108TH CONGRESS
1ST SESSION

S. 2003

To amend the Public Health Service Act to promote higher quality health care and better health by strengthening health information, information infrastructure, and the use of health information by providers and patients.

IN THE SENATE OF THE UNITED STATES

DECEMBER 9, 2003

Mrs. CLINTON introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend the Public Health Service Act to promote higher quality health care and better health by strengthening health information, information infrastructure, and the use of health information by providers and patients.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Health Information for Quality Improvement Act''.

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

SEC. 2. FINDINGS AND PURPOSE.

(a) FINDINGS.—Congress makes the following findings:

(1) In spite of the best intentions of clinicians and patients, the United States health care system

is plagued with underuse, overuse, and misuse. Only about 50 percent of health care treatments of services that are known to be effective are provided. At the same time, only 20 percent of the treatments and services that are provided are supported by scientific evidence.

(2) The pace of the dissemination of new evidence relating to appropriate health care treatments and services is shockingly slow. It may take up to 15 years for treatments found to be effective to become common practice.

(3) These problems cannot be redressed until the United States has the right information and that information is provided to the right people at the right time.

(b) PURPOSE.—It is the purpose of this Act to promote higher quality health care and better health by strengthening health information, its infrastructure, and its use by clinicians and consumers.

TITLE I—INFORMATION TECHNOLOGY

SEC. 101. INFORMATION INFRASTRUCTURE IMPROVEMENT.

(a) IN GENERAL.—Part B of title IX of the Public Health Service Act (42 U.S.C. 299b et seq) is amended by adding at the end the following:

"SEC. 918. NATIONAL HEALTHCARE INFORMATION INFRASTRUCTURE.

''(a) IN GENERAL.—By not later than 6 months after the date of the enactment of this Act, the Secretary shall establish within the Office of the Secretary an Office of National Healthcare Information Infrastructure (in this section referred to as the 'Office'). The Office shall be headed by a Director who shall report directly to the Secretary and who shall be responsible for providing ongoing national leadership in the planning, development, and adoption of a national healthcare information infrastructure. The Office shall, in cooperation with key stakeholders, develop a strategic plan to create a comprehensive national healthcare information infrastructure that encompasses public-sector and private-sector health information activities, and that includes a national agenda to guide policymaking, technology investments, research, and integration with ongoing health care and health care information technology activities.

''(b) GOALS.—The goals of the national healthcare information infrastructure are—

''(1) to maximize positive outcomes in clinical care;

''(2) to minimize preventable medical errors, especially in hospitals and in the administration of contraindicated drugs;

''(3) to reduce redundant paperwork, such as the repeated taking of patient histories;

''(4) to decrease costs from duplicative or otherwise unnecessary testing or procedures; and

''(5) to establish a compatible information technology architecture that facilitates future quality and cost-saving needs and that avoids the financing and development of information technology systems that are not readily compatible.

''(c) COLLABORATION WITH STAKEHOLDERS.—

''(1) IN GENERAL.—The Secretary shall assure that activities of the Department of Health and Human Services that relate to the national healthcare information infrastructure are undertaken after consultation with and based on the recommendations of the parties described in paragraph (3).

''(2) PERIODIC MEETINGS.—The Secretary, through the Office, shall convene as a group the parties described in paragraph (3). Such group shall meet periodically and collaborate to make recommendations to the Office and the Secretary on the matters described in subsection (d).

''(3) PARTIES REPRESENTED.—The parties described in this paragraph are the following:

''(A) The National Committee on Vital and Health Statistics.

''(B) Experts from the fields of healthcare information, information technology, medical continuous quality improvement, and medical records security and privacy.

''(C) Representatives from individual and institutional health care clinical providers, including teaching hospitals, children's hospitals, and small hospitals.

''(D) Clinical and health services researchers.

''(E) Health care purchasers.

''(F) One or more representatives of clinical professional societies or associations.

''(G) Representatives of private organizations with expertise in medical informatics.

''(H) One or more representatives of patient groups.

''(I) One ore more representatives from State or local public health departments.

''(J) One or more representatives of the health care information technology industry and national alliances formed to achieve standards-based health care information systems.

''(K) Appropriate staff experts from Federal agencies, including those within the Department of Health and Human Services and the Department of Veterans Affairs.

''(d) DUTIES.—In carrying out subsection (a), the Office shall make recommendations to and advise the Secretary on the following, in order to promote the goals described in subsection (b):

''(1)(A) An assessment of the best current practices in the development, purchase, and maintenance of medical information technology.

''(B) Recommendations, and the specifications, for a uniform healthcare information system interface, and methods for its adoption (not later than 2 years after the date of the enactment of this Act) to ensure compatibility between and among old and new information systems.

''(C) Recommendations for health care data standards (such as vocabulary and messaging), communications standards, and other medical standards (including a common lexicon) necessary to achieve the interoperability of healthcare information systems.

''(2) Coordination of the evolution of the national healthcare information infrastructure and

working with other key stakeholders in the public and private sectors to develop a strategic plan that will ensure the interoperability of all elements of such infrastructure.

''(3) Coordination of spending across Federal agencies relating to the establishment of such infrastructure.

''(4) Development of policies to ensure compliance with the security and confidentiality standards of this part C for protected health information and promote patient control of protected health information.

''(5) Ensure thorough testing of data and communications standards prior to their adoption.

''(e) DETAIL OF FEDERAL EMPLOYEES.—Upon the request of the Secretary, the head of any Federal agency is authorized to detail, 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. Any such detail shall not interrupt or otherwise affect the civil service status or privileges of the Federal employee.

''SEC. 919. DATA AND COMMUNICATIONS STANDARDS FOR INTEROPERABILITY.

''(a) IN GENERAL.—By not later than 2 years after the date of the enactment of this Act, the Secretary shall

as needed adopt (and shall periodically review, update, and expand) a set of voluntary, national data and communications standards that promote the interoperability of health care information technology systems across all public and private health care settings. In adopting such standards, the Secretary shall ensure that such standards are designed and are carefully monitored to ensure that linkage of data resulting from such interoperability does not compromise privacy and security. The Secretary shall take into account—

''(1) the ability of such standards to enable clinically-specific data collection in order to promote evidence-based medicine and the electronic exchange of patient medical record information; and

''(2) the costs of compliance and the savings and other benefits from improved efficiency and quality in health care delivery.

''(b) REPORTS.—

''(1) INITIAL REPORT.—No later than 12 months after the date of the enactment of this Act, the Secretary shall submit to Congress a comprehensive national healthcare information infrastructure strategic plan that includes—

''(A) a survey of health care information technology standards being developed by private sector and public-private groups;

''(B) recommendations for accelerating the development of common health care vocabulary standards;

''(C) recommendations for completing development of health care information system messaging standards; and

''(D) progress toward meeting the deadline described in section 2(d)(1)(B) for adoption of methods described in such paragraph (relating to a uniform system interface).

''(2) SUBSEQUENT REPORTS.—During each of the 2 years after the year in which the report is submitted under paragraph (1), the Secretary shall submit to Congress an annual report relating to additional recommendations, best practices, results of information technology improvements, analyses of private sector efforts to implement the data and communications standards established under this section, and such other matters as may help ensure the most rapid dissemination of best practices in health care information technology.

''(c) CONTRACT AUTHORITY.—The Secretary is authorized—

''(1) to enter into contracts for services and activities necessary to carry out this section and section 918; and

''(2) to the extent practicable, to test the standards under consideration under this section.

