Notwithstanding any other provision of this subsection, as the sole means of achieving any reduction in outlays under the milk price support program, the Secretary of Agriculture shall provide for a reduction to be made in the price received by producers for all milk produced in the United States and marketed by producers for commercial use. That price reduction (measured in cents per hundred weight of milk marketed) shall occur under section 201(d)(2)(A) of the Agricultural Act of 1949 (7 U.S.C. 1446(d)(2)(A)), shall begin on the day any sequestration order is issued under section 254, and shall not exceed the aggregate amount of the reduction in outlays under the milk price support program that otherwise would have been achieved by reducing payments for the purchase of milk or the products of milk under this subsection during the applicable fiscal year.

(6) CERTAIN AUTHORITY NOT TO BE LIMITED.—Nothing in this joint resolution shall limit or reduce, in any way, any appropriation that provides the Commodity Credit Corporation with budget authority to cover the Corporation's net realized losses.

(k) EFFECTS OF SEQUESTRATION.—The effects of sequestration shall be as follows:

(1) Budgetary resources sequestered from any account shall be permanently cancelled, except as provided in paragraph (6).

(2) Except as otherwise provided, the same percentage sequestration shall apply to all programs, projects, and activities within a budget account (with programs, projects, and activities as delineated in the appropriation Act or accompanying report for the relevant fiscal year covering that account, or for accounts not included in appropriation Acts, as delineated in the most recently submitted President's budget).

(3) Administrative regulations or similar actions implementing a sequestration shall be made within 120 days of the

sequestration order. To the extent that formula allocations differ at different levels of budgetary resources within an account, program, project, or activity, the sequestration shall be interpreted as producing a lower total appropriation, with the remaining amount of the appropriation being obligated in a manner consistent with program allocation formulas in substantive law.

(4) Except as otherwise provided, obligations in sequestered accounts shall be reduced only in the fiscal year in which a sequester occurs.

(5) If an automatic spending increase is sequestered, the increase (in the applicable index) that was disregarded as a result of that sequestration shall not be taken into account in any subsequent fiscal year.

(6) Budgetary resources sequestered in revolving, trust, and special fund accounts and offsetting collections sequestered in appropriation accounts shall not be available for obligation during the fiscal year in which the sequestration occurs, but shall be available in subsequent years to the extent otherwise provided in law.

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HITECH ACT

TITLE XIII—HEALTH INFORMATION TECHNOLOGY

SEC. 13001. SHORT TITLE; TABLE OF CONTENTS OF TITLE

(a) SHORT TITLE.—This title (and title IV of division B) may be cited as the "Health Information Technology for Economic and Clinical Health Act" or the "HITECH Act".

(b) TABLE OF CONTENTS OF TITLE.—The table of contents of this title is as follows:

Sec. 13001. Short title; table of contents of title.

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Subtitle D—Privacy

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PART 4—ACCESSING, SHARING, AND USING HEALTH DATA FOR RESEARCH PURPOSES

Sec. 13441. References.
Sec. 13442. Defining health data research as part of health care operations.
Sec. 13443. Treating disclosures of protected health information for research similarly to disclosures of such information for public health purposes.
Sec. 13444. Permitting remote access to protected health information by researchers.
Sec. 13445. Allowing one-time authorization of use and disclosure of protected health information for research purposes.

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Subtitle A—Promotion of Health Information Technology

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PART 2—APPLICATION AND USE OF ADOPTED HEALTH INFORMATION TECHNOLOGY STANDARDS; REPORTS

SEC. 13111. COORDINATION OF FEDERAL ACTIVITIES WITH ADOPTED STANDARDS AND IMPLEMENTATION SPECIFICATIONS

(a) SPENDING ON HEALTH INFORMATION TECHNOLOGY SYSTEMS.—As each agency (as defined by the Director of the Office of Management and Budget, in consultation with the Secretary of Health and Human Services) implements, acquires, or upgrades health information technology systems used for the direct exchange of individually identifiable health information between agencies and with non-Federal entities, it shall utilize, where available, health information technology systems and products that meet standards and implementation specifications adopted under section 3004 of the Public Health Service Act, as added by section 13101 *(and, beginning on January 1, 2018, that are also interoperable under section 3010 of such Act, including by being in compliance with interoperability standards adopted under section 3004 of such Act)*.

(b) FEDERAL INFORMATION COLLECTION ACTIVITIES.—With respect to a standard or implementation specification adopted under section 3004 of the Public Health Service Act, as added by section 13101, *(and, beginning on January 1, 2018, including an interoperability standard adopted under section 3004 of such Act)* the President shall take measures to ensure that Federal activities involving the broad collection and submission of health information are consistent with such standard or implementation specification, respectively, within three years after the date of such adoption.

