TITLE IX—QUALITY AND CONSUMER AND WORKFORCE PROTECTION

Subtitle A—Quality Management and Improvement

PART 1—NATIONAL QUALITY MANAGEMENT PROGRAM

SEC. 9001. NATIONAL QUALITY MANAGEMENT PROGRAM.

(a) ESTABLISHMENT.—The Secretary shall establish and oversee a performance-based program of quality management and improvement designed to enhance the quality, appropriateness, and effectiveness of health care services rendered in the United States. The program shall be known as the National Quality Management Program.

(b) ELEMENTS.—Subject to the specific provisions of this part, the National Quality Management Program shall consist of the following:

(1) The consumer surveys described in section 9002.

(2) The national measures of quality performance described in section 9003.

(3) The national quality standards for approved sponsors described in section 9004.

(4) The models for profiling patterns of clinical practice and improving quality of care described in section 9005.

(5) The quality-related profiling data described in section 9006.

(6) The compliance monitoring described in section 9007.

(7) The guideline development and certification and the research on health care quality described in section 9008.

(8) The contracts with approved quality improvement organizations entered into by the Secretary under section 9009.

(9) The quality management grants made to approved States by the Secretary under section 9010.

SEC. 9002. CONSUMER SURVEYS.

(a) IN GENERAL.—The Secretary shall conduct annual surveys of health care consumers to gather information, with respect to a year to which a survey pertains, concerning access to care, use of health services, health outcomes, and patient satisfaction. The surveys shall be conducted using the standard design and the sampling strategies developed under subsection (d).

(b) AUTHORITY TO CONTRACT.—The Secretary may carry out subsection (a) by entering into contracts with private individuals or entities or States pursuant to which the individuals, entities, or States undertake the duties applicable to the Secretary under the subsection.

(c) TRANSMISSION OF SURVEY RESULTS.—

(1) APPROVED SPONSORS.—The Secretary shall forward the results of any survey conducted under this section that pertains to an approved health plan provided or sponsored by an approved sponsor in a State to—

(A) the State (if the State is an approved State); and

(B) the approved quality improvement organization responsible for the geographic area that includes the State.

(2) QUALIFIED PROVIDERS.—The Secretary shall forward the results of any survey conducted under this section that pertains to health care services rendered in a State by a qualified provider to—

(A) the State (if the State is an approved State); and

(B) the approved quality improvement organization responsible for the geographic area that includes the State.

(d) DESIGN AND SAMPLING STRATEGIES.—

(1) STANDARD DESIGN.—The Secretary shall develop and approve a standard design for the surveys conducted under

this section. The design shall ensure the collection of valid, reliable, and comparable survey responses.

(2) SAMPLING STRATEGIES.—The Secretary shall develop sampling strategies that ensure that survey samples adequately measure populations that are considered to be at risk of receiving inadequate health care, including individuals with disabilities.

(3) DEADLINE.—The Secretary shall develop and approve the design under paragraph (1) and the sampling strategies under paragraph (2) not later than 12 months after the date of the enactment of this Act.

(e) TIMELINESS.—The Secretary shall carry out subsections (a) and (c) in a manner that permits a State to include the results of consumer surveys that pertain to a year in the performance report published by the State under section 9003(g) that pertains to the year.

SEC. 9003. NATIONAL MEASURES OF QUALITY PERFORMANCE.

(a) DEVELOPMENT AND UPDATING.—

(1) IN GENERAL.—The Secretary shall develop and update a uniform set of national measures of quality performance to be used to assess—

(A) the performance of approved sponsors, network providers, and health institutions;

(B) the satisfaction of individuals enrolled under an approved health plan with the access to, and quality of, items and services provided by the approved sponsor providing or sponsoring the plan and network providers with respect to the plan;

(C) the satisfaction of individuals receiving health care items and services from a health institution; and

(D) the degree to which approved sponsors, network providers, and health institutions are meeting the needs of special patient populations, including individuals with disabilities.

(2) MINIMUM INFORMATION REQUIRED TO BE PROVIDED.—The measures shall be developed and selected in a manner that ensures that approved plan sponsors and health institutions are required to provide the minimum amount of information that is necessary to perform the assessments referred to in paragraph (1).

(3) BASES FOR MEASURES.—In developing and selecting the national measures of quality performance, the Secretary shall consider the recommendations of the Health Care Quality Advisory Commission established under section 9012 (in this part referred to as the "Commission"). The measures also may be based on guidelines developed or certified under title IX of the Public Health Service Act, research sponsored under such title, or other guidelines or research, if the guidelines or research are determined to be appropriate for such purpose by the Secretary.