''(d) DISSEMINATION.—The Secretary shall provide for the maintenance and dissemination of the standards developed and updated under this section.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out this section and section 918.

''SEC. 920. GRANTS TO HOSPITALS AND OTHER HEALTH CARE PROVIDERS FOR INFORMATION TECHNOLOGIES.

''(a) IN GENERAL.—The Secretary, in consultation with the Director of the Agency for Healthcare Research and Quality, shall award grants to hospitals and other health care providers (but not more than 1 such grant may be awarded to any 1 hospital or provider) to pay the costs of acquiring or implementing information technologies—

''(1) to improve quality of care and patient safety; and

''(2) to reduce adverse events and health care complications resulting from medication errors.

''(b) SPECIAL CONSIDERATIONS.—In awarding grants under subsection (a), the Secretary shall give special consideration to applicants who seek to promote the following:

''(1) Interoperability across hospital services or departments using standards referred to in section 919.

''(2) Electronic communication of patient data across the spectrum of health care delivery.

''(3) Computerized physician order entry or bar coding applications.

''(4) Electronic communication of patient data in hospitals that provide services to underserved or low-income populations.

''(5) Improved clinical decisionmaking through the acquisition and implementation of decision-support technologies.

''(6) The sharing by hospitals of electronic health records with patients.

''(c) CERTAIN GRANT CONDITIONS.—A condition for the receipt of a grant under subsection (a) is that the applicant involved meet the following requirements:

''(1) The applicant agrees—

''(A) to carry out a program to measure, analyze, and report patient safety and medical errors at the hospital or other health care provider involved to patient safety organizations;

''(B) to submit to the Secretary a description of the methodology that will be used for such program; and

''(C) to have such program in effect as soon as practicable after the application for the grant is approved, without regard to whether information technologies under the grant have been implemented.

''(2) The applicant has—

''(A) arranged for an evaluation that addresses the effectiveness and cost-effectiveness of the information technology for which the grant is provided and its impact on the quality and safety of patient care;

''(B) submitted the evaluation plan to the Secretary; and

''(C) received approval from the Secretary of the methodology described in the plan.

''(3) The applicant has or is developing a patient safety evaluation system for reporting health care errors to a patient safety organization.

''(4) The applicant agrees to provide the Secretary with such information as the Secretary may require regarding the use of funds under this program or its impact.

''(5) The applicant provides assurances satisfactory to the Secretary that any information technology planned, acquired, or implemented with grant funds under this section will be part of an information program that—

''(A) carries out the purposes described in subsection (a); and

''(B) is comprehensive or will be expanded to become comprehensive, regardless of whether Federal assistance is available for such expansion.

''(d) TECHNICAL ASSISTANCE TO GRANTEES.—The Secretary, acting through the Director, shall provide technical assistance to applicants and grantees to ensure the appropriate evaluation of the information technologies for which grants are awarded under this section, such as—

''(1) reviewing and providing technical assistance on the applicant's proposed evaluation;

''(2) developing mechanisms to ensure ongoing communications between grantees and evaluators to facilitate the identification and resolution of prob-

lems as they arise, ensure mutual learning, and promote the rapid dissemination of information;

''(3) reviewing the interim and final reports required under subsection (e); and

''(4) disseminating evidence-based information in interim and final reports to patient safety organizations, as appropriate.

''(e) EVALUATION REPORTS BY GRANTEE.—

''(1) IN GENERAL.—A condition for the receipt of a grant under subsection (a) is that the applicant agree to submit an interim and a final report to the Secretary in accordance with this subsection.

''(2) INTERIM REPORT.—Not later than 1 year after the implementation of information technologies under a grant under this section is completed, the applicant shall submit an interim report to the Secretary describing the initial effectiveness of such technologies in carrying out the purposes described in subsection (a).

''(3) FINAL REPORT.—Not later than 3 years after the implementation of information technologies under a grant under this section is completed, the applicant shall submit a final report to the Secretary describing the effectiveness and cost-effectiveness of such technologies and addressing other issues deter-

mined to be important in carrying out the purposes described in subsection (a).

''(4) RELATION TO DISBURSEMENT OF GRANT.—In making payments under a grant under subsection (a), the Secretary shall withhold ⅓ of the amount of the grant until the grantee submits to the Secretary the report required under paragraph (2).

''(f) REPORTS BY THE SECRETARY.—

''(1) INTERIM REPORTS.—

''(A) IN GENERAL.—Through the fiscal year preceding the fiscal year in which the final report under paragraph (2) is prepared, 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 periodic reports on the grant program under subsection (a). Such reports shall be submitted not less frequently than once each fiscal year, beginning with fiscal year 2004.

''(B) CONTENTS.—A report under subparagraph (A) shall include information on—

''(i) the number of grants awarded;

''(ii) the nature of the projects for which funding is provided under the grant program;

''(iii) the geographic distribution of grant recipients; and

''(iv) such other matters as the Secretary determines appropriate.

''(2) FINAL REPORT.—Not later than 180 days after the date on which the last of the reports is due under subsection (e)(3), the Secretary shall submit a final report to the committees referred to in paragraph (1)(A) on the grant program under subsection (a), together with such recommendations for legislation and administrative action as the Secretary determines appropriate.

''(g) DEFINITIONS.—In this section:

''(1) COSTS.—The term 'costs', with respect to information technologies referred to in subsection (a), includes total expenditures incurred for—

''(A) purchasing, leasing, and installing computer software and hardware, including hand-held computer technologies;

''(B) making improvements to existing computer software and hardware; and

''(C) purchasing or leasing communications capabilities necessary for clinical data access, storage, and exchange.

''(2) HEALTH CARE PROVIDER.—The term 'health care provider' includes a physician or other health care professional, as well as an institutional or other facility or agency that provides health care services and that is licensed, accredited, or certified to provide health care items and services under applicable State law.

''(h) TERMINATION OF GRANT AUTHORITIES.—The authority of the Secretary to award grants under subsection (a) terminates upon the expiration of fiscal year 2011.

''(i) MATCHING FUNDS.—

''(1) IN GENERAL.—With respect to the costs of a grant to be carried out under this section, such grant may be made only if the applicant agrees to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 50 percent of such costs ($1 for each $1 of Federal funds provided under the grant).

''(2) DETERMINATION OF AMOUNTS CONTRIBUTED.—Amounts provided by the Federal Govern-

ment, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

''(j) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $20,000,000 for each of fiscal years 2004 and 2005.''.

(b) UNDERSTANDING BARRIERS TO INFORMATION TECHNOLOGY ADOPTION AND EFFECTIVE USE.—Section 914(a) of the Public Health Service Act (42 U.S.C. 299b–3(a)) is amended—

(1) in paragraph (6), by striking ''and'' at the end;

(2) in paragraph (7), by striking the period and inserting ''; and''; and

(3) by adding at the end the following:

''(8) and understand the barriers to information technology adoption and effective use as well as methods to overcome those barriers.''.

SEC. 102. IMPROVING CLINICAL PRACTICE AND REDUCING BARRIERS TO INFORMATION TECHNOLOGY.