(c) APPLICATION OF DEFINITIONS.—The definitions contained in section 3000 of the Public Health Service Act, as added by section 13101, shall apply for purposes of this part.

SEC. 13112. APPLICATION TO PRIVATE ENTITIES

Each agency (as defined in such Executive Order issued on August 22, 2006, relating to promoting quality and efficient health care in Federal government administered or sponsored health care programs) shall require in contracts or agreements with health care providers, health plans, or health insurance issuers that as each provider, plan, or issuer implements, acquires, or upgrades health information technology systems, it shall utilize, where available, health information technology systems and products that meet standards and implementation specifications adopted under section 3004 of the Public Health Service Act, as added by section 13101 *(and, beginning on January 1, 2018, that are also interoperable under section 3010 of such Act, including by being in compliance with interoperability standards adopted under section 3004 of such Act)*.

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Subtitle D—Privacy

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PART 4—ACCESSING, SHARING, AND USING HEALTH DATA FOR RESEARCH PURPOSES

SEC. 13441. REFERENCES.

In this part:

(1) THE RULE.—References to "the Rule" refer to part 160 or part 164, as appropriate, of title 45, Code of Federal Regulations (or any successor regulation).

(2) PART 164.—References to a specified section of "part 164", refer to such specified section of part 164 of title 45, Code of Federal Regulations (or any successor section).

SEC. 13442. DEFINING HEALTH DATA RESEARCH AS PART OF HEALTH CARE OPERATIONS.

(a) IN GENERAL.—Subject to subsection (b), the Secretary shall revise or clarify the Rule to allow the use and disclosure of protected health information by a covered entity for research purposes, including studies whose purpose is to obtain generalizable knowledge, to be treated as the use and disclosure of such information for health care operations described in subparagraph (1) of the definition of health care operations in section 164.501 of part 164.

(b) MODIFICATIONS TO RULES FOR DISCLOSURES FOR HEALTH CARE OPERATIONS.—In applying section 164.506 of part 164 to the disclosure of protected health information described in subsection (a)—

(1) the Secretary shall revise or clarify the Rule so that the disclosure may be made by the covered entity to only—

(A) another covered entity for health care operations (as defined in section 164.501 of part 164);

(B) a business associate that has entered into a contract under section 164.504(e) of part 164 with a disclosing covered entity to perform health care operations; or

(C) a business associate that has entered into a contract under section 164.504(e) of part 164 for the purpose of data aggregation (as defined in section 164.501 of part 164); and

(2) the Secretary shall further revise or clarify the Rule so that the limitation specified by section 164.506(c)(4) of part 164 does not apply to disclosures that are described by subsection (a).

(c) RULE OF CONSTRUCTION.—This section shall not be construed as prohibiting or restricting a use or disclosure of protected health information for research purposes that is otherwise permitted under part 164.

SEC. 13443. TREATING DISCLOSURES OF PROTECTED HEALTH INFORMATION FOR RESEARCH SIMILARLY TO DISCLOSURES OF SUCH INFORMATION FOR PUBLIC HEALTH PURPOSES.

(a) REMUNERATION.—The Secretary shall revise or clarify the Rule so that disclosures of protected health information for research purposes are not subject to the limitation on remuneration described in section 164.502(a)(5)(ii)(B)(2)(ii) of part 164.

(b) PERMITTED USES AND DISCLOSURES.—The Secretary shall revise or clarify the Rule so that research activities, including comparative research activities, related to the quality, safety, or effectiveness of a product or activity that is regulated by the Food and Drug Administration are included as public health activities for

purposes of which a covered entity may disclose protected health information to a person described in section 164.512(b)(1)(iii) of part 164.

SEC. 13444. PERMITTING REMOTE ACCESS TO PROTECTED HEALTH INFORMATION BY RESEARCHERS.

The Secretary shall revise or clarify the Rule so that subparagraph (B) of section 164.512(i)(1)(ii) of part 164 (prohibiting the removal of protected health information by a researcher) shall not prohibit remote access to health information by a researcher so long as—

(1) appropriate security and privacy safeguards are maintained by the covered entity and the researcher; and

(2) the protected health information is not copied or otherwise retained by the researcher.

SEC. 13445. ALLOWING ONE-TIME AUTHORIZATION OF USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES.