(4) SEQUENTIAL SETS.—The set of national measures of quality performance shall be established through the development and use of a series of interim sets of quality measures. The Secretary, in consultation with the Commission, shall establish a sequence for such sets. The initial set of national measures of quality performance shall provide information on access to care and, with respect to an approved sponsor, information on the number, types, and locations of qualified providers who are authorized to provide services or receive payments under each approved health plan provided or sponsored by the sponsor. Subsequent sets of measures shall provide additional information as such information becomes valid and available (as determined by the Secretary).

(b) SUBJECT OF MEASURES.—The national measures of quality performance shall be selected in a manner that provides accurate, comparable information on the following subjects:

(1) Access to health care services and procedures by individuals enrolled in approved health plans.

(2) Outcomes (including patient functional status), effectiveness, and appropriateness of such health care services and procedures.

(3) Risk management and reduction, through health promotion and disease prevention.

(4) Consumer experience and satisfaction.

(c) CRITERIA.—The following criteria shall be used in developing and selecting national measures of quality performance:

(1) SIGNIFICANCE.—When a measure relates to a specific disease, disorder, or other health condition, the disease, disorder, or condition shall be of significance in terms of prevalence, morbidity, mortality, or the costs associated with the prevention, diagnosis, treatment, or clinical management of the disease, disorder, or condition.

(2) RANGE OF SERVICES.—The set of measures, taken as a whole, shall be representative of the range of services provided to consumers of health care.

(3) RELIABILITY AND VALIDITY.—To the extent practicable, the measures shall be reliable and valid.

(4) UNDUE BURDEN.—The data needed to calculate the measures shall be obtained without undue burden on the entity or individual providing the data.

(5) RURAL PRACTICE.—The measures shall take into account criteria appropriate to rural clinical practice.

(6) VARIATION.—Performance with respect to a measure shall be expected to vary widely among the individuals and entities whose performance is assessed using the measure.

(7) LINKAGE TO HEALTH OUTCOME.—When a measure is established relating to a process of care, the process shall be linked to a health outcome based upon the best available scientific evidence.

(8) PROVIDER CONTROL AND RISK ADJUSTMENT.—When a measure is an outcome of the provision of care, the outcome shall be within the control of the provider and one with respect to which an adequate risk adjustment can be made.

(9) PUBLIC HEALTH.—The measures shall reflect goals identified by the Secretary for meeting public health objectives.

(d) DATA TRANSMISSION.—

(1) APPROVED SPONSORS.—An approved sponsor shall transmit the data determined by the Secretary (consistent with subtitle C) to be necessary to assess under this section the performance of the sponsor with respect to an approved health plan provided or sponsored by the sponsor in a State, and the performance of network providers with respect to the plan, to the State (if the State is an approved State).

(2) HEALTH INSTITUTIONS.—A health institution shall transmit the data determined by the Secretary (consistent with subtitle C) to be necessary to assess the performance of the institution under this section with respect to health care services rendered in a State by the institution to the State (if the State is an approved State).

(3) APPLICATION OF SUBTITLE B.—Subsections (b), (c), and (d) of section 9104 and section 9107 shall apply to the transmission of data under this subsection, to the extent that such data are health information described in paragraph (1) or (2) of section 9104(b).

(e) DATA VALIDATION.—An approved State shall conduct such audits of the data submitted to the State under subsection (d) as are necessary to ensure that the data are valid, reliable, and complete. An approved sponsor and a health institution shall maintain such records, make such reports, and cooperate with the audits to the extent necessary to permit a State to satisfy the preceding sentence.

(f) ASSESSMENT OF PERFORMANCE.—

(1) STATES.—Each approved State annually shall assess, using the national measures of quality performance, the performance of each—

(A) approved sponsor providing or sponsoring an approved health plan in the State;

(B) network provider with respect to such a plan; and

(C) health institution licensed by the State.

(2) PLAN SPONSORS.—An approved sponsor shall use the national measures of quality performance to assess—

(A) the satisfaction of individuals enrolled under an approved health plan provided or sponsored by the sponsor with the services of the sponsor and network providers with respect to the plan; and

(B) the quality of such services, as measured by access to health care and appropriateness and outcomes of health care.

(g) PERFORMANCE REPORTS.—

(1) PREPARATION.—Using a standard format prescribed by the Secretary, and not later than January 1 of each year, an approved State shall compile in the form of a performance report the results of assessments conducted by the State under subsection (f), the results of the consumer surveys conducted by the Secretary under section 9002, and any other relevant information with respect to the national quality standards under section 9004 concerning approved sponsors providing or sponsoring an approved health plan in the State. The report shall be written in language calculated to be understood by the typical individual enrolled under such a plan and in a form which will assist consumers in selecting among such plans.

(2) PUBLICATION.—An approved State—

(A) shall publish any performance report prepared under paragraph (1);

(B) shall transmit any such published report to—

(i) the Consumer Health Advocacy Office for the State or a geographic region that includes the State established through a grant made under part O of title III of the Public Health Service Act (relating to consumer resources regarding health plans);

(ii) the enrollment assistance program for the State established under section 5011(b);

(iii) any consumer purchasing cooperatives in the State; and

(iv) the Secretary; and

(C) shall otherwise make available to the public any such published report.