(a) IMPROVING CLINICAL PRACTICES.—

(1) TELEMEDICINE.—

(A) LICENSING.—Section 1834(m)(4)(C)(i) of the Social Security Act (42 U.S.C. 1395m(m)(4)(C)(i)) is amended—

(i) in subclause (II), by striking ''or'' at the end;

(ii) in subclause (III), by striking the period and inserting ''; or''; and

(iii) by adding at the end the following:

''(IV) in a State in which the respective State medical board has adopted a formal policy regarding licensing or certification requirements for providers at distant sites who do not have a license to practice medicine at the originating site.''.

(B) EXPANDING ELIGIBILITY FOR REIMBURSEMENT.—Section 1834(m)(4)(C)(i)(I) (42 U.S.C. 1395m(m)(4)(C)(i)(I)) is amended by striking ''rural''.

(2) CLINICAL TRIALS FOR INFORMATION AND SYSTEMS TECHNOLOGY IN ADDITION TO MEDICAL TECHNOLOGY.—

(A) FINDINGS.—Congress makes the following findings:

(i) An estimated 80,000 to 100,000 patients die every year from errors suffered during hospitalization.

(ii) Many of these errors could have been avoided with changes to the system of health care delivery.

(iii) These systemwide changes have the potential to decrease the cost of providing health care and to increase the quality of services provided.

(iv) These improvements in cost and quality can be as dramatic as improvements seen with new medical technology or pharmaceutical advances.

(v) Currently new medical devices and medications undergo rigorous randomized controlled clinical trials to document their effect on a patient's health.

(vi) These clinical trials form the basis for providers to practice evidence-based medicine and to change their practices to improve their patients' outcomes.

(vii) Similar controlled clinical studies of new information technologies and systems-based approaches to changing prac-

tice can help providers implement systems-based measures to improve outcomes.

(B) RESEARCH ON INFORMATION TECHNOLOGY AND OTHER SYSTEMS-BASED APPROACHES TO CHANGING CLINICAL PRACTICE.—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. 409J. RESEARCH ON INFORMATION TECHNOLOGY AND OTHER SYSTEMS-BASED APPROACHES TO CHANGING CLINICAL PRACTICE.

''(a) ESTABLISHMENT.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality and in collaboration with the Director of NIH, shall establish a Medical Systems Safety Initiative (referred to in this section as the 'Initiative') to conduct and support research regarding information technology and other systems-based approaches to improving and advancing medical care.

''(b) PURPOSE.—The purpose of the Initiative is to enable the Director of the Agency for Healthcare Research and Quality and the Director of NIH—

''(1) to conduct and support research (including both intramural and extramural research), research training, the dissemination of health information,

and other programs with respect to systems research, user-centered design, and human factors engineering (including research related to information technology) to realize the expanding opportunities for improving health outcomes through the analysis and redesign of medical systems;

''(2) to enhance collaborative efforts among Federal agencies to conduct and support multidisciplinary research in the areas that the Director determines to be most promising; and

''(3) to encourage and support studies, including clinical studies, to provide scientifically and statistically rigorous and meaningful information about the utility and effectiveness of various systems-based interventions, including information technology developments.

''(c) APPROPRIATE SCIENTIFIC EXPERTISE AND COORDINATION WITH FEDERAL AGENCIES.—The Director of the Agency for Healthcare Research and Quality and the Director of NIH shall ensure that scientists with appropriate expertise in research on health systems, information technology, user-centered design, and human factors engineering are incorporated into the review, oversight, and management processes of all research projects and other activities funded by the Initiative. In carrying out

this subsection, the Directors, as necessary, may establish review groups with appropriate scientific expertise. The Directors shall coordinate efforts with other Federal agencies to ensure appropriate scientific input and management.

''(d) DEFINITIONS.—In this section:

''(1) HUMAN FACTORS ENGINEERING.—The term 'human factors engineering' means the study and optimization of the interaction of humans, machines, and the environment to achieve the performance objectives of a given health care workplace.

''(2) SYSTEMS RESEARCH.—The term 'systems research' means research into the organization and design of the work environment within a health care setting, and their effects on health outcomes, as well as research to improve such designs so as to improve health outcomes.''.

(b) IMPROVING AND PROMOTING ELECTRONIC HEALTH RECORDS.—

(1) AUTHENTICATION STANDARDS.—The Director of the National Center for Vital and Health Statistics shall provide assistance to the Secretary of Health and Human Services in the development of authentication standards for health records. In de-

veloping such standards, the Secretary shall take into consideration the following:

(A) Recommendations for authentication technology and identification information standards that—

(i) provide for the reliable identification and retrieval of a patient's electronic health data;

(ii) allow the patient to have detailed control over the access of individual components of his or her electronic health record by being able to specify specific providers, each of whom will have access to limited portions of the electronic health record;

(iii) minimize security risks, including the potential for—

(I) the patient to misrepresent his or her true identity;

(II) a health care provider to access data for which the patient has not consented to grant such access;

(III) a third party to access identification information; or

(IV) a third party to circumvent or exploit the authentication process in order to access electronic health data without the consent of the patient;

(iv) allow for the timely and convenient creation of identification information at the time of contact between a patient and a provider, so as to minimize any disruption or delay in the provision of needed medical services to a patient who does not already have identification information; and

(v) maximize the probability of accurate identification, secure authentication, and rapid access to health data even in situations where the patient—

(I) does not possess the identification information that is usually required for successful authentication, but wishes to grant consent to the provider to access necessary health data;

(II) possesses the identification information but is not able to provide

consent for the emergency access of health data due to incapacitation; and

(III) is not able to provide identification information nor consent for emergency data access due to incapacitation.

(2) FRAUD AND ABUSE.—Section 1128D of the Social Security Act (42 U.S.C. 1320a–7d) is amended—

(1) in subsection (a)(2), by adding at the end the following:

''(J) The arrangements and information exchange allowed for the purposes of promoting the use of electronic health records, including personal health records.''; and

(2) in subsection (b)(2), by adding at the end the following:

''(F) Whether the arrangements and information exchange allowed for the purposes of promoting the use of electronic health records, including personal health records achieve their purposes.''.

(3) PERSONAL HEALTH RECORD.—

(A) FEDERAL HEALTH INFORMATION EXCHANGE STANDARDS INITIATIVE.—The Sec-

retary of Health and Human Services, the Secretary of Defense, and the Secretary of Veterans' Affairs, in carrying out activities under the Federal e-Goverment Health Information Exchange Standards Initiative, shall develop, implement, and evaluate procedures and methods to enable patients to access and append to their personal health data through personal health records that—

(i) include the capability for patients to append to their electronic record information about—

(I) illnesses for which the patient did not seek professional medical care;

(II) health information not related to a specific disease, episode, or illness; and

(III) information related to the correction of errors of omission and commission; and

(ii) permit patients convenient access to their full electronic medical record and permit them to share data with their providers.

(B) MEDICAL TRANSLATION RESEARCH.—

(i) IN GENERAL.—The Director of the Agency for Healthcare Research and Quality shall award grants to public and nonprofit private entities for the conduct of research on innovative approaches to improve patients' understanding and comprehension of their electronic health record. Research areas may include technology for the automated—

(I) translation of medical information to improve patient comprehension;

(II) reorganization of the electronic health record for improved utility for the patient; and

(III) integration of links to relevant information from other sources into the electronic health record.

(ii) MERIT REVIEW; COMPETITION.—Grants shall be awarded under this subparagraph on a merit-reviewed competitive basis.