(a) IN GENERAL.—The Secretary shall revise or clarify the Rule to specify that an authorization for the use or disclosure of protected health information, with respect to an individual, for future research purposes shall be deemed to contain a sufficient description of the purpose of the use or disclosure if the authorization—

(1) sufficiently describes the purposes such that it would be reasonable for the individual to expect that the protected health information could be used or disclosed for such future research;

(2) either—

(A) states that the authorization will expire on a particular date or on the occurrence of a particular event; or

(B) states that the authorization will remain valid unless and until it is revoked by the individual; and

(3) provides instruction to the individual on how to revoke such authorization at any time.

(b) REVOCATION OF AUTHORIZATION.—The Secretary shall revise or clarify the Rule to specify that, if an individual revokes an authorization for future research purposes such as is described by subsection (a), the covered entity may not make any further uses or disclosures based on that authorization, except, as provided in paragraph (b)(5) of section 164.508 of part 164, to the extent that the covered entity has taken action in reliance on the authorization.

SECTION 106 OF THE MEDICARE ACCESS AND CHIP REAUTHORIZATION ACT OF 2015

SEC. 106. REDUCING ADMINISTRATIVE BURDEN AND OTHER PROVISIONS.

(a) MEDICARE PHYSICIAN AND PRACTITIONER OPT-OUT TO PRIVATE CONTRACT.—

(1) INDEFINITE, CONTINUING AUTOMATIC EXTENSION OF OPT OUT ELECTION.—

(A) IN GENERAL.—Section 1802(b)(3) of the Social Security Act (42 U.S.C. 1395a(b)(3)) is amended—

(i) in subparagraph (B)(ii), by striking "during the 2-year period beginning on the date the affidavit is signed" and inserting "during the applicable 2-year period (as defined in subparagraph (D))";

(ii) in subparagraph (C), by striking "during the 2-year period described in subparagraph (B)(ii)" and inserting "during the applicable 2-year period"; and

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

"(D) APPLICABLE 2-YEAR PERIODS FOR EFFECTIVENESS OF AFFIDAVITS.—In this subsection, the term 'applicable 2-year period' means, with respect to an affidavit of a physician or practitioner under subparagraph (B), the 2-year period beginning on the date the affidavit is signed and includes each subsequent 2-year period unless the physician or practitioner involved provides notice to the Secretary (in a form and manner specified by the Secretary), not later than 30 days before the end of the previous 2-year period, that the physician or practitioner does not want to extend the application of the affidavit for such subsequent 2-year period.".

(B) EFFECTIVE DATE.—The amendments made by subparagraph (A) shall apply to affidavits entered into on or after the date that is 60 days after the date of the enactment of this Act.

(2) PUBLIC AVAILABILITY OF INFORMATION ON OPT-OUT PHYSICIANS AND PRACTITIONERS.—Section 1802(b) of the Social Security Act (42 U.S.C. 1395a(b)) is amended—

(A) in paragraph (5), by adding at the end the following new subparagraph:

"(D) OPT-OUT PHYSICIAN OR PRACTITIONER.—The term 'opt-out physician or practitioner' means a physician or practitioner who has in effect an affidavit under paragraph (3)(B).";

(B) by redesignating paragraph (5) as paragraph (6); and

(C) by inserting after paragraph (4) the following new paragraph:

"(5) POSTING OF INFORMATION ON OPT-OUT PHYSICIANS AND PRACTITIONERS.—

"(A) IN GENERAL.—Beginning not later than February 1, 2016, the Secretary shall make publicly available through an appropriate publicly accessible website of the Department of Health and Human Services information on the number and characteristics of opt-out physicians and practitioners and shall update such information on such website not less often than annually.

"(B) INFORMATION TO BE INCLUDED.—The information to be made available under subparagraph (A) shall include at least the following with respect to opt-out physicians and practitioners:

"(i) Their number.

"(ii) Their physician or professional specialty or other designation.

"(iii) Their geographic distribution.

"(iv) The timing of their becoming opt-out physicians and practitioners, relative, to the extent feasible, to when they first enrolled in the program under this title and with respect to applicable 2-year periods.

"(v) The proportion of such physicians and practitioners who billed for emergency or urgent care services.".

[(b) PROMOTING INTEROPERABILITY OF ELECTRONIC HEALTH RECORD SYSTEMS.—

[(1) RECOMMENDATIONS FOR ACHIEVING WIDESPREAD EHR INTEROPERABILITY.—

[(A) OBJECTIVE.—As a consequence of a significant Federal investment in the implementation of health information technology through the Medicare and Medicaid EHR incentive programs, Congress declares it a national objective to achieve widespread exchange of health information through interoperable certified EHR technology nationwide by December 31, 2018.