(3) COMPILATION FOR CONGRESS.—The Secretary annually shall compile a national performance report from the reports transmitted to the Secretary under paragraph (2). The Secretary annually shall transmit such national report to the Congress.

(h) AUTHORITY TO CONTRACT.—An approved State may carry out subsections (f) and (g) by entering into contracts with individuals or entities pursuant to which the individuals or entities undertake the duties applicable to the State under the subsection.

(i) OTHER QUALITY IMPROVEMENT ACTIVITIES.—Consistent with subtitle C, an approved State shall make any data transmitted to the State under subsection (d) available to an quality improvement organization responsible for the geographic area that includes the State, upon request by the organization. An approved quality improvement organization may use such data, consistent with subtitle C, to carry out any function of the organization under this part.

(j) DEADLINE.—The Secretary shall develop an initial set of national measures of quality performance and the standard format for the performance reports under subsection (g) not later than 12 months after the date of the enactment of this Act.

SEC. 9004. NATIONAL QUALITY STANDARDS FOR APPROVED SPONSORS.

(a) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall establish national quality standards for approved sponsors. The standards established by the Secretary shall include the standards described in subsections (b) and (c).

(b) REQUIREMENTS FOR PLAN SPONSORS.—The quality standards for approved sponsors shall require each such sponsor—

(1) to establish an internal quality improvement program to measure, assess, and improve—

(A) the satisfaction of individuals enrolled under an approved health plan provided or sponsored by the sponsor with the services provided by the sponsor and by network providers with respect to the plan;

(B) the health status of such individuals; and

(C) the quality and outcomes of such services;

(2) through such program, to cooperate with—

(A) the performance monitoring activities undertaken by approved States under section 9007; and

(B) the activities undertaken by approved quality improvement organizations under sections 9004 and 9009;

(3) to make available to individuals enrolled in an approved health plan provided or sponsored by the sponsor information about the rights and responsibilities of enrollees;

(4) to provide an appeals procedure for review of benefit determinations that satisfies the requirements of part 1 of subtitle D;

(5) to provide a grievance procedure that provides for effective and timely response to complaints for enrollees to use in pursuing complaints with respect to the sponsor that are not based on a benefit determination reviewable under part 1 of subtitle D;

(6) to establish procedures for taking appropriate remedial action whenever inappropriate or substandard services are provided by an officer or employee of the sponsor or a qualified provider who is a network provider with respect to an approved health plan provided or sponsored by the sponsor;

(7) to verify the credentials of qualified providers who are network providers with respect to an approved health plan provided or sponsored by the sponsor;

(8) to establish a policy to identify and investigate sources of dissatisfaction with a provider who is a network provider with respect to an approved health plan provided or sponsored by the sponsor, outline actions to follow up on the findings, and inform the provider of the findings;

(9) to give reasonable consideration, in selecting among qualified providers for participation in a plan network serving a geographic area, to all providers who are legally authorized to provide health care services in the area; and

(10) to establish written policies and procedures to ensure that the confidentiality of protected health information (as defined in section 9200(a)) is protected in a manner consistent with subtitle C.

(c) OTHER REQUIREMENTS.—The quality standards for approved sponsors—

(1) shall ensure that any physician incentive plan (as defined in subsection (d)) operated by an approved sponsor is required to satisfy the requirements of clauses (i) and (ii) of section 1876(i)(8)(A) of the Social Security Act in the same manner as a physician incentive plan operated by an eligible organization (as defined in section 1876(b) of such Act) is required to satisfy the requirements of such clauses;

(2) shall require each approved sponsor to provide each State in which the sponsor provides or sponsors an approved health plan with descriptive information sufficient to permit the State to determine whether the sponsor is in compliance

with any requirement established with respect to such incentive plans under this section;

(3) shall require that if a physician incentive plan operated by an approved sponsor places a physician or physician group at substantial financial risk (as determined by the Secretary) for services not provided by the physician or physician group, the sponsor shall make available, upon request by enrollees, qualified providers, or potential enrollees or providers, descriptive information regarding any financial arrangements in the plan relating to controlling utilization or costs; and

(4) shall prohibit approved sponsors from engaging in any formal or informal practice that in any way restricts a qualified provider from communicating with a patient of the provider concerning the compensation of the provider, a term of any contract between the sponsor and the provider, or practices, protocols, or patterns of applying utilization review procedures of the sponsor, where such compensation, contract term, practice, protocol, or pattern may affect the patient's access to care.

(d) PHYSICIAN INCENTIVE PLAN DEFINED.—In this section, the term "physician incentive plan" means any compensation arrