

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Health Information for Quality Improvement Act”.

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

Sec. 1. Short title; table of contents.

Sec. 2. Findings and purpose.

TITLE I—INFORMATION TECHNOLOGY

- Sec. 101. Information infrastructure improvement.
 “Sec. 918. National healthcare information infrastructure.
 “Sec. 919. Data and communications standards for interoperability.
 “Sec. 920. Grants to hospitals and other health care providers for information technologies.
 Sec. 102. Improving clinical practice and reducing barriers to information technology.
 “Sec. 409J. Research on information technology and other systems-based approaches to changing clinical practice.
 “Sec. 478B. Certification of information websites.

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

- Sec. 201. Coverage for individuals participating in approved clinical trials.
 Sec. 202. Grants for primary care research for older patients.
 Sec. 203. Study on effectiveness of certain prescription drugs.

TITLE III—MEASURING AND COMPARING QUALITY

- Sec. 301. Priority area quality indicators.
 Sec. 302. Standardized quality indicators for Federal agencies.
 Sec. 303. Demonstration program for community health care quality data reporting.
 Sec. 304. Demonstration project for the collection of data on race and ethnicity.

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

- Sec. 401. Production, evaluation, and distribution of practice guidelines for care.

TITLE V—REWARDING QUALITY

- Sec. 501. Institute of medicine report on payment incentives and performance.

TITLE VI—INFORMATION TO CONSUMERS

- Sec. 601. Dissemination of information to consumers.

TITLE VII—PROMOTING PATIENT ENGAGEMENT

- Sec. 701. Promoting patient engagement.

1 **SEC. 2. FINDINGS AND PURPOSE.**

2 (a) FINDINGS.—Congress makes the following find-
 3 ings:

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

1 is plagued with underuse, overuse, and misuse. Only
 2 about 50 percent of health care treatments of serv-
 3 ices that are known to be effective are provided. At
 4 the same time, only 20 percent of the treatments
 5 and services that are provided are supported by sci-
 6 entific evidence.

7 (2) The pace of the dissemination of new evi-
 8 dence relating to appropriate health care treatments
 9 and services is shockingly slow. It may take up to
 10 15 years for treatments found to be effective to be-
 11 come common practice.

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

16 (b) PURPOSE.—It is the purpose of this Act to pro-
 17 mote higher quality health care and better health by
 18 strengthening health information, its infrastructure, and
 19 its use by clinicians and consumers.

20 **TITLE I—INFORMATION** 21 **TECHNOLOGY**

22 **SEC. 101. INFORMATION INFRASTRUCTURE IMPROVEMENT.**

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

1 **“SEC. 918. NATIONAL HEALTHCARE INFORMATION INFRA-**
2 **STRUCTURE.**

3 “(a) IN GENERAL.—By not later than 6 months after
4 the date of the enactment of this Act, the Secretary shall
5 establish within the Office of the Secretary an Office of
6 National Healthcare Information Infrastructure (in this
7 section referred to as the ‘Office’). The Office shall be
8 headed by a Director who shall report directly to the Sec-
9 retary and who shall be responsible for providing ongoing
10 national leadership in the planning, development, and
11 adoption of a national healthcare information infrastruc-
12 ture. The Office shall, in cooperation with key stake-
13 holders, develop a strategic plan to create a comprehensive
14 national healthcare information infrastructure that en-
15 compasses public-sector and private-sector health informa-
16 tion activities, and that includes a national agenda to
17 guide policymaking, technology investments, research, and
18 integration with ongoing health care and health care infor-
19 mation technology activities.

20 “(b) GOALS.—The goals of the national healthcare
21 information infrastructure are—

22 “(1) to maximize positive outcomes in clinical
23 care;

24 “(2) to minimize preventable medical errors, es-
25 pecially in hospitals and in the administration of
26 contraindicated drugs;

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

3 “(4) to decrease costs from duplicative or other-
4 wise unnecessary testing or procedures; and

5 “(5) to establish a compatible information tech-
6 nology architecture that facilitates future quality
7 and cost-saving needs and that avoids the financing
8 and development of information technology systems
9 that are not readily compatible.

10 “(c) COLLABORATION WITH STAKEHOLDERS.—

11 “(1) IN GENERAL.—The Secretary shall assure
12 that activities of the Department of Health and
13 Human Services that relate to the national
14 healthcare information infrastructure are under-
15 taken after consultation with and based on the rec-
16 ommendations of the parties described in paragraph
17 (3).

18 “(2) PERIODIC MEETINGS.—The Secretary,
19 through the Office, shall convene as a group the par-
20 ties described in paragraph (3). Such group shall
21 meet periodically and collaborate to make rec-
22 ommendations to the Office and the Secretary on
23 the matters described in subsection (d).

24 “(3) PARTIES REPRESENTED.—The parties de-
25 scribed in this paragraph are the following:

1 “(A) The National Committee on Vital and
2 Health Statistics.

3 “(B) Experts from the fields of healthcare
4 information, information technology, medical
5 continuous quality improvement, and medical
6 records security and privacy.

7 “(C) Representatives from individual and
8 institutional health care clinical providers, in-
9 cluding teaching hospitals, children’s hospitals,
10 and small hospitals.

11 “(D) Clinical and health services research-
12 ers.

13 “(E) Health care purchasers.

14 “(F) One or more representatives of clin-
15 ical professional societies or associations.

16 “(G) Representatives of private organiza-
17 tions with expertise in medical informatics.

18 “(H) One or more representatives of pa-
19 tient groups.

20 “(I) One ore more representatives from
21 State or local public health departments.

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

1 “(K) Appropriate staff experts from Fed-
2 eral agencies, including those within the De-
3 partment of Health and Human Services and
4 the Department of Veterans Affairs.

5 “(d) DUTIES.—In carrying out subsection (a), the
6 Office shall make recommendations to and advise the Sec-
7 retary on the following, in order to promote the goals de-
8 scribed in subsection (b):

9 “(1)(A) An assessment of the best current prac-
10 tices in the development, purchase, and maintenance
11 of medical information technology.

12 “(B) Recommendations, and the specifications,
13 for a uniform healthcare information system inter-
14 face, and methods for its adoption (not later than 2
15 years after the date of the enactment of this Act) to
16 ensure compatibility between and among old and
17 new information systems.

18 “(C) Recommendations for health care data
19 standards (such as vocabulary and messaging), com-
20 munications standards, and other medical standards
21 (including a common lexicon) necessary to achieve
22 the interoperability of healthcare information sys-
23 tems.

24 “(2) Coordination of the evolution of the na-
25 tional healthcare information infrastructure and

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

5 “(3) Coordination of spending across Federal
6 agencies relating to the establishment of such infra-
7 structure.

8 “(4) Development of policies to ensure compli-
9 ance with the security and confidentiality standards
10 of this part C for protected health information and
11 promote patient control of protected health informa-
12 tion.

13 “(5) Ensure thorough testing of data and com-
14 munications standards prior to their adoption.

15 “(e) DETAIL OF FEDERAL EMPLOYEES.—Upon the
16 request of the Secretary, the head of any Federal agency
17 is authorized to detail, without reimbursement from the
18 Office, any of the personnel of such agency to the Office
19 to assist it in carrying out its duties under this section.
20 Any such detail shall not interrupt or otherwise affect the
21 civil service status or privileges of the Federal employee.

22 **“SEC. 919. DATA AND COMMUNICATIONS STANDARDS FOR**
23 **INTEROPERABILITY.**

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

1 as needed adopt (and shall periodically review, update, and
2 expand) a set of voluntary, national data and communica-
3 tions standards that promote the interoperability of health
4 care information technology systems across all public and
5 private health care settings. In adopting such standards,
6 the Secretary shall ensure that such standards are de-
7 signed and are carefully monitored to ensure that linkage
8 of data resulting from such interoperability does not com-
9 promise privacy and security. The Secretary shall take
10 into account—

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

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

18 “(b) REPORTS.—

19 “(1) INITIAL REPORT.—No later than 12
20 months after the date of the enactment of this Act,
21 the Secretary shall submit to Congress a comprehen-
22 sive national healthcare information infrastructure
23 strategic plan that includes—

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

4 “(B) recommendations for accelerating the
5 development of common health care vocabulary
6 standards;

7 “(C) recommendations for completing de-
8 velopment of health care information system
9 messaging standards; and

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

14 “(2) SUBSEQUENT REPORTS.—During each of
15 the 2 years after the year in which the report is sub-
16 mitted under paragraph (1), the Secretary shall sub-
17 mit to Congress an annual report relating to addi-
18 tional recommendations, best practices, results of in-
19 formation technology improvements, analyses of pri-
20 vate sector efforts to implement the data and com-
21 munications standards established under this sec-
22 tion, and such other matters as may help ensure the
23 most rapid dissemination of best practices in health
24 care information technology.