[(B) DEFINITIONS.—In this paragraph:

[(i) WIDESPREAD INTEROPERABILITY.—The term "widespread interoperability" means interoperability between certified EHR technology systems employed by meaningful EHR users under the Medicare and Medicaid EHR incentive programs and other clinicians and health care providers on a nationwide basis.

[(ii) INTEROPERABILITY.—The term "interoperability" means the ability of two or more health information systems or components to exchange clinical and other information and to use the information that has been exchanged using common standards as to provide access to longitudinal information for health care providers in order to facilitate coordinated care and improved patient outcomes.

[(C) ESTABLISHMENT OF METRICS.—Not later than July 1, 2016, and in consultation with stakeholders, the Secretary shall establish metrics to be used to determine if and to the extent that the objective described in subparagraph (A) has been achieved.

[(D) RECOMMENDATIONS IF OBJECTIVE NOT ACHIEVED.—If the Secretary of Health and Human Services determines that the objective described in subparagraph (A) has not been achieved by December 31, 2018, then the Secretary shall submit to Congress a report, by not later than December 31, 2019, that identifies barriers to such objective and recommends actions that the Federal Government can take to achieve such objective. Such recommended actions may include recommendations—

[(i) to adjust payments for not being meaningful EHR users under the Medicare EHR incentive programs; and

[(ii) for criteria for decertifying certified EHR technology products.

[(2) PREVENTING BLOCKING THE SHARING OF INFORMATION.—

[(A) FOR MEANINGFUL USE EHR PROFESSIONALS.—Section 1848(o)(2)(A)(ii) of the Social Security Act (42 U.S.C. 1395w–4(o)(2)(A)(ii)) is amended by inserting before the period at the end the following: ", and the professional demonstrates (through a process specified by the Secretary, such as the use of an attestation) that the profes-

sional has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of the certified EHR technology".

[(B) FOR MEANINGFUL USE EHR HOSPITALS.—Section 1886(n)(3)(A)(ii) of the Social Security Act (42 U.S.C. 1395ww(n)(3)(A)(ii)) is amended by inserting before the period at the end the following: ", and the hospital demonstrates (through a process specified by the Secretary, such as the use of an attestation) that the hospital has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of the certified EHR technology".

[(C) EFFECTIVE DATE.—The amendments made by this subsection shall apply to meaningful EHR users as of the date that is one year after the date of the enactment of this Act.

[(3) STUDY AND REPORT ON THE FEASIBILITY OF ESTABLISHING A MECHANISM TO COMPARE CERTIFIED EHR TECHNOLOGY PRODUCTS.—

[(A) STUDY.—The Secretary shall conduct a study to examine the feasibility of establishing one or more mechanisms to assist providers in comparing and selecting certified EHR technology products. Such mechanisms may include—

[(i) a website with aggregated results of surveys of meaningful EHR users on the functionality of certified EHR technology products to enable such users to directly compare the functionality and other features of such products; and

[(ii) information from vendors of certified products that is made publicly available in a standardized format.

The aggregated results of the surveys described in clause (i) may be made available through contracts with physicians, hospitals, or other organizations that maintain such comparative information described in such clause.

[(B) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to Congress a report on mechanisms that would assist providers in comparing and selecting certified EHR technology products. The report shall include information on the benefits of, and resources needed to develop and maintain, such mechanisms.

[(4) DEFINITIONS.—In this subsection:

[(A) The term "certified EHR technology" has the meaning given such term in section 1848(o)(4) of the Social Security Act (42 U.S.C. 1395w–4(o)(4)).

[(B) The term "meaningful EHR user" has the meaning given such term under the Medicare EHR incentive programs.

[(C) The term "Medicare and Medicaid EHR incentive programs" means—

[(i) in the case of the Medicare program under title XVIII of the Social Security Act, the incentive programs under section 1814(l)(3), section 1848(o), sub-

sections (l) and (m) of section 1853, and section 1886(n) of the Social Security Act (42 U.S.C. 1395f(l)(3), 1395w–4(o), 1395w–23, 1395ww(n)); and

[(ii) in the case of the Medicaid program under title XIX of such Act, the incentive program under subsections (a)(3)(F) and (t) of section 1903 of such Act (42 U.S.C. 1396b).

[(D) The term "Secretary" means the Secretary of Health and Human Services.]

(c) GAO STUDIES AND REPORTS ON THE USE OF TELEHEALTH UNDER FEDERAL PROGRAMS AND ON REMOTE PATIENT MONITORING SERVICES.—

(1) STUDY ON TELEHEALTH SERVICES.—The Comptroller General of the United States shall conduct a study on the following:

(A) How the definition of telehealth across various Federal programs and Federal efforts can inform the use of telehealth in the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(B) Issues that can facilitate or inhibit the use of telehealth under the Medicare program under such title, including oversight and professional licensure, changing technology, privacy and security, infrastructure requirements, and varying needs across urban and rural areas.

(C) Potential implications of greater use of telehealth with respect to payment and delivery system transformations under the Medicare program under such title XVIII and the Medicaid program under title XIX of such Act (42 U.S.C. 1396 et seq.).

(D) How the Centers for Medicare & Medicaid Services monitors payments made under the Medicare program under such title XVIII to providers for telehealth services.

(2) STUDY ON REMOTE PATIENT MONITORING SERVICES.—

(A) IN GENERAL.—The Comptroller General of the United States shall conduct a study—

(i) of the dissemination of remote patient monitoring technology in the private health insurance market;

(ii) of the financial incentives in the private health insurance market relating to adoption of such technology;

(iii) of the barriers to adoption of such services under the Medicare program under title XVIII of the Social Security Act;

(iv) that evaluates the patients, conditions, and clinical circumstances that could most benefit from remote patient monitoring services; and

(v) that evaluates the challenges related to establishing appropriate valuation for remote patient monitoring services under the Medicare physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) in order to accurately reflect the resources involved in furnishing such services.

(B) DEFINITIONS.—For purposes of this paragraph:

(i) REMOTE PATIENT MONITORING SERVICES.—The term "remote patient monitoring services" means serv-

ices furnished through remote patient monitoring technology.

(ii) REMOTE PATIENT MONITORING TECHNOLOGY.—The term "remote patient monitoring technology" means a coordinated system that uses one or more home-based or mobile monitoring devices that automatically transmit vital sign data or information on activities of daily living and may include responses to assessment questions collected on the devices wirelessly or through a telecommunications connection to a server that complies with the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, as part of an established plan of care for that patient that includes the review and interpretation of that data by a health care professional.

(3) REPORTS.—Not later than 24 months after the date of the enactment of this Act, the Comptroller General shall submit to Congress—

(A) a report containing the results of the study conducted under paragraph (1); and

(B) a report containing the results of the study conducted under paragraph (2).

A report required under this paragraph shall be submitted together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate. The Comptroller General may submit one report containing the results described in subparagraphs (A) and (B) and the recommendations described in the previous sentence.

(d) RULE OF CONSTRUCTION REGARDING HEALTH CARE PROVIDERS.—

(1) IN GENERAL.—Subject to paragraph (3), the development, recognition, or implementation of any guideline or other standard under any Federal health care provision shall not be construed to establish the standard of care or duty of care owed by a health care provider to a patient in any medical malpractice or medical product liability action or claim.

(2) DEFINITIONS.—For purposes of this subsection:

(A) FEDERAL HEALTH CARE PROVISION The term "Federal health care provision" means any provision of the Patient Protection and Affordable Care Act (Public Law 111–148), title I or subtitle B of title II of the Health Care and Education Reconciliation Act of 2010 (Public Law 111–152), or title XVIII or XIX of the Social Security Act (42 U.S.C. 1395 et seq., 42 U.S.C. 1396 et seq.).

(B) HEALTH CARE PROVIDER.—The term "health care provider" means any individual, group practice, corporation of health care professionals, or hospital—

(i) licensed, registered, or certified under Federal or State laws or regulations to provide health care services; or

(ii) required to be so licensed, registered, or certified but that is exempted by other statute or regulation.

(C) MEDICAL MALPRACTICE OR MEDICAL PRODUCT LIABILITY ACTION OR CLAIM.—The term "medical malpractice or medical product liability action or claim" means a medical malpractice action or claim (as defined in section 431(7) of the Health Care Quality Improvement Act of 1986 (42 U.S.C. 11151(7))) and includes a liability action or claim relating to a health care provider's prescription or provision of a drug, device, or biological product (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) or section 351 of the Public Health Service Act (42 U.S.C. 262)).

(D) STATE.—The term "State" includes the District of Columbia, Puerto Rico, and any other commonwealth, possession, or territory of the United States.

(3) NO PREEMPTION.—Nothing in paragraph (1) or any provision of the Patient Protection and Affordable Care Act (Public Law 111–148), title I or subtitle B of title II of the Health Care and Education Reconciliation Act of 2010 (Public Law 111–152), or title XVIII or XIX of the Social Security Act (42 U.S.C. 1395 et seq., 42 U.S.C. 1396 et seq.) shall be construed to preempt any State or common law governing medical professional or medical product liability actions or claims.

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