(iii) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Agency for Healthcare Re-

search and Quality to carry out this subparagraph $5,000,000 for fiscal year 2004, and such sums as may be necessary for each fiscal year thereafter.

(3) DEFINITIONS.—In this subsection:

(A) IDENTIFICATION INFORMATION.—The term ''identification information'' with respect to the health records of a patient, means any data necessary to reliably associate a patient with their health data.

(B) AUTHENTICATION.—The term ''authentication'' means the process of using the identification information to validate the patient's identification and gain access to his or her electronic health data.

(c) IMPROVING INFORMATION TECHNOLOGY INFRASTRUCTURE IN THE BASIC LIFE SCIENCES.—Not later than 18 months after the date of enactment of this Act, the Director of the National Institute of General Medical Sciences shall submit to Congress a report on the activities of the Biomedical Information Science and Technology Initiative. Such report shall include—

(1) a description of current activities of the Biomedical Information Science and Technology Initiative Consortium;

(2) a summary of recently completed and ongoing grant programs; and

(3) recommendations for the further advancement of the Biomedical Information Science and Technology Initiative and bioinformatics and computational biology research in general.

(d) ELECTRONIC BILLING.—

(1) IN GENERAL.—The Director of the Centers for Medicare & Medicaid Services shall conduct a demonstration project to test and evaluate a process to certify software programs that analyze medical records or other health care provider documentation to determine appropriate billing categories for each medicare billing criteria under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(2) USE OF APPROVED SOFTWARE.—If the Secretary of Health and Human Services determines—

(A) that a health care provider, physician, practitioner, or other supplier in good faith uses a software program that is certified under the project established under paragraph (1); and

(B) there is no indication of fraud or abuse committed by the provider, physician, practitioner, or supplier against the program under title XVIII of the Social Security Act;

the provider, physician, practitioner, or supplier shall not be subject to any penalty or interest under such title XVIII, or the provisions of title XI of such Act insofar as they relate to such title XVIII, relating to the provision of such items or service or such claim.

TITLE II—INCREASED EVIDENCE-BASE FOR QUALITY IMPROVEMENT AND MEASUREMENT

SEC. 201. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

(a) GROUP HEALTH PLANS.—

(1) PUBLIC HEALTH SERVICE ACT.—Subpart 2 of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–4 et seq.) is amended by adding at the end the following:

"SEC. 2707. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

''(a) COVERAGE.—

''(1) IN GENERAL.—If a group health plan, or a health insurance issuer that offers health insurance coverage in connection with a group health plan, provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer—

"(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

"(B) subject to subsections (b), (c), and (d) may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

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

"(2) EXCLUSION OF CERTAIN COSTS.—

"(A) IN GENERAL.—For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services provided in the clinical trial that are otherwise generally available to the qualified individual, except—

"(i) in the cases of drugs and devices, the investigational item or service, itself; or

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

"(B) EXCLUSION.—Such routine patient costs do include costs for the following:

"(i) CONVENTIONAL CARE.—Items or services that are typically provided absent a clinical trial.

"(ii) ADMINISTRATIVE ITEMS.—Items or services required solely for the provision of the investigational item or service, the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.

"(iii) REASONABLE AND NECESSARY CARE.—Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, including the diagnosis or treatment of complications.

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

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

''(1)(A) The individual has a life-threatening or serious illness for which no standard treatment is effective.

''(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

''(C) The individual's participation in the trial offers meaningful potential for significant clinical benefit for the individual.

''(2) Either—

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

''(B) the participant, beneficiary, or enrollee provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based

upon the individual meeting the conditions described in paragraph (1).

''(c) PAYMENT.—

''(1) IN GENERAL.—Under this section a group health plan, and a health insurance issuer that offers health insurance coverage in connection with a group health plan, shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are reasonably expected to be paid for by the sponsors of an approved clinical trial.

''(2) PAYMENT RATE.—In the case of covered items and services provided by—

''(A) a participating provider, the payment rate shall be at the agreed upon rate; or

''(B) a nonparticipating provider, the payment rate shall be at the rate the plan or issuer would normally pay for comparable services under subparagraph (A).

''(d) APPROVED CLINICAL TRIAL DEFINED.—

''(1) IN GENERAL.—In this section, the term 'approved clinical trial' means a clinical research study or clinical investigation and is described in any of the following subparagraphs:

"(A) FEDERALLY FUNDED TRIALS.—The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

"(i) NIH.—The National Institutes of Health.

"(ii) CDC.—The Centers for Disease Control and Prevention.

"(iii) AHRQ.—The Agency for Health Care Research and Quality.

"(iv) CMS.—The Center for Medicare & Medicaid Services.

"(v) COOPERATIVE CENTER.—A cooperative group or center of any of the entities described in clauses (i) through (iv) or the Departments of Defense or Veterans Affairs.

"(vi) CENTER SUPPORT GRANTEES.—A qualified nongovernmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

"(vii) DOD; VA; DOE.—Any of the following if the conditions described in paragraph (2) are met:

''(I) The Department of Veterans Affairs.

''(II) The Department of Defense.

''(III) The Department of Energy.

''(B) FDA DRUG TRIAL UNDER IND.—The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

''(C) EXEMPT DRUG TRIAL.—The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

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

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

''(B) assures unbiased review of the highest scientific standards by qualified individuals

who have no interest in the outcome of the review.

''(e) CONSTRUCTION.—Nothing in this section shall be construed to preclude a plan or issuer from offering coverage that is broader than the coverage required under this section with respect to clinical trials.''.

(2) ERISA AMENDMENTS.—

(A) IN GENERAL.—Subpart B of put 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185 et seq.) is amended by adding at the end the following:

''SEC. 714. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

''(a) COVERAGE.—

''(1) IN GENERAL.—If a group health plan, or a health insurance issuer that offers health insurance coverage in connection with a group health plan, provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer—

''(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

"(B) subject to subsections (b), (c), and (d) may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

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

"(2) EXCLUSION OF CERTAIN COSTS.—

"(A) IN GENERAL.—For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services provided in the clinical trial that are otherwise generally available to the qualified individual, except—

"(i) in the cases of drugs and devices, the investigational item or service, itself; or

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

"(B) EXCLUSION.—Such routine patient costs do include costs for the following:

"(i) CONVENTIONAL CARE.—Items or services that are typically provided absent a clinical trial.

"(ii) ADMINISTRATIVE ITEMS.—Items or services required solely for the provision of the investigational item or service, the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.

"(iii) REASONABLE AND NECESSARY CARE.—Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, including the diagnosis or treatment of complications.

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

"(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term 'qualified individual'

means an individual who is a participant or beneficiary in a group health plan or an enrollee in health insurance coverage and who meets the following conditions:

''(1)(A) The individual has a life-threatening or serious illness for which no standard treatment is effective.

''(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

''(C) The individual's participation in the trial offers meaningful potential for significant clinical benefit for the individual.

''(2) Either—

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

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

''(c) PAYMENT.—

''(1) IN GENERAL.—Under this section a group health plan, and a health insurance issuer that offers health insurance coverage in connection with a group health plan, shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are reasonably expected to be paid for by the sponsors of an approved clinical trial.

''(2) PAYMENT RATE.—In the case of covered items and services provided by—

''(A) a participating provider, the payment rate shall be at the agreed upon rate; or

''(B) a nonparticipating provider, the payment rate shall be at the rate the plan or issuer would normally pay for comparable services under subparagraph (A).

''(d) APPROVED CLINICAL TRIAL DEFINED.—

''(1) IN GENERAL.—In this section, the term 'approved clinical trial' means a clinical research study or clinical investigation and is described in any of the following subparagraphs:

''(A) FEDERALLY FUNDED TRIALS.—The study or investigation is approved or funded

(which may include funding through in-kind contributions) by one or more of the following:

"(i) NIH.—The National Institutes of Health.

"(ii) CDC.—The Centers for Disease Control and Prevention.

"(iii) AHRQ.—The Agency for Health Care Research and Quality.

"(iv) CMS.—The Center for Medicare & Medicaid Services.

"(v) COOPERATIVE CENTER.—A cooperative group or center of any of the entities described in clauses (i) through (iv) or the Departments of Defense or Veterans Affairs.

"(vi) CENTER SUPPORT GRANTEES.—A qualified nongovernmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

"(vii) DOD; VA; DOE.—Any of the following if the conditions described in paragraph (2) are met:

"(I) The Department of Veterans Affairs.

''(II) The Department of Defense.

''(III) The Department of Energy.

''(B) FDA DRUG TRIAL UNDER IND.—The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

''(C) EXEMPT DRUG TRIAL.—The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

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

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

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

''(e) CONSTRUCTION.—Nothing in this section shall be construed to preclude a plan or issuer from offering coverage that is broader than the coverage required under this section with respect to clinical trials.''.

(B) TECHNICAL AMENDMENT.—Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191a(a)) is amended by striking ''section 711'' and inserting ''sections 711 and 714''.

(C) TABLE OF CONTENTS.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by inserting after the item relating to section 713 the following new item:

''Sec. 714. Coverage for individuals participating in approved cancer clinical trials.''.

(3) INTERNAL REVENUE CODE OF 1986.—

(A) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended—

(i) in the table of sections, by inserting after the item relating to section 9812 the following new item:

''Sec. 9813. Coverage for individuals participating in approved clinical trials.'';

and

(ii) by inserting after section 9812 the following:

"SEC. 9813. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

"(a) COVERAGE.—

"(1) IN GENERAL.—If a group health plan provides coverage to a qualified individual (as defined in subsection (b)), the plan—

"(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

"(B) subject to subsections (b), (c), and (d) may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

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

"(2) EXCLUSION OF CERTAIN COSTS.—

"(A) IN GENERAL.—For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services provided in the clinical trial that are otherwise

generally available to the qualified individual, except—

"(i) in the cases of drugs and devices, the investigational item or service, itself; or

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

"(B) EXCLUSION.—Such routine patient costs do include costs for the following:

"(i) CONVENTIONAL CARE.—Items or services that are typically provided absent a clinical trial.

"(ii) ADMINISTRATIVE ITEMS.—Items or services required solely for the provision of the investigational item or service, the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.

"(iii) REASONABLE AND NECESSARY CARE.—Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, including the diagnosis or treatment of complications.

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

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

''(1)(A) The individual has a life-threatening or serious illness for which no standard treatment is effective.

''(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

''(C) The individual's participation in the trial offers meaningful potential for significant clinical benefit for the individual.

''(2) Either—

''(A) the referring physician is a participating health care professional and has concluded that the individual's participation in

such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

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

''(c) PAYMENT.—

''(1) IN GENERAL.—Under this section a group health plan shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are reasonably expected to be paid for by the sponsors of an approved clinical trial.

''(2) PAYMENT RATE.—In the case of covered items and services provided by—

''(A) a participating provider, the payment rate shall be at the agreed upon rate; or

''(B) a nonparticipating provider, the payment rate shall be at the rate the plan would normally pay for comparable services under subparagraph (A).

''(d) APPROVED CLINICAL TRIAL DEFINED.—

''(1) IN GENERAL.—In this section, the term 'approved clinical trial' means a clinical research study or clinical investigation and is described in any of the following subparagraphs:

''(A) FEDERALLY FUNDED TRIALS.—The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

''(i) NIH.—The National Institutes of Health.

''(ii) CDC.—The Centers for Disease Control and Prevention.

''(iii) AHRQ.—The Agency for Health Care Research and Quality.

''(iv) CMS.—The Center for Medicare & Medicaid Services.

''(v) COOPERATIVE CENTER.—A cooperative group or center of any of the entities described in clauses (i) through (iv) or the Departments of Defense or Veterans Affairs.

''(vi) CENTER SUPPORT GRANTEES.—A qualified nongovernmental research entity identified in the guidelines issued by the

National Institutes of Health for center support grants.

''(vii) DOD; VA; DOE.—Any of the following if the conditions described in paragraph (2) are met:

''(I) The Department of Veterans Affairs.

''(II) The Department of Defense.

''(III) The Department of Energy.

''(B) FDA DRUG TRIAL UNDER IND.—The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

''(C) EXEMPT DRUG TRIAL.—The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

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

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

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

''(e) CONSTRUCTION.—Nothing in this section shall be construed to preclude a plan from offering coverage that is broader than the coverage required under this section with respect to clinical trials.''.

(b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—Part B of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–41 et seq.) is amended—

(1) by redesignating the first subpart 3 (relating to other requirements) as subpart 2; and

(2) by adding at the end of subpart 2 the following:

''SEC. 2753. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

''The provisions of section 2707 shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as they apply to health insurance coverage offered by a health insurance

issuer in connection with a group health plan in the small or large group market.''.

(c) EFFECTIVE DATES.—

(1) GROUP HEALTH PLANS.—Subject to paragraph (3), the amendments made by subsection (a) apply with respect to group health plans for plan years beginning on or after January 1, 2004.

(2) INDIVIDUAL HEALTH INSURANCE COVERAGE.—The amendments made by subsection (b) apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after January 1, 2004.

(3) COLLECTIVE BARGAINING EXCEPTION.—In the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and 1 or more employers ratified before the date of enactment of this Act, the amendments made by subsection (a) shall not apply to plan years beginning before the later of—

(A) the date on which the last collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of enactment of this Act); or

(B) January 1, 2004.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by subsection (a) shall not be treated as a termination of such collective bargaining agreement.

(d) COORDINATION OF ADMINISTRATION.—The Secretary of Labor, the Secretary of the Treasury, and the Secretary of Health and Human Services shall ensure, through the execution of an interagency memorandum of understanding among such Secretaries, that—

(1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which two or more such Secretaries have responsibility under the provisions of this section (and the amendments made thereby) are administered so as to have the same effect at all times; and

(2) coordination of policies relating to enforcing the same requirements through such Secretaries in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement.

(e) STUDY AND REPORT.—

(1) STUDY.—The Secretary of Health and Human Services, jointly with the Secretary of Labor and the Secretary of the Treasury, shall study the impact on group health plans and health insurance issuers for covering routine patient care costs for individuals who are entitled to benefits under this section and who are enrolled in an approved clinical trial program.

(2) REPORT.—Not later than January 1, 2006, the Secretary of Health and Human Services shall submit a report to Congress that contains an assessment of—

(A) any incremental cost to group health plans and health insurance issuers resulting from the provisions of this section;

(B) a projection of expenditures to such plans and issuers resulting from this section;

(C) any impact on premiums resulting from this section; and

(D) any impact on the ability of health plans to make coverage decisions in a more timely fashion.

SEC. 202. GRANTS FOR PRIMARY CARE RESEARCH FOR OLDER PATIENTS.

Part B of title IX of the Public Health Service Act (42 U.S.C. 299b et seq.), as amended by section 101, is further amended by adding at the end the following:

"SEC. 920A. GRANTS FOR PRIMARY CARE RESEARCH FOR OLDER PATIENTS.

''(a) IN GENERAL.—The Director shall award grants to public and nonprofit private entities for primary care research relating to older patients with multiple chronic conditions to gather information on how best to care for such patients.

''(b) FOCUS.—In awarding grants under subsection (a), the Director shall ensure that research is focused on the population of individuals who are 65 years of age and older.

''(c) REQUIREMENTS.—Research conducted under a grant under this section shall—

''(1) examine the role of disease-specific guidelines in the population described in subsection (a);

''(2) examine the feasibility of developing guidelines that focus on the interaction of diseases and conditions; and

''(3) investigate appropriate outcomes of care to be considered in evaluating the quality of care for

such population, including outcomes from the perspective of patients, families, and clinicians.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $10,000,000 for fiscal year 2004, and such sums as may be necessary for each fiscal year thereafter.''.

SEC. 203. STUDY ON EFFECTIVENESS OF CERTAIN PRESCRIPTION DRUGS.

(a) IN GENERAL.—

(1) RESEARCH BY NIH.—The Director of the National Institutes of Health, in coordination with the Director of the Agency for Healthcare Research and Quality and the Commissioner of Food and Drugs, shall conduct research, which may include clinical research, to develop valid scientific evidence regarding the comparative effectiveness and, where appropriate, comparative safety of covered prescription drugs relative to other drugs and treatments for the same disease or condition.

(2) ANALYSIS BY THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY.—

(A) IN GENERAL.—The Agency for Healthcare Research and Quality, taking into consideration the research and data from the National Institutes of Health and the Food and

Drug Administration, shall use evidence-based practice centers to synthesize available data or conduct other analyses of the comparative effectiveness and, where appropriate, comparative safety of covered prescription drugs relative to other drugs and treatments for the same disease or condition.

(B) SAFETY.—In any analysis of comparative effectiveness under this subparagraph, the Institute of Medicine shall include a discussion of available information on relative safety.

(3) STANDARDS.—The Director of the Agency for Healthcare Research and Quality, in consultation with the Commissioner of Food and Drugs, the Director of the National Institutes of Health, and with input from stakeholders, shall develop standards for the design and conduct of studies under this subsection.

(b) COVERED PRESCRIPTION DRUGS.—For purposes of this section, the term ''covered prescription drugs'' means prescription drugs that, as determined by the Director of the Agency for Healthcare Research and Quality in consultation with the Administrator of the Centers for Medicare & Medicaid Services, the Secretary of Defense, and the Secretary of Veterans Affairs, account for high

levels of use or high levels of risk to individuals in federally funded health programs, including Medicare and Medicaid.

(c) DISSEMINATION.—

(1) BIENNIAL REPORT.—Every 2 years, the Secretary shall prepare a report on the progress and results, if available, of the research, studies, and analyses conducted by the National Institutes of Health and the Agency for Healthcare Research and Quality, and the Food and Drug Administration under this section and submit the report to the following:

(A) Congress.

(B) The President.

(C) The Secretary of Defense.

(D) The Secretary of Veterans Affairs.

(2) REPORTS FOR PRACTITIONERS AND PATIENTS.—As soon as possible, but not later than a year after the completion of any study pursuant to subsection (a)(2), the Director of the Agency for Healthcare Research and Quality shall—

(A) prepare a report on the results of such study for the purpose of informing health care practitioners and patients; and

(B) transmit the report to the Director of the National Institutes of Health.

(3) FDA DRUG INFORMATION.—The Commissioner of Food and Drugs shall—

(A) review all data and information from studies and analyses conducted or prepared under this section; and

(B) when determined appropriate by the Commissioner, develop summaries of such information for inclusion in adequate directions for use under section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act and in summaries relating to side effects, contraindications, and effectiveness under section 502(n) of that Act.

(4) NIH INTERNET SITE.—The Director of the National Institutes of Health shall publish on the Institutes' Internet site and through other means that will facilitate access by practitioners and patients each report prepared under this subsection by the Director of the Agency for Healthcare Research and Quality.

(d) EVIDENCE.—In carrying out this section, the Director of the National Institutes of Health and the Agency for Healthcare Research and Quality shall consider only

methodologically sound studies, giving preference to studies for which the Directors have access to sufficient underlying data and analysis to address any significant concerns about methodology or the reliability of data.

(e) AUTHORIZATIONS OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $75,000,000 for fiscal year 2004, and such sums as may be necessary for each fiscal year thereafter.

TITLE III—MEASURING AND COMPARING QUALITY

SEC. 301. PRIORITY AREA QUALITY INDICATORS.

Part B of title IX of the Public Health Service Act (42 U.S.C. 299b et seq.), as amended by section 201, is further amended by adding at the end the following:

"SEC. 920B. PRIORITY AREA QUALITY INDICATORS.

''(a) IN GENERAL.—The Director, in consultation with the Quality Interagency Coordination Task Force, the Institute of Medicine, the Joint Commission on Accreditation of Healthcare Organizations, the National Committee for Quality Assurance, the American Health Quality Association, the National Quality Forum, the Medicare Payment Advisory Committee, and other individuals and organizations determined appropriate by the Secretary, shall assemble, evaluate, and, where necessary, develop or update quality indicators for each of the 20 pri-

ority areas for improvement in health care quality as identified by the Institute of Medicine in their report entitled 'Priority Areas for National Action' in 2003, or other such areas as identified by the Secretary in order to assist beneficiaries in making informed choices about health plans or care delivery systems, and make such indicators available for purchasers to develop or align payment and performance. The selection of appropriate quality indicators under this subsection shall include the evaluation criteria formulated by clinical professionals, consumers, and data collection experts. Performance indicators developed or updated under this subsection shall in the aggregate reflect the spectrum of care patients receive and may include a range of process and outcome measures such as clinical outcome measures and indicators reflecting the provision of culturally and linguistically appropriate care.

''(b) RISK ADJUSTMENT.—In developing the quality indicators under subsection (a), the Director shall ensure that adequate risk adjustment is provided for.

''(c) BEST PRACTICES.—In carrying out this section, the Director shall—

''(1) assess data concerning appropriate clinical treatments based on the best scientific evidence available;

''(2) determine areas in which there is insufficient evidence to determine best practices; and

''(3) compare existing quality indicators to best clinical practices, validate appropriate indicators, and report on areas where additional research is needed before indicators can be developed.

''(d) REPORT.—Not later than 1 year after the date of enactment of this section, and annually thereafter, the Director shall—

''(1) submit to the Director of the National Institutes of Health a report concerning areas of clinical care requiring further research necessary to establish effective clinical treatments that will serve as a basis for quality indicators; and

''(2) submit to Congress a report on the state of quality measurement for priority areas that links data to the report submitted under paragraph (1) for the year involved.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $12,000,000 for fiscal year 2004, and $8,000,000 for each of fiscal years 2005 through 2009.''.

SEC. 302. STANDARDIZED QUALITY INDICATORS FOR FEDERAL AGENCIES.