1 “(c) CONTRACT AUTHORITY.—The Secretary is au-
2 thorized—

3 “(1) to enter into contracts for services and ac-
4 tivities necessary to carry out this section and sec-
5 tion 918; and

6 “(2) to the extent practicable, to test the stand-
7 ards under consideration under this section.

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

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

15 **“SEC. 920. GRANTS TO HOSPITALS AND OTHER HEALTH**
16 **CARE PROVIDERS FOR INFORMATION TECH-**
17 **NOLOGIES.**

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

24 “(1) to improve quality of care and patient
25 safety; and

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

3 “(b) SPECIAL CONSIDERATIONS.—In awarding
4 grants under subsection (a), the Secretary shall give spe-
5 cial consideration to applicants who seek to promote the
6 following:

7 “(1) Interoperability across hospital services or
8 departments using standards referred to in section
9 919.

10 “(2) Electronic communication of patient data
11 across the spectrum of health care delivery.

12 “(3) Computerized physician order entry or bar
13 coding applications.

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

17 “(5) Improved clinical decisionmaking through
18 the acquisition and implementation of decision-sup-
19 port technologies.

20 “(6) The sharing by hospitals of electronic
21 health records with patients.

22 “(c) CERTAIN GRANT CONDITIONS.—A condition for
23 the receipt of a grant under subsection (a) is that the ap-
24 plicant involved meet the following requirements:

25 “(1) The applicant agrees—

1 “(A) to carry out a program to measure,
2 analyze, and report patient safety and medical
3 errors at the hospital or other health care pro-
4 vider involved to patient safety organizations;

5 “(B) to submit to the Secretary a descrip-
6 tion of the methodology that will be used for
7 such program; and

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

13 “(2) The applicant has—

14 “(A) arranged for an evaluation that ad-
15 dresses the effectiveness and cost-effectiveness
16 of the information technology for which the
17 grant is provided and its impact on the quality
18 and safety of patient care;

19 “(B) submitted the evaluation plan to the
20 Secretary; and

21 “(C) received approval from the Secretary
22 of the methodology described in the plan.

23 “(3) The applicant has or is developing a pa-
24 tient safety evaluation system for reporting health
25 care errors to a patient safety organization.

1 “(4) The applicant agrees to provide the Sec-
2 retary with such information as the Secretary may
3 require regarding the use of funds under this pro-
4 gram or its impact.

5 “(5) The applicant provides assurances satisfac-
6 tory to the Secretary that any information tech-
7 nology planned, acquired, or implemented with grant
8 funds under this section will be part of an informa-
9 tion program that—

10 “(A) carries out the purposes described in
11 subsection (a); and

12 “(B) is comprehensive or will be expanded
13 to become comprehensive, regardless of whether
14 Federal assistance is available for such expan-
15 sion.

16 “(d) TECHNICAL ASSISTANCE TO GRANTEES.—The
17 Secretary, acting through the Director, shall provide tech-
18 nical assistance to applicants and grantees to ensure the
19 appropriate evaluation of the information technologies for
20 which grants are awarded under this section, such as—

21 “(1) reviewing and providing technical assist-
22 ance on the applicant’s proposed evaluation;

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

1 lems as they arise, ensure mutual learning, and pro-
 2 mote the rapid dissemination of information;

3 “(3) reviewing the interim and final reports re-
 4 quired under subsection (e); and

5 “(4) disseminating evidence-based information
 6 in interim and final reports to patient safety organi-
 7 zations, as appropriate.

8 “(e) EVALUATION REPORTS BY GRANTEE.—

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

13 “(2) INTERIM REPORT.—Not later than 1 year
 14 after the implementation of information technologies
 15 under a grant under this section is completed, the
 16 applicant shall submit an interim report to the Sec-
 17 retary describing the initial effectiveness of such
 18 technologies in carrying out the purposes described
 19 in subsection (a).

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

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

3 “(4) RELATION TO DISBURSEMENT OF
4 GRANT.—In making payments under a grant under
5 subsection (a), the Secretary shall withhold $\frac{1}{3}$ of the
6 amount of the grant until the grantee submits to the
7 Secretary the report required under paragraph (2).

8 “(f) REPORTS BY THE SECRETARY.—

9 “(1) INTERIM REPORTS.—

10 “(A) IN GENERAL.—Through the fiscal
11 year preceding the fiscal year in which the final
12 report under paragraph (2) is prepared, the
13 Secretary shall submit to the Committee on En-
14 ergy and Commerce of the House of Represent-
15 atives and the Committee on Health, Edu-
16 cation, Labor, and Pensions of the Senate peri-
17 odic reports on the grant program under sub-
18 section (a). Such reports shall be submitted not
19 less frequently than once each fiscal year, be-
20 ginning with fiscal year 2004.

21 “(B) CONTENTS.—A report under sub-
22 paragraph (A) shall include information on—

23 “(i) the number of grants awarded;

1 “(ii) the nature of the projects for
 2 which funding is provided under the grant
 3 program;

4 “(iii) the geographic distribution of
 5 grant recipients; and

6 “(iv) such other matters as the Sec-
 7 retary determines appropriate.

8 “(2) FINAL REPORT.—Not later than 180 days
 9 after the date on which the last of the reports is due
 10 under subsection (e)(3), the Secretary shall submit
 11 a final report to the committees referred to in para-
 12 graph (1)(A) on the grant program under subsection
 13 (a), together with such recommendations for legisla-
 14 tion and administrative action as the Secretary de-
 15 termines appropriate.

16 “(g) DEFINITIONS.—In this section:

17 “(1) COSTS.—The term ‘costs’, with respect to
 18 information technologies referred to in subsection
 19 (a), includes total expenditures incurred for—

20 “(A) purchasing, leasing, and installing
 21 computer software and hardware, including
 22 hand-held computer technologies;

23 “(B) making improvements to existing
 24 computer software and hardware; and

1 “(C) purchasing or leasing communications
2 capabilities necessary for clinical data access,
3 storage, and exchange.

4 “(2) HEALTH CARE PROVIDER.—The term
5 ‘health care provider’ includes a physician or other
6 health care professional, as well as an institutional
7 or other facility or agency that provides health care
8 services and that is licensed, accredited, or certified
9 to provide health care items and services under ap-
10 plicable State law.

11 “(h) TERMINATION OF GRANT AUTHORITIES.—The
12 authority of the Secretary to award grants under sub-
13 section (a) terminates upon the expiration of fiscal year
14 2011.

15 “(i) MATCHING FUNDS.—

16 “(1) IN GENERAL.—With respect to the costs of
17 a grant to be carried out under this section, such
18 grant may be made only if the applicant agrees to
19 make available (directly or through donations from
20 public or private entities) non-Federal contributions
21 toward such costs in an amount that is not less than
22 50 percent of such costs (\$1 for each \$1 of Federal
23 funds provided under the grant).

24 “(2) DETERMINATION OF AMOUNTS CONTRIB-
25 UTED.—Amounts provided by the Federal Govern-

1 ment, or services assisted or subsidized to any sig-
 2 nificant extent by the Federal Government, may not
 3 be included in determining the amount of such non-
 4 Federal contributions.

5 “(j) AUTHORIZATION OF APPROPRIATIONS.—For the
 6 purpose of carrying out this section, there are authorized
 7 to be appropriated \$20,000,000 for each of fiscal years
 8 2004 and 2005.”.

9 (b) UNDERSTANDING BARRIERS TO INFORMATION
 10 TECHNOLOGY ADOPTION AND EFFECTIVE USE.—Section
 11 914(a) of the Public Health Service Act (42 U.S.C. 299b–
 12 3(a)) is amended—

13 (1) in paragraph (6), by striking “and” at the
 14 end;

15 (2) in paragraph (7), by striking the period and
 16 inserting “; and”; and

17 (3) by adding at the end the following:

18 “(8) and understand the barriers to information
 19 technology adoption and effective use as well as
 20 methods to overcome those barriers.”.

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

23 (a) IMPROVING CLINICAL PRACTICES.—

24 (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:

1 (i) An estimated 80,000 to 100,000
2 patients die every year from errors suf-
3 fered during hospitalization.

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

7 (iii) These systemwide changes have
8 the potential to decrease the cost of pro-
9 viding health care and to increase the qual-
10 ity of services provided.

11 (iv) These improvements in cost and
12 quality can be as dramatic as improve-
13 ments seen with new medical technology or
14 pharmaceutical advances.

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

19 (vi) These clinical trials form the
20 basis for providers to practice evidence-
21 based medicine and to change their prac-
22 tices to improve their patients' outcomes.

23 (vii) Similar controlled clinical studies
24 of new information technologies and sys-
25 tems-based approaches to changing prac-

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

3 (B) RESEARCH ON INFORMATION TECH-
4 NOLOGY AND OTHER SYSTEMS-BASED AP-
5 PROACHES TO CHANGING CLINICAL PRAC-
6 TICE.—Part B of title IV of the Public Health
7 Service Act (42 U.S.C. 284 et seq.) is amended
8 by adding at the end the following:

9 **“SEC. 409J. RESEARCH ON INFORMATION TECHNOLOGY**
10 **AND OTHER SYSTEMS-BASED APPROACHES**
11 **TO CHANGING CLINICAL PRACTICE.**

12 “(a) ESTABLISHMENT.—The Secretary, acting
13 through the Director of the Agency for Healthcare Re-
14 search and Quality and in collaboration with the Director
15 of NIH, shall establish a Medical Systems Safety Initiative
16 (referred to in this section as the ‘Initiative’) to conduct
17 and support research regarding information technology
18 and other systems-based approaches to improving and ad-
19 vancing medical care.

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

23 “(1) to conduct and support research (including
24 both intramural and extramural research), research
25 training, the dissemination of health information,

1 and other programs with respect to systems re-
2 search, user-centered design, and human factors en-
3 gineering (including research related to information
4 technology) to realize the expanding opportunities
5 for improving health outcomes through the analysis
6 and redesign of medical systems;

7 “(2) to enhance collaborative efforts among
8 Federal agencies to conduct and support multidisci-
9 plinary research in the areas that the Director deter-
10 mines to be most promising; and

11 “(3) to encourage and support studies, includ-
12 ing clinical studies, to provide scientifically and sta-
13 tistically rigorous and meaningful information about
14 the utility and effectiveness of various systems-based
15 interventions, including information technology de-
16 velopments.

17 “(c) APPROPRIATE SCIENTIFIC EXPERTISE AND CO-
18 ORDINATION WITH FEDERAL AGENCIES.—The Director
19 of the Agency for Healthcare Research and Quality and
20 the Director of NIH shall ensure that scientists with ap-
21 propriate expertise in research on health systems, informa-
22 tion technology, user-centered design, and human factors
23 engineering are incorporated into the review, oversight,
24 and management processes of all research projects and
25 other activities funded by the Initiative. In carrying out

1 this subsection, the Directors, as necessary, may establish
 2 review groups with appropriate scientific expertise. The
 3 Directors shall coordinate efforts with other Federal agen-
 4 cies to ensure appropriate scientific input and manage-
 5 ment.

6 “(d) DEFINITIONS.—In this section:

7 “(1) HUMAN FACTORS ENGINEERING.—The
 8 term ‘human factors engineering’ means the study
 9 and optimization of the interaction of humans, ma-
 10 chines, and the environment to achieve the perform-
 11 ance objectives of a given health care workplace.

12 “(2) SYSTEMS RESEARCH.—The term ‘systems
 13 research’ means research into the organization and
 14 design of the work environment within a health care
 15 setting, and their effects on health outcomes, as well
 16 as research to improve such designs so as to improve
 17 health outcomes.”.

18 (b) IMPROVING AND PROMOTING ELECTRONIC
 19 HEALTH RECORDS.—

20 (1) AUTHENTICATION STANDARDS.—The Direc-
 21 tor of the National Center for Vital and Health Sta-
 22 tistics shall provide assistance to the Secretary of
 23 Health and Human Services in the development of
 24 authentication standards for health records. In de-

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

3 (A) Recommendations for authentication
4 technology and identification information stand-
5 ards that—

6 (i) provide for the reliable identifica-
7 tion and retrieval of a patient’s electronic
8 health data;

9 (ii) allow the patient to have detailed
10 control over the access of individual com-
11 ponents of his or her electronic health
12 record by being able to specify specific pro-
13 viders, each of whom will have access to
14 limited portions of the electronic health
15 record;

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

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

20 (II) a health care provider to ac-
21 cess data for which the patient has
22 not consented to grant such access;

23 (III) a third party to access iden-
24 tification information; or

1 (IV) a third party to circumvent
2 or exploit the authentication process
3 in order to access electronic health
4 data without the consent of the pa-
5 tient;

6 (iv) allow for the timely and conven-
7 ient creation of identification information
8 at the time of contact between a patient
9 and a provider, so as to minimize any dis-
10 ruption or delay in the provision of needed
11 medical services to a patient who does not
12 already have identification information;
13 and

14 (v) maximize the probability of accu-
15 rate identification, secure authentication,
16 and rapid access to health data even in sit-
17 uations where the patient—

18 (I) does not possess the identi-
19 fication information that is usually re-
20 quired for successful authentication,
21 but wishes to grant consent to the
22 provider to access necessary health
23 data;

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

1 consent for the emergency access of
 2 health data due to incapacitation; and
 3 (III) is not able to provide identi-
 4 fication information nor consent for
 5 emergency data access due to inca-
 6 pacitation.

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

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

12 “(J) The arrangements and information
 13 exchange allowed for the purposes of promoting
 14 the use of electronic health records, including
 15 personal health records.”; and

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

18 “(F) Whether the arrangements and infor-
 19 mation exchange allowed for the purposes of
 20 promoting the use of electronic health records,
 21 including personal health records achieve their
 22 purposes.”.

23 (3) PERSONAL HEALTH RECORD.—

24 (A) FEDERAL HEALTH INFORMATION EX-
 25 CHANGE 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-Government 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.—

1 (i) IN GENERAL.—The Director of the
2 Agency for Healthcare Research and Qual-
3 ity shall award grants to public and non-
4 profit private entities for the conduct of re-
5 search on innovative approaches to improve
6 patients' understanding and comprehension
7 of their electronic health record. Research
8 areas may include technology for the auto-
9 mated—

10 (I) translation of medical infor-
11 mation to improve patient comprehen-
12 sion;

13 (II) reorganization of the elec-
14 tronic health record for improved util-
15 ity for the patient; and

16 (III) integration of links to rel-
17 evant information from other sources
18 into the electronic health record.

19 (ii) MERIT REVIEW; COMPETITION.—
20 Grants shall be awarded under this sub-
21 paragraph on a merit-reviewed competitive
22 basis.

23 (iii) AUTHORIZATION OF APPROPRIA-
24 TIONS.—There are authorized to be appro-
25 priated to the Agency for Healthcare Re-

1 search and Quality to carry out this sub-
2 paragraph \$5,000,000 for fiscal year 2004,
3 and such sums as may be necessary for
4 each fiscal year thereafter.

5 (3) DEFINITIONS.—In this subsection:

6 (A) IDENTIFICATION INFORMATION.—The
7 term “identification information” with respect
8 to the health records of a patient, means any
9 data necessary to reliably associate a patient
10 with their health data.

11 (B) AUTHENTICATION.—The term “au-
12 thentication” means the process of using the
13 identification information to validate the pa-
14 tient’s identification and gain access to his or
15 her electronic health data.

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

23 (1) a description of current activities of the
24 Biomedical Information Science and Technology Ini-
25 tiative Consortium;

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

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

7 (d) ELECTRONIC BILLING.—

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

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

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

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

1 the provider, physician, practitioner, or supplier
 2 shall not be subject to any penalty or interest under
 3 such title XVIII, or the provisions of title XI of such
 4 Act insofar as they relate to such title XVIII, relat-
 5 ing to the provision of such items or service or such
 6 claim.

7 **TITLE II—INCREASED EVI-**
 8 **DENCE-BASE FOR QUALITY**
 9 **IMPROVEMENT AND MEAS-**
 10 **UREMENT**

11 **SEC. 201. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**
 12 **APPROVED CLINICAL TRIALS.**

13 (a) GROUP HEALTH PLANS.—

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

18 **“SEC. 2707. COVERAGE FOR INDIVIDUALS PARTICIPATING**
 19 **IN APPROVED CLINICAL TRIALS.**

20 “(a) COVERAGE.—

21 “(1) IN GENERAL.—If a group health plan, or
 22 a health insurance issuer that offers health insur-
 23 ance coverage in connection with a group health
 24 plan, provides coverage to a qualified individual (as
 25 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.

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

3 “(i) CONVENTIONAL CARE.—Items or
4 services that are typically provided absent
5 a clinical trial.

6 “(ii) ADMINISTRATIVE ITEMS.—Items
7 or services required solely for the provision
8 of the investigational item or service, the
9 clinically appropriate monitoring of the ef-
10 fects of the item or service, or the preven-
11 tion of complications.

12 “(iii) REASONABLE AND NECESSARY
13 CARE.—Items or services needed for rea-
14 sonable and necessary care arising from
15 the provision of an investigational item or
16 service, including the diagnosis or treat-
17 ment of complications.

18 “(3) USE OF IN-NETWORK PROVIDERS.—If one
19 or more participating provider is participating in a
20 clinical trial, nothing in paragraph (1) shall be con-
21 strued as preventing a plan or issuer from requiring
22 that a qualified individual participate in the trial
23 through such a participating provider if the provider
24 will accept the individual as a participant in the
25 trial.

1 “(b) QUALIFIED INDIVIDUAL DEFINED.—For pur-
2 poses of subsection (a), the term ‘qualified individual’
3 means an individual who is a participant or beneficiary
4 in a group health plan or an enrollee in health insurance
5 coverage and who meets the following conditions:

6 “(1)(A) The individual has a life-threatening or
7 serious illness for which no standard treatment is ef-
8 fective.

9 “(B) The individual is eligible to participate in
10 an approved clinical trial according to the trial pro-
11 tocol with respect to treatment of such illness.

12 “(C) The individual’s participation in the trial
13 offers meaningful potential for significant clinical
14 benefit for the individual.

15 “(2) Either—

16 “(A) the referring physician is a partici-
17 pating health care professional and has con-
18 cluded that the individual’s participation in
19 such trial would be appropriate based upon the
20 individual meeting the conditions described in
21 paragraph (1); or

22 “(B) the participant, beneficiary, or en-
23 rollee provides medical and scientific informa-
24 tion establishing that the individual’s participa-
25 tion in such trial would be appropriate based

1 upon the individual meeting the conditions de-
2 scribed in paragraph (1).

3 “(c) PAYMENT.—

4 “(1) IN GENERAL.—Under this section a group
5 health plan, and a health insurance issuer that of-
6 fers health insurance coverage in connection with a
7 group health plan, shall provide for payment for rou-
8 tine patient costs described in subsection (a)(2) but
9 is not required to pay for costs of items and services
10 that are reasonably expected to be paid for by the
11 sponsors of an approved clinical trial.

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

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

16 “(B) a nonparticipating provider, the pay-
17 ment rate shall be at the rate the plan or issuer
18 would normally pay for comparable services
19 under subparagraph (A).

20 “(d) APPROVED CLINICAL TRIAL DEFINED.—

21 “(1) IN GENERAL.—In this section, the term
22 ‘approved clinical trial’ means a clinical research
23 study or clinical investigation and is described in any
24 of the following subparagraphs:

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

5 “(i) NIH.—The National Institutes of
 6 Health.

7 “(ii) CDC.—The Centers for Disease
 8 Control and Prevention.

9 “(iii) AHRQ.—The Agency for Health
 10 Care Research and Quality.

11 “(iv) CMS.—The Center for Medicare
 12 & Medicaid Services.

13 “(v) COOPERATIVE CENTER.—A coop-
 14 erative group or center of any of the enti-
 15 ties described in clauses (i) through (iv) or
 16 the Departments of Defense or Veterans
 17 Affairs.

18 “(vi) CENTER SUPPORT GRANTEES.—
 19 A qualified nongovernmental research enti-
 20 ty identified in the guidelines issued by the
 21 National Institutes of Health for center
 22 support grants.

23 “(vii) DOD; VA; DOE.—Any of the fol-
 24 lowing if the conditions described in para-
 25 graph (2) are met:

1 “(I) The Department of Veterans
2 Affairs.

3 “(II) The Department of De-
4 fense.

5 “(III) The Department of En-
6 ergy.

7 “(B) FDA DRUG TRIAL UNDER IND.—The
8 study or investigation is conducted under an in-
9 vestigational new drug application reviewed by
10 the Food and Drug Administration.

11 “(C) EXEMPT DRUG TRIAL.—The study or
12 investigation is a drug trial that is exempt from
13 having such an investigational new drug appli-
14 cation.

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

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

24 “(B) assures unbiased review of the high-
25 est scientific standards by qualified individuals

1 who have no interest in the outcome of the re-
2 view.

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

8 (2) ERISA AMENDMENTS.—

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

14 **“SEC. 714. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**
15 **APPROVED CLINICAL TRIALS.**

16 “(a) COVERAGE.—

17 “(1) IN GENERAL.—If a group health plan, or
18 a health insurance issuer that offers health insur-
19 ance coverage in connection with a group health
20 plan, provides coverage to a qualified individual (as
21 defined in subsection (b)), the plan or issuer—

22 “(A) may not deny the individual partici-
23 pation in the clinical trial referred to in sub-
24 section (b)(2);

1 “(B) subject to subsections (b), (c), and
2 (d) may not deny (or limit or impose additional
3 conditions on) the coverage of routine patient
4 costs for items and services furnished in con-
5 nection with participation in the trial; and

6 “(C) may not discriminate against the in-
7 dividual on the basis of the enrollee’s participa-
8 tion in such trial.

9 “(2) EXCLUSION OF CERTAIN COSTS.—

10 “(A) IN GENERAL.—For purposes of para-
11 graph (1)(B), subject to subparagraph (B), rou-
12 tine patient costs include all items and services
13 provided in the clinical trial that are otherwise
14 generally available to the qualified individual,
15 except—

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

18 “(ii) items and services that are pro-
19 vided solely to satisfy data collection and
20 analysis needs and that are not used in the
21 direct clinical management of the patient.

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

1 “(i) CONVENTIONAL CARE.—Items or
 2 services that are typically provided absent
 3 a clinical trial.

4 “(ii) ADMINISTRATIVE ITEMS.—Items
 5 or services required solely for the provision
 6 of the investigational item or service, the
 7 clinically appropriate monitoring of the ef-
 8 fects of the item or service, or the preven-
 9 tion of complications.

10 “(iii) REASONABLE AND NECESSARY
 11 CARE.—Items or services needed for rea-
 12 sonable and necessary care arising from
 13 the provision of an investigational item or
 14 service, including the diagnosis or treat-
 15 ment of complications.

16 “(3) USE OF IN-NETWORK PROVIDERS.—If one
 17 or more participating provider is participating in a
 18 clinical trial, nothing in paragraph (1) shall be con-
 19 strued as preventing a plan or issuer from requiring
 20 that a qualified individual participate in the trial
 21 through such a participating provider if the provider
 22 will accept the individual as a participant in the
 23 trial.

24 “(b) QUALIFIED INDIVIDUAL DEFINED.—For pur-
 25 poses of subsection (a), the term ‘qualified individual’

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

4 “(1)(A) The individual has a life-threatening or
5 serious illness for which no standard treatment is ef-
6 fective.

7 “(B) The individual is eligible to participate in
8 an approved clinical trial according to the trial pro-
9 tocol with respect to treatment of such illness.

10 “(C) The individual’s participation in the trial
11 offers meaningful potential for significant clinical
12 benefit for the individual.

13 “(2) Either—

14 “(A) the referring physician is a partici-
15 pating health care professional and has con-
16 cluded that the individual’s participation in
17 such trial would be appropriate based upon the
18 individual meeting the conditions described in
19 paragraph (1); or

20 “(B) the participant, beneficiary, or en-
21 rollee provides medical and scientific informa-
22 tion establishing that the individual’s participa-
23 tion in such trial would be appropriate based
24 upon the individual meeting the conditions de-
25 scribed in paragraph (1).