(a) IN GENERAL.—In addition to other activities to be carried out by the Quality Interagency Coordination Taskforce (as established by executive order on March 13, 1998), such Taskforce shall use indicators standardized by the National Quality Forum to standardize indicators of health care quality that are used in all Federal agencies, as appropriate.

(b) CONSULTATION.—In carrying out subsection (a), the Quality Interagency Coordination Taskforce shall consult with a public-private consensus organization (such as the National Quality Forum) to enhance the likelihood of the simultaneous application of the standardized indicators under subsection (a) in the private sector.

(c) REPORT.—Not later than 1 year after the date of enactment of this Act, and annually thereafter, the Secretary of Health and Human Services shall submit to Congress a report on the progress made by the Quality Interagency Coordination Taskforce to standardizing quality indicators throughout the Federal Government.

SEC. 303. DEMONSTRATION PROGRAM FOR COMMUNITY HEALTH CARE QUALITY DATA REPORTING.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention and the Director

of the Agency for Healthcare Quality and Research, shall award not to exceed 20 grants to eligible communities for the establishment of demonstration programs for the reporting of health care quality information at the community level.

(b) QUALITY INDICATORS.—

(1) IN GENERAL.—For purposes of reporting information under the demonstration programs under this section, indicators of health care quality shall include the indicators developed for the 20 priority areas as identified by the Institute of Medicine in the report entitled ''Priority Areas for National Action'', 2003, or other indicators determined appropriate by the Secretary of Health and Human Services.

(2) TYPE OF DATA.—All quality indicators with respect to which reporting will be carried out under the demonstration program shall be reported by race, ethnicity, gender, and age and shall be appropriately risk-adjusted.

(c) ELIGIBILITY.—The Secretary of Health and Human Services shall award grants to communities (which may be cities, standard metropolitan statistical areas, counties, Indian tribes, or States) under this section based on competitive proposals and criteria to be determined

jointly by the Director of the Centers for Disease Control and Prevention and the Director of the Agency for Healthcare Research and Quality. Such criteria may include a demonstrated ability of the community to collect data on quality indicators and a demonstrated ability to effectively transmit community-level health status results to relevant stakeholders, including clinicians and patients.

(d) TECHNICAL ADVISORY COMMITTEE.—The Secretary of Health and Human Services shall establish an external technical advisory committee to assist grantees in data collection, data analysis, and report dissemination.

(e) REPORT.—Not later than 1 year after the date of enactment of this Act, and annually thereafter, the Director of the Centers for Disease Control and Prevention and the Director of the Agency for Healthcare Research and Quality shall—

(1) submit to the Congress a report on the progress and results of the demonstration programs under this section; and

(2) make such reports publicly available, including by posting the reports on the Internet.

(f) EVALUATION.—The Secretary of Health and Human Services shall, upon awarding grants under subsection (a), enter into a contract for the evaluation of demonstration programs under this section. Such evaluation

shall compare the effectiveness of such demonstration programs in collecting and reporting required data, and on the effectiveness of distributing information to key stakeholders in a timely fashion. Such evaluations shall provide for a report on best practices.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $25,000,000 for fiscal year 2004, and such sums as may be necessary for each fiscal year thereafter.

SEC. 304. DEMONSTRATION PROJECT FOR THE COLLECTION OF DATA ON RACE, ETHNICITY, AND LINGUISTIC PREFERENCES.

Section 903(c) of the Public Health Service Act (42 U.S.C. 299a–1(c)) is amended by adding at the end the following:

''(4) COLLECTION OF DATA ON RACE, ETHNICITY, AND LINGUISTIC PREFERENCES.—

''(A) IN GENERAL.—The Secretary, acting through the Director, shall conduct demonstration programs in conjunction with physicians, physician groups, patients, and consumer groups to investigate effective ways to collect reliable and valid data regarding an individual patient's race, ethnicity, and linguistic preferences. Such demonstrations may include—

''(i) the use of focus groups to develop appropriate language and modalities for requesting such information;

''(ii) the conduct of training programs for front line staff and clinical professionals;

''(iii) the use of specific culturally and linguistically appropriate scripts, translation of scripts and supporting material,

''(iv) the use of general informational materials;

''(v) designs for community awareness programs that are culturally and linguistically appropriate; and

''(vi) the collection and dissemination of best practices for the collection of race, ethnicity, and linguistic preference information.

''(B) ELIGIBILITY.—To be eligible to participate in a demonstration project under subparagraph (A), an individual or entity shall—

''(i) be a domestic or foreign, public or private not-for-profit organization, including a university, clinic, unit of State or

local government, or an eligible agency of the Federal Government; and

''(ii) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including—

''(I) a description of the populations to be included in the project;

''(II) documentation of the willingness to participate in the project from appropriate community groups;

''(III) documentation of the previous ability of the applicant to work with such groups; and

''(IV) evidence of necessary skill sets to develop needed materials and interventions.

''(C) DURATION.—A demonstration project under this paragraph shall be for 1 or 2 years and shall be conducted over a period commencing not later than 6 months after the date of enactment of this paragraph.

''(D) REPORTS.—Not later than 1 year after the date of enactment of this paragraph, and annually thereafter for the duration of

projects under this paragraph, the Secretary shall submit to Congress annual reports on such projects. The final report submitted under this subparagraph shall contain a summation of best practices to be posted on appropriate websites and disseminated to providers and communities.

''(E) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $5,000,000 for each of fiscal years 2004 and 2005.''.

TITLE IV—PRODUCTION, EVALUATION, AND DISTRIBUTION OF PRACTICE GUIDELINES FOR CARE

SEC. 401. PRODUCTION, EVALUATION, AND DISTRIBUTION OF PRACTICE GUIDELINES FOR CARE.

(a) IN GENERAL.—The Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine of the National Academy of Sciences, or another appropriate entity, to conduct a study on approaches to developing and disseminating seed practice guidelines to be used as a basis for regional or local application in accordance with subsection (b).

(b) CONTENT.—The study conducted under subsection (a) shall—

(1) study how and under what circumstances the coordinated development of evidence-based practice guidelines would be feasible and would improve health outcomes;

(2) identify any available prototypes for the development and dissemination of guidelines regionally, in the United States, or in other countries;

(3) consider how to involve health care consumers in the development of such guidelines and gain the acceptance of clinicians;

(4) consider how guidelines should account for cultural and linguistic differences among patients;

(5) consider how guidelines should reflect variations in patients preferences;

(6) determine potential guideline models, including public and private options;

(7) compare and contrast the strengths and limitations of each such model;

(8) determine both start-up and operating costs of different guideline development and dissemination models;

(9) explore alternative funding options;

(10) evaluate guideline dissemination strategies; and

(11) develop a recommended strategy for implementation in the United States, including the potential role of the Federal Government.

(c) REPORT.—Not later than 12 months after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress a report containing the results of the study conducted under this section.

(d) DISSEMINATION OF FINDINGS.—The Secretary shall disseminate the findings of the study conducted under subsection (a) to appropriate public and private entities, including the posting of such findings on appropriate websites.

(e) DEFINITION.—In this section, the term ''seed practice guidelines'' means guidelines that represent a synthesis of the scientific evidence to support clinical practice.

(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $750,000 for fiscal year 2004.

TITLE V—REWARDING QUALITY

SEC. 501. INSTITUTE OF MEDICINE REPORT ON PAYMENT INCENTIVES AND PERFORMANCE.