1 “(c) PAYMENT.—

2 “(1) IN GENERAL.—Under this section a group
3 health plan, and a health insurance issuer that of-
4 fers health insurance coverage in connection with a
5 group health plan, shall provide for payment for rou-
6 tine patient costs described in subsection (a)(2) but
7 is not required to pay for costs of items and services
8 that are reasonably expected to be paid for by the
9 sponsors of an approved clinical trial.

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

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

14 “(B) a nonparticipating provider, the pay-
15 ment rate shall be at the rate the plan or issuer
16 would normally pay for comparable services
17 under subparagraph (A).

18 “(d) APPROVED CLINICAL TRIAL DEFINED.—

19 “(1) IN GENERAL.—In this section, the term
20 ‘approved clinical trial’ means a clinical research
21 study or clinical investigation and is described in any
22 of the following subparagraphs:

23 “(A) FEDERALLY FUNDED TRIALS.—The
24 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.

1 “(II) The Department of De-
2 fense.

3 “(III) The Department of En-
4 ergy.

5 “(B) FDA DRUG TRIAL UNDER IND.—The
6 study or investigation is conducted under an in-
7 vestigational new drug application reviewed by
8 the Food and Drug Administration.

9 “(C) EXEMPT DRUG TRIAL.—The study or
10 investigation is a drug trial that is exempt from
11 having such an investigational new drug appli-
12 cation.

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

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

22 “(B) assures unbiased review of the high-
23 est scientific standards by qualified individuals
24 who have no interest in the outcome of the re-
25 view.

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

5 (B) TECHNICAL AMENDMENT.—Section
 6 732(a) of the Employee Retirement Income Se-
 7 curity Act of 1974 (29 U.S.C. 1191a(a)) is
 8 amended by striking “section 711” and insert-
 9 ing “sections 711 and 714”.

10 (C) TABLE OF CONTENTS.—The table of
 11 contents in section 1 of the Employee Retire-
 12 ment Income Security Act of 1974 is amended
 13 by inserting after the item relating to section
 14 713 the following new item:

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

15 (3) INTERNAL REVENUE CODE OF 1986.—

16 (A) IN GENERAL.—Subchapter B of chap-
 17 ter 100 of the Internal Revenue Code of 1986
 18 is amended—

19 (i) in the table of sections, by insert-
 20 ing after the item relating to section 9812
 21 the following new item:

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

22 and

1 (ii) by inserting after section 9812 the
 2 following:

3 **“SEC. 9813. COVERAGE FOR INDIVIDUALS PARTICIPATING**
 4 **IN APPROVED CLINICAL TRIALS.**

5 “(a) COVERAGE.—

6 “(1) IN GENERAL.—If a group health plan pro-
 7 vides coverage to a qualified individual (as defined in
 8 subsection (b)), the plan—

9 “(A) may not deny the individual partici-
 10 pation in the clinical trial referred to in sub-
 11 section (b)(2);

12 “(B) subject to subsections (b), (c), and
 13 (d) may not deny (or limit or impose additional
 14 conditions on) the coverage of routine patient
 15 costs for items and services furnished in con-
 16 nection with participation in the trial; and

17 “(C) may not discriminate against the in-
 18 dividual on the basis of the enrollee’s participa-
 19 tion in such trial.

20 “(2) EXCLUSION OF CERTAIN COSTS.—

21 “(A) IN GENERAL.—For purposes of para-
 22 graph (1)(B), subject to subparagraph (B), rou-
 23 tine patient costs include all items and services
 24 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 pro-
vided 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 ef-
fects of the item or service, or the preven-
tion of complications.

“(iii) REASONABLE AND NECESSARY
CARE.—Items or services needed for rea-
sonable and necessary care arising from
the provision of an investigational item or
service, including the diagnosis or treat-
ment of complications.

1 “(3) USE OF IN-NETWORK PROVIDERS.—If one
 2 or more participating provider is participating in a
 3 clinical trial, nothing in paragraph (1) shall be con-
 4 strued as preventing a plan from requiring that a
 5 qualified individual participate in the trial through
 6 such a participating provider if the provider will ac-
 7 cept the individual as a participant in the trial.

8 “(b) QUALIFIED INDIVIDUAL DEFINED.—For pur-
 9 poses of subsection (a), the term ‘qualified individual’
 10 means an individual who is a participant or beneficiary
 11 in a group health plan and who meets the following condi-
 12 tions:

13 “(1)(A) The individual has a life-threatening or
 14 serious illness for which no standard treatment is ef-
 15 fective.

16 “(B) The individual is eligible to participate in
 17 an approved clinical trial according to the trial pro-
 18 tocol with respect to treatment of such illness.

19 “(C) The individual’s participation in the trial
 20 offers meaningful potential for significant clinical
 21 benefit for the individual.

22 “(2) Either—

23 “(A) the referring physician is a partici-
 24 pating health care professional and has con-
 25 cluded that the individual’s participation in

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

4 “(B) the participant, beneficiary, or en-
 5 rollee provides medical and scientific informa-
 6 tion establishing that the individual’s participa-
 7 tion in such trial would be appropriate based
 8 upon the individual meeting the conditions de-
 9 scribed in paragraph (1).

10 “(c) PAYMENT.—

11 “(1) IN GENERAL.—Under this section a group
 12 health plan shall provide for payment for routine pa-
 13 tient costs described in subsection (a)(2) but is not
 14 required to pay for costs of items and services that
 15 are reasonably expected to be paid for by the spon-
 16 sors of an approved clinical trial.

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

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

21 “(B) a nonparticipating provider, the pay-
 22 ment rate shall be at the rate the plan would
 23 normally pay for comparable services under
 24 subparagraph (A).

25 “(d) APPROVED CLINICAL TRIAL DEFINED.—

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

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

9 “(i) NIH.—The National Institutes of
10 Health.

11 “(ii) CDC.—The Centers for Disease
12 Control and Prevention.

13 “(iii) AHRQ.—The Agency for Health
14 Care Research and Quality.

15 “(iv) CMS.—The Center for Medicare
16 & Medicaid Services.

17 “(v) COOPERATIVE CENTER.—A coop-
18 erative group or center of any of the enti-
19 ties described in clauses (i) through (iv) or
20 the Departments of Defense or Veterans
21 Affairs.

22 “(vi) CENTER SUPPORT GRANTEEES.—
23 A qualified nongovernmental research enti-
24 ty identified in the guidelines issued by the

1 National Institutes of Health for center
2 support grants.

3 “(vii) DOD; VA; DOE.—Any of the fol-
4 lowing if the conditions described in para-
5 graph (2) are met:

6 “(I) The Department of Veterans
7 Affairs.

8 “(II) The Department of De-
9 fense.

10 “(III) The Department of En-
11 ergy.

12 “(B) FDA DRUG TRIAL UNDER IND.—The
13 study or investigation is conducted under an in-
14 vestigational new drug application reviewed by
15 the Food and Drug Administration.

16 “(C) EXEMPT DRUG TRIAL.—The study or
17 investigation is a drug trial that is exempt from
18 having such an investigational new drug appli-
19 cation.

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

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

4 “(B) assures unbiased review of the high-
 5 est scientific standards by qualified individuals
 6 who have no interest in the outcome of the re-
 7 view.

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

12 (b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—
 13 Part B of title XXVII of the Public Health Service Act
 14 (42 U.S.C. 300gg–41 et seq.) is amended—

15 (1) by redesignating the first subpart 3 (relat-
 16 ing to other requirements) as subpart 2; and

17 (2) by adding at the end of subpart 2 the fol-
 18 lowing:

19 **“SEC. 2753. COVERAGE FOR INDIVIDUALS PARTICIPATING**
 20 **IN APPROVED CLINICAL TRIALS.**

21 “The provisions of section 2707 shall apply to health
 22 insurance coverage offered by a health insurance issuer
 23 in the individual market in the same manner as they apply
 24 to health insurance coverage offered by a health insurance

1 issuer in connection with a group health plan in the small
2 or large group market.”.

3 (c) EFFECTIVE DATES.—

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

8 (2) INDIVIDUAL HEALTH INSURANCE COV-
9 ERAGE.—The amendments made by subsection (b)
10 apply with respect to health insurance coverage of-
11 fered, sold, issued, renewed, in effect, or operated in
12 the individual market on or after January 1, 2004.

13 (3) COLLECTIVE BARGAINING EXCEPTION.—In
14 the case of a group health plan maintained pursuant
15 to 1 or more collective bargaining agreements be-
16 tween employee representatives and 1 or more em-
17 ployers ratified before the date of enactment of this
18 Act, the amendments made by subsection (a) shall
19 not apply to plan years beginning before the later
20 of—

21 (A) the date on which the last collective
22 bargaining agreements relating to the plan ter-
23 minates (determined without regard to any ex-
24 tension thereof agreed to after the date of en-
25 actment of this Act); or

1 (B) January 1, 2004.

2 For purposes of subparagraph (A), any plan amend-
3 ment made pursuant to a collective bargaining
4 agreement relating to the plan which amends the
5 plan solely to conform to any requirement added by
6 subsection (a) shall not be treated as a termination
7 of such collective bargaining agreement.

8 (d) COORDINATION OF ADMINISTRATION.—The Sec-
9 retary of Labor, the Secretary of the Treasury, and the
10 Secretary of Health and Human Services shall ensure,
11 through the execution of an interagency memorandum of
12 understanding among such Secretaries, that—

13 (1) regulations, rulings, and interpretations
14 issued by such Secretaries relating to the same mat-
15 ter over which two or more such Secretaries have re-
16 sponsibility under the provisions of this section (and
17 the amendments made thereby) are administered so
18 as to have the same effect at all times; and

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

24 (e) STUDY AND REPORT.—

1 (1) STUDY.—The Secretary of Health and
2 Human Services, jointly with the Secretary of Labor
3 and the Secretary of the Treasury, shall study the
4 impact on group health plans and health insurance
5 issuers for covering routine patient care costs for in-
6 dividuals who are entitled to benefits under this sec-
7 tion and who are enrolled in an approved clinical
8 trial program.

9 (2) REPORT.—Not later than January 1, 2006,
10 the Secretary of Health and Human Services shall
11 submit a report to Congress that contains an assess-
12 ment of—

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

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

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

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

1 **SEC. 202. GRANTS FOR PRIMARY CARE RESEARCH FOR**
2 **OLDER PATIENTS.**

3 Part B of title IX of the Public Health Service Act
4 (42 U.S.C. 299b et seq.), as amended by section 101, is
5 further amended by adding at the end the following:

6 **“SEC. 920A. GRANTS FOR PRIMARY CARE RESEARCH FOR**
7 **OLDER PATIENTS.**

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

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

17 “(c) REQUIREMENTS.—Research conducted under a
18 grant under this section shall—

19 “(1) examine the role of disease-specific guide-
20 lines in the population described in subsection (a);

21 “(2) examine the feasibility of developing guide-
22 lines that focus on the interaction of diseases and
23 conditions; and

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

1 such population, including outcomes from the per-
 2 spective of patients, families, and clinicians.

3 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
 4 are authorized to be appropriated to carry out this section,
 5 \$10,000,000 for fiscal year 2004, and such sums as may
 6 be necessary for each fiscal year thereafter.”.

7 **SEC. 203. STUDY ON EFFECTIVENESS OF CERTAIN PRE-**
 8 **SCRIPTION DRUGS.**

9 (a) IN GENERAL.—

10 (1) RESEARCH BY NIH.—The Director of the
 11 National Institutes of Health, in coordination with
 12 the Director of the Agency for Healthcare Research
 13 and Quality and the Commissioner of Food and
 14 Drugs, shall conduct research, which may include
 15 clinical research, to develop valid scientific evidence
 16 regarding the comparative effectiveness and, where
 17 appropriate, comparative safety of covered prescrip-
 18 tion drugs relative to other drugs and treatments for
 19 the same disease or condition.

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

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

1 Drug Administration, shall use evidence-based
2 practice centers to synthesize available data or
3 conduct other analyses of the comparative effective-
4 ness and, where appropriate, comparative
5 safety of covered prescription drugs relative to
6 other drugs and treatments for the same dis-
7 ease or condition.

8 (B) SAFETY.—In any analysis of compara-
9 tive effectiveness under this subparagraph, the
10 Institute of Medicine shall include a discussion
11 of available information on relative safety.

12 (3) STANDARDS.—The Director of the Agency
13 for Healthcare Research and Quality, in consultation
14 with the Commissioner of Food and Drugs, the Di-
15 rector of the National Institutes of Health, and with
16 input from stakeholders, shall develop standards for
17 the design and conduct of studies under this sub-
18 section.

19 (b) COVERED PRESCRIPTION DRUGS.—For purposes
20 of this section, the term “covered prescription drugs”
21 means prescription drugs that, as determined by the Di-
22 rector of the Agency for Healthcare Research and Quality
23 in consultation with the Administrator of the Centers for
24 Medicare & Medicaid Services, the Secretary of Defense,
25 and the Secretary of Veterans Affairs, account for high

1 levels of use or high levels of risk to individuals in federally
2 funded health programs, including Medicare and Med-
3 icaid.

4 (c) DISSEMINATION.—

5 (1) BIENNIAL REPORT.—Every 2 years, the
6 Secretary shall prepare a report on the progress and
7 results, if available, of the research, studies, and
8 analyses conducted by the National Institutes of
9 Health and the Agency for Healthcare Research and
10 Quality, and the Food and Drug Administration
11 under this section and submit the report to the fol-
12 lowing:

13 (A) Congress.

14 (B) The President.

15 (C) The Secretary of Defense.

16 (D) The Secretary of Veterans Affairs.

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

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

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

3 (3) FDA DRUG INFORMATION.—The Commis-
4 sioner of Food and Drugs shall—

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

8 (B) when determined appropriate by the
9 Commissioner, develop summaries of such infor-
10 mation for inclusion in adequate directions for
11 use under section 502(f)(1) of the Federal
12 Food, Drug, and Cosmetic Act and in sum-
13 maries relating to side effects, contraindica-
14 tions, and effectiveness under section 502(n) of
15 that Act.

16 (4) NIH INTERNET SITE.—The Director of the
17 National Institutes of Health shall publish on the
18 Institutes' Internet site and through other means
19 that will facilitate access by practitioners and pa-
20 tients each report prepared under this subsection by
21 the Director of the Agency for Healthcare Research
22 and Quality.

23 (d) EVIDENCE.—In carrying out this section, the Di-
24 rector of the National Institutes of Health and the Agency
25 for Healthcare Research and Quality shall consider only

1 methodologically sound studies, giving preference to stud-
 2 ies for which the Directors have access to sufficient under-
 3 lying data and analysis to address any significant concerns
 4 about methodology or the reliability of data.

5 (e) AUTHORIZATIONS OF APPROPRIATIONS.—There
 6 are authorized to be appropriated to carry out this section,
 7 \$75,000,000 for fiscal year 2004, and such sums as may
 8 be necessary for each fiscal year thereafter.

9 **TITLE III—MEASURING AND** 10 **COMPARING QUALITY**

11 **SEC. 301. PRIORITY AREA QUALITY INDICATORS.**

12 Part B of title IX of the Public Health Service Act
 13 (42 U.S.C. 299b et seq.), as amended by section 201, is
 14 further amended by adding at the end the following:

15 **“SEC. 920B. PRIORITY AREA QUALITY INDICATORS.**

16 “(a) IN GENERAL.—The Director, in consultation
 17 with the Quality Interagency Coordination Task Force,
 18 the Institute of Medicine, the Joint Commission on Ac-
 19 creditation of Healthcare Organizations, the National
 20 Committee for Quality Assurance, the American Health
 21 Quality Association, the National Quality Forum, the
 22 Medicare Payment Advisory Committee, and other individ-
 23 uals and organizations determined appropriate by the Sec-
 24 retary, shall assemble, evaluate, and, where necessary, de-
 25 velop or update quality indicators for each of the 20 pri-

1 ority areas for improvement in health care quality as iden-
2 tified by the Institute of Medicine in their report entitled
3 ‘Priority Areas for National Action’ in 2003, or other such
4 areas as identified by the Secretary in order to assist bene-
5 ficiaries in making informed choices about health plans or
6 care delivery systems, and make such indicators available
7 for purchasers to develop or align payment and perform-
8 ance. The selection of appropriate quality indicators under
9 this subsection shall include the evaluation criteria formu-
10 lated by clinical professionals, consumers, and data collec-
11 tion experts. Performance indicators developed or updated
12 under this subsection shall in the aggregate reflect the
13 spectrum of care patients receive and may include a range
14 of process and outcome measures such as clinical outcome
15 measures and indicators reflecting the provision of cul-
16 turally and linguistically appropriate care.

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

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

22 “(1) assess data concerning appropriate clinical
23 treatments based on the best scientific evidence
24 available;

1 “(2) determine areas in which there is insuffi-
2 cient evidence to determine best practices; and

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

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

10 “(1) submit to the Director of the National In-
11 stitutes of Health a report concerning areas of clin-
12 ical care requiring further research necessary to es-
13 tablish effective clinical treatments that will serve as
14 a basis for quality indicators; and

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

19 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
20 are authorized to be appropriated to carry out this section
21 \$12,000,000 for fiscal year 2004, and \$8,000,000 for each
22 of fiscal years 2005 through 2009.”.

1 **SEC. 302. STANDARDIZED QUALITY INDICATORS FOR FED-**
2 **ERAL AGENCIES.**

3 (a) IN GENERAL.—In addition to other activities to
4 be carried out by the Quality Interagency Coordination
5 Taskforce (as established by executive order on March 13,
6 1998), such Taskforce shall use indicators standardized
7 by the National Quality Forum to standardize indicators
8 of health care quality that are used in all Federal agencies,
9 as appropriate.

10 (b) CONSULTATION.—In carrying out subsection (a),
11 the Quality Interagency Coordination Taskforce shall con-
12 sult with a public-private consensus organization (such as
13 the National Quality Forum) to enhance the likelihood of
14 the simultaneous application of the standardized indica-
15 tors under subsection (a) in the private sector.

16 (c) REPORT.—Not later than 1 year after the date
17 of enactment of this Act, and annually thereafter, the Sec-
18 retary of Health and Human Services shall submit to Con-
19 gress a report on the progress made by the Quality Inter-
20 agency Coordination Taskforce to standardizing quality
21 indicators throughout the Federal Government.

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

24 (a) IN GENERAL.—The Secretary of Health and
25 Human Services, acting through the Director of the Cen-
26 ters for Disease Control and Prevention and the Director

1 of the Agency for Healthcare Quality and Research, shall
2 award not to exceed 20 grants to eligible communities for
3 the establishment of demonstration programs for the re-
4 porting of health care quality information at the commu-
5 nity level.

6 (b) QUALITY INDICATORS.—

7 (1) IN GENERAL.—For purposes of reporting
8 information under the demonstration programs
9 under this section, indicators of health care quality
10 shall include the indicators developed for the 20 pri-
11 ority areas as identified by the Institute of Medicine
12 in the report entitled “Priority Areas for National
13 Action”, 2003, or other indicators determined appro-
14 priate by the Secretary of Health and Human Serv-
15 ices.

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

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

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

8 (d) TECHNICAL ADVISORY COMMITTEE.—The Sec-
9 retary of Health and Human Services shall establish an
10 external technical advisory committee to assist grantees
11 in data collection, data analysis, and report dissemination.

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

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

20 (2) make such reports publicly available, includ-
21 ing by posting the reports on the Internet.

22 (f) EVALUATION.—The Secretary of Health and
23 Human Services shall, upon awarding grants under sub-
24 section (a), enter into a contract for the evaluation of dem-
25 onstration programs under this section. Such evaluation

1 shall compare the effectiveness of such demonstration pro-
 2 grams in collecting and reporting required data, and on
 3 the effectiveness of distributing information to key stake-
 4 holders in a timely fashion. Such evaluations shall provide
 5 for a report on best practices.

6 (g) AUTHORIZATION OF APPROPRIATIONS.—There
 7 are authorized to be appropriated to carry out this section
 8 \$25,000,000 for fiscal year 2004, and such sums as may
 9 be necessary for each fiscal year thereafter.

10 **SEC. 304. DEMONSTRATION PROJECT FOR THE COLLEC-**
 11 **TION OF DATA ON RACE, ETHNICITY, AND**
 12 **LINGUISTIC PREFERENCES.**

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

16 “(4) COLLECTION OF DATA ON RACE, ETH-
 17 NICITY, AND LINGUISTIC PREFERENCES.—

18 “(A) IN GENERAL.—The Secretary, acting
 19 through the Director, shall conduct demonstra-
 20 tion programs in conjunction with physicians,
 21 physician groups, patients, and consumer
 22 groups to investigate effective ways to collect
 23 reliable and valid data regarding an individual
 24 patient’s race, ethnicity, and linguistic pref-
 25 erences. Such demonstrations may include—

1 “(i) the use of focus groups to develop
 2 appropriate language and modalities for
 3 requesting such information;

4 “(ii) the conduct of training programs
 5 for front line staff and clinical profes-
 6 sionals;

7 “(iii) the use of specific culturally and
 8 linguistically appropriate scripts, trans-
 9 lation of scripts and supporting material,

10 “(iv) the use of general informational
 11 materials;

12 “(v) designs for community awareness
 13 programs that are culturally and linguis-
 14 tically appropriate; and

15 “(vi) the collection and dissemination
 16 of best practices for the collection of race,
 17 ethnicity, and linguistic preference infor-
 18 mation.

19 “(B) ELIGIBILITY.—To be eligible to par-
 20 ticipate in a demonstration project under sub-
 21 paragraph (A), an individual or entity shall—

22 “(i) be a domestic or foreign, public
 23 or private not-for-profit organization, in-
 24 cluding a university, clinic, unit of State or

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

3 “(ii) submit to the Secretary an appli-
4 cation at such time, in such manner, and
5 containing such information as the Sec-
6 retary may require, including—

7 “(I) a description of the popu-
8 lations to be included in the project;

9 “(II) documentation of the will-
10 ingness to participate in the project
11 from appropriate community groups;

12 “(III) documentation of the pre-
13 vious ability of the applicant to work
14 with such groups; and

15 “(IV) evidence of necessary skill
16 sets to develop needed materials and
17 interventions.

18 “(C) DURATION.—A demonstration project
19 under this paragraph shall be for 1 or 2 years
20 and shall be conducted over a period com-
21 mencing not later than 6 months after the date
22 of enactment of this paragraph.

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

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

8 “(E) AUTHORIZATION OF APPROPRIA-
 9 TIONS.—There are authorized to be appro-
 10 priated to carry out this section, \$5,000,000 for
 11 each of fiscal years 2004 and 2005.”.

12 **TITLE IV—PRODUCTION, EVAL-**
 13 **UATION, AND DISTRIBUTION**
 14 **OF PRACTICE GUIDELINES**
 15 **FOR CARE**

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

18 (a) IN GENERAL.—The Secretary of Health and
 19 Human Services shall enter into a contract with the Insti-
 20 tute of Medicine of the National Academy of Sciences, or
 21 another appropriate entity, to conduct a study on ap-
 22 proaches to developing and disseminating seed practice
 23 guidelines to be used as a basis for regional or local appli-
 24 cation in accordance with subsection (b).

1 (b) CONTENT.—The study conducted under sub-
2 section (a) shall—

3 (1) study how and under what circumstances
4 the coordinated development of evidence-based prac-
5 tice guidelines would be feasible and would improve
6 health outcomes;

7 (2) identify any available prototypes for the de-
8 velopment and dissemination of guidelines regionally,
9 in the United States, or in other countries;

10 (3) consider how to involve health care con-
11 sumers in the development of such guidelines and
12 gain the acceptance of clinicians;

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

15 (5) consider how guidelines should reflect vari-
16 ations in patients preferences;

17 (6) determine potential guideline models, in-
18 cluding public and private options;

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

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

24 (9) explore alternative funding options;

1 (10) evaluate guideline dissemination strategies;
2 and

3 (11) develop a recommended strategy for imple-
4 mentation in the United States, including the poten-
5 tial role of the Federal Government.

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

11 (d) DISSEMINATION OF FINDINGS.—The Secretary
12 shall disseminate the findings of the study conducted
13 under subsection (a) to appropriate public and private en-
14 tities, including the posting of such findings on appro-
15 priate websites.

16 (e) DEFINITION.—In this section, the term “seed
17 practice guidelines” means guidelines that represent a
18 synthesis of the scientific evidence to support clinical prac-
19 tice.

20 (f) AUTHORIZATION OF APPROPRIATIONS.—There is
21 authorized to be appropriated to carry out this section
22 \$750,000 for fiscal year 2004.

1 **TITLE V—REWARDING QUALITY**

2 **SEC. 501. INSTITUTE OF MEDICINE REPORT ON PAYMENT**

3 **INCENTIVES AND PERFORMANCE.**

4 (a) EVALUATION.—

5 (1) IN GENERAL.—Not later than 2 months
6 after the date of enactment of this Act, the Sec-
7 retary of Health and Human Services shall enter
8 into an arrangement under which the Institute of
9 Medicine of the National Academy of Sciences (in
10 this section referred to as the “Institute”) shall con-
11 duct an evaluation of options to align performance
12 with payment, including payment under the medi-
13 care program under title XVIII of the Social Secu-
14 rity Act (42 U.S.C. 1395 et seq.).

15 (2) SPECIFIC MATTERS EVALUATED.—In con-
16 ducting the evaluation under paragraph (1), the In-
17 stitute shall—

18 (A) catalogue, review, and evaluate the va-
19 lidity of leading health care performance meas-
20 ures to determine what subset of measures is
21 appropriate for payment;

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

1 (C) identify and prioritize options to imple-
 2 ment policies that align performance with pay-
 3 ment under the medicare program that indi-
 4 cate—

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

8 (ii) the payment policy that will re-
 9 ward performance; and

10 (iii) the key implementation issues
 11 (such as data and information technology
 12 requirements, and necessary risk adjust-
 13 ment) that must be addressed.

14 (3) SCOPE OF HEALTH CARE PERFORMANCE
 15 MEASURES.—The evaluation and selection of health
 16 care performance measures described in paragraph
 17 (2)(A) shall reflect a variety of perspectives, includ-
 18 ing clinical professionals, hospitals, health plans,
 19 purchasers, and consumers, and data collection ex-
 20 perts.

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

1 (b) REPORT.—Not later than 6 months after the
2 issuance of a report by the Secretary on priority area qual-
3 ity indicators, the Institute shall submit to the Secretary
4 of Health and Human Services, the Committees on Ways
5 and Means and Energy and Commerce of the House of
6 Representatives, and the Committees on Finance and
7 Health, Education, Labor and Pensions of the Senate a
8 report on the evaluation conducted under subsection (a)(1)
9 that describes the findings of such evaluation and contains
10 recommendations for an overall strategy and approach for
11 aligning payment with performance in various types of pri-
12 vate and public health plans, including, the original medi-
13 care fee-for-service program under parts A and B of title
14 XVIII of the Social Security Act, the Medicare+Choice
15 program under part C of such title, and any other pro-
16 grams under such title XVIII.

17 (c) AUTHORIZATION OF APPROPRIATIONS.—There
18 are authorized to be appropriated, \$1,000,000 for pur-
19 poses of conducting the evaluation and preparing the re-
20 port required by this section.

1 **TITLE VI—INFORMATION TO**
2 **CONSUMERS**

3 **SEC. 601. DISSEMINATION OF INFORMATION TO CON-**
4 **SUMERS.**

5 Part B of title IX of the Public Health Service Act
6 (42 U.S.C. 299b et seq.), as amended by section 301, is
7 further amended by adding at the end the following:

8 **“SEC. 920C. DISSEMINATION OF INFORMATION TO CON-**
9 **SUMERS.**

10 “(a) DEMONSTRATION PROJECTS.—

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

17 “(2) REQUIREMENTS.—The research and dem-
18 onstration projects under paragraph (1) shall ad-
19 dress the following:

20 “(A) The ability and costs to train staff in
21 community-based and voluntary public and pri-
22 vate organizations to disseminate such informa-
23 tion.

24 “(B) The materials needed for such train-
25 ing.

1 “(C) The types of audiences reached by
2 such community-based and voluntary public and
3 private organizations.

4 “(D) The effectiveness of the transmission
5 of information from such community-based and
6 voluntary public and private organizations to
7 the target audiences.

8 “(3) REPORT.—Not later than 3 years after the
9 date of enactment of this section, the Secretary shall
10 ensure that a report containing the results of the re-
11 search and demonstration projects under paragraph
12 (1) is submitted to the appropriate committees of
13 Congress.

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

17 “(b) TRAINING FOR LONG-TERM CARE OMBUDS-
18 MAN.—

19 “(1) IN GENERAL.—The Secretary, acting
20 through the Director of the Administration on Aging
21 and in consultation with the Director of the Agency
22 for Healthcare Research and Quality and the Ad-
23 ministrator of the Centers for Medicare & Medicaid
24 Services, shall authorize a program, to be developed
25 and implemented by the National Long-Term Care

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

4 “(2) TRAINING.—Under the program developed
5 under paragraph (2), training shall be provided to
6 long-term care ombudsman to enable such ombuds-
7 man to educate consumers concerning—

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

10 “(B) available nursing home and home
11 health care quality of care reports, including ex-
12 isting quality data that the Administrator of
13 the Centers for Medicare & Medicaid Services
14 has released for use by the public in choosing
15 long-term care facilities or home health care
16 services; and

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

21 “(3) DUTIES OF RESOURCE CENTER.—The Na-
22 tional Long-Term Care Ombudsman Resource Cen-
23 ter shall—

24 “(A) develop and maintain a curriculum
25 for ombudsmen;

1 “(B) develop, produce, and maintain train-
2 ing materials;

3 “(C) conduct train-the-trainer programs at
4 regional and national levels; and

5 “(D) act as a clearinghouse for best prac-
6 tices in communicating the significance of nurs-
7 ing home and home health care quality indica-
8 tors to residents and their caregivers.

9 “(4) PILOT PROGRAMS.—The Secretary shall
10 award grants for the establishment of 1-year pilot
11 demonstration programs in 10 States using dedi-
12 cated long-term care ombudsmen to educate con-
13 sumers regarding nursing home and home health
14 care quality. Such pilot demonstration programs
15 shall test the effectiveness of having a committed po-
16 sition within the State dedicated to helping con-
17 sumers use nursing home and home health care
18 quality indicators.

19 “(5) REPORT.—Not later than 18 months after
20 the date of enactment of this section, and annually
21 thereafter, the Secretary shall submit to Congress a
22 report concerning the effectiveness of the program
23 established under this subsection, including the ben-
24 efits of providing for dedicated staff who are respon-
25 sible for educating consumers to use nursing home

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

3 “(6) AUTHORIZATION.—In addition to any
4 other amounts authorized to be appropriated for
5 long-term care ombudsman programs, there are au-
6 thorized to be appropriated to carry out this sub-
7 section \$4,000,000 for fiscal year 2004 (of which
8 \$1,000,000 shall be used to carry out paragraph
9 (4)), and \$2,000,000 for each fiscal year there-
10 after.”.

11 **TITLE VII—PROMOTING** 12 **PATIENT ENGAGEMENT**

13 **SEC. 701. PROMOTING PATIENT ENGAGEMENT.**

14 Part B of title IX of the Public Health Service Act
15 (42 U.S.C. 299b et seq.), as amended by section 601, is
16 further amended by adding at the end the following:

17 **“SEC. 920D. PROMOTING PATIENT ENGAGEMENT.**

18 “(a) GRANTS.—

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

23 “(2) REQUIREMENTS.—Activities conducted
24 under grants awarded under paragraph (1) shall—

1 “(A) evaluate the impact of sharing health
2 records with patients;

3 “(B) provide for the conduct of studies on
4 understanding and describing patient value sys-
5 tems, including risk aversion, self-care orienta-
6 tion, and time horizon;

7 “(C) evaluate how patients seek health in-
8 formation and how they use it;

9 “(D) evaluate how changes in consumer
10 behavior based on information about quality af-
11 fect changes in provider behavior; and

12 “(E) study how the effects of the studies
13 conducted under this subsection vary by race,
14 ethnicity, cultural and linguistic groups, edu-
15 cation, age, and gender.

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

19 “(b) HEALTH LITERACY STANDARDS.—

20 “(1) IN GENERAL.—For purposes of assisting
21 eligible entities in providing quality assurance meas-
22 ures, the Secretary, acting through the Director, the
23 Administrator of Health Resources and Services Ad-
24 ministration, the Director of the National Library of
25 Medicine, and the Commissioner of Food and Drugs,

1 shall develop standardized materials that phar-
2 macists may use to assist non-English speaking or
3 functionally illiterate patients in the safe and appro-
4 priate use of prescription drugs. Such materials may
5 include the use of pictures and the development of
6 standardized translations in multiple languages of
7 prescription labels and bottle labels and other pa-
8 tient safety initiative information. Such materials
9 shall be available electronically for direct access by
10 pharmacists.

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

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