(a) EVALUATION.—

(1) IN GENERAL.—Not later than 2 months after the date of enactment of this Act, the Secretary of Health and Human Services shall enter into an arrangement under which the Institute of Medicine of the National Academy of Sciences (in this section referred to as the ''Institute'') shall conduct an evaluation of options to align performance with payment, including payment under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(2) SPECIFIC MATTERS EVALUATED.—In conducting the evaluation under paragraph (1), the Institute shall—

(A) catalogue, review, and evaluate the validity of leading health care performance measures to determine what subset of measures is appropriate for payment;

(B) catalogue and evaluate the success, utility, and effects of alternative performance incentive programs in public or private sector settings; and

(C) identify and prioritize options to implement policies that align performance with payment under the medicare program that indicate—

(i) the performance measurement set to be used and how that measurement set will be updated;

(ii) the payment policy that will reward performance; and

(iii) the key implementation issues (such as data and information technology requirements, and necessary risk adjustment) that must be addressed.

(3) SCOPE OF HEALTH CARE PERFORMANCE MEASURES.—The evaluation and selection of health care performance measures described in paragraph (2)(A) shall reflect a variety of perspectives, including clinical professionals, hospitals, health plans, purchasers, and consumers, and data collection experts.

(4) CONSULTATION WITH MEDPAC.—In evaluating the matters described in paragraph (2)(C), the Institute shall consult with the Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6).

(b) REPORT.—Not later than 6 months after the issuance of a report by the Secretary on priority area quality indicators, the Institute shall submit to the Secretary of Health and Human Services, the Committees on Ways and Means and Energy and Commerce of the House of Representatives, and the Committees on Finance and Health, Education, Labor and Pensions of the Senate a report on the evaluation conducted under subsection (a)(1) that describes the findings of such evaluation and contains recommendations for an overall strategy and approach for aligning payment with performance in various types of private and public health plans, including, the original medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act, the Medicare+Choice program under part C of such title, and any other programs under such title XVIII.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated, $1,000,000 for purposes of conducting the evaluation and preparing the report required by this section.

TITLE VI—INFORMATION TO CONSUMERS

SEC. 601. DISSEMINATION OF INFORMATION TO CONSUMERS.

Part B of title IX of the Public Health Service Act (42 U.S.C. 299b et seq.), as amended by section 301, is further amended by adding at the end the following:

"SEC. 920C. DISSEMINATION OF INFORMATION TO CONSUMERS.

''(a) DEMONSTRATION PROJECTS.—

''(1) IN GENERAL.—The Secretary, acting through the Director, shall support research and demonstration projects to assess the feasibility of using community-based and voluntary public and private organizations to disseminate information about health care quality to consumers.

''(2) REQUIREMENTS.—The research and demonstration projects under paragraph (1) shall address the following:

''(A) The ability and costs to train staff in community-based and voluntary public and private organizations to disseminate such information.

''(B) The materials needed for such training.

''(C) The types of audiences reached by such community-based and voluntary public and private organizations.

''(D) The effectiveness of the transmission of information from such community-based and voluntary public and private organizations to the target audiences.

''(3) REPORT.—Not later than 3 years after the date of enactment of this section, the Secretary shall ensure that a report containing the results of the research and demonstration projects under paragraph (1) is submitted to the appropriate committees of Congress.

''(4) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this subsection.

''(b) TRAINING FOR LONG-TERM CARE OMBUDSMAN.—

''(1) IN GENERAL.—The Secretary, acting through the Director of the Administration on Aging and in consultation with the Director of the Agency for Healthcare Research and Quality and the Administrator of the Centers for Medicare & Medicaid Services, shall authorize a program, to be developed and implemented by the National Long-Term Care

Ombudsman Resource Center, for the training of long-term care ombudsmen in the use of quality of care information.

''(2) TRAINING.—Under the program developed under paragraph (2), training shall be provided to long-term care ombudsman to enable such ombudsman to educate consumers concerning—

''(A) nursing home, home health care, and other long-term care quality of care issues;

''(B) available nursing home and home health care quality of care reports, including existing quality data that the Administrator of the Centers for Medicare & Medicaid Services has released for use by the public in choosing long-term care facilities or home health care services; and

''(C) the manner in which an individual can successfully integrate quality information into health care decision making regarding nursing home and home health care decisions.

''(3) DUTIES OF RESOURCE CENTER.—The National Long-Term Care Ombudsman Resource Center shall—

''(A) develop and maintain a curriculum for ombudsmen;

''(B) develop, produce, and maintain training materials;

''(C) conduct train-the-trainer programs at regional and national levels; and

''(D) act as a clearinghouse for best practices in communicating the significance of nursing home and home health care quality indicators to residents and their caregivers.

''(4) PILOT PROGRAMS.—The Secretary shall award grants for the establishment of 1-year pilot demonstration programs in 10 States using dedicated long-term care ombudsmen to educate consumers regarding nursing home and home health care quality. Such pilot demonstration programs shall test the effectiveness of having a committed position within the State dedicated to helping consumers use nursing home and home health care quality indicators.

''(5) REPORT.—Not later than 18 months after the date of enactment of this section, and annually thereafter, the Secretary shall submit to Congress a report concerning the effectiveness of the program established under this subsection, including the benefits of providing for dedicated staff who are responsible for educating consumers to use nursing home

and home health quality indicators in their health care decision-making.

''(6) AUTHORIZATION.—In addition to any other amounts authorized to be appropriated for long-term care ombudsman programs, there are authorized to be appropriated to carry out this subsection $4,000,000 for fiscal year 2004 (of which $1,000,000 shall be used to carry out paragraph (4)), and $2,000,000 for each fiscal year thereafter.''.

TITLE VII—PROMOTING PATIENT ENGAGEMENT

SEC. 701. PROMOTING PATIENT ENGAGEMENT.

Part B of title IX of the Public Health Service Act (42 U.S.C. 299b et seq.), as amended by section 601, is further amended by adding at the end the following:

''SEC. 920D. PROMOTING PATIENT ENGAGEMENT.

''(a) GRANTS.—

''(1) IN GENERAL.—The Secretary, acting through the Director, shall award grants to public and private non-profit entities to conduct research on patient experiences in their care.

''(2) REQUIREMENTS.—Activities conducted under grants awarded under paragraph (1) shall—

''(A) evaluate the impact of sharing health records with patients;

''(B) provide for the conduct of studies on understanding and describing patient value systems, including risk aversion, self-care orientation, and time horizon;

''(C) evaluate how patients seek health information and how they use it;

''(D) evaluate how changes in consumer behavior based on information about quality affect changes in provider behavior; and

''(E) study how the effects of the studies conducted under this subsection vary by race, ethnicity, cultural and linguistic groups, education, age, and gender.

''(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this subsection.

''(b) HEALTH LITERACY STANDARDS.—

''(1) IN GENERAL.—For purposes of assisting eligible entities in providing quality assurance measures, the Secretary, acting through the Director, the Administrator of Health Resources and Services Administration, the Director of the National Library of Medicine, and the Commissioner of Food and Drugs,

shall develop standardized materials that pharmacists may use to assist non-English speaking or functionally illiterate patients in the safe and appropriate use of prescription drugs. Such materials may include the use of pictures and the development of standardized translations in multiple languages of prescription labels and bottle labels and other patient safety initiative information. Such materials shall be available electronically for direct access by pharmacists.

''(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for each of fiscal years 2004 and 2005.''.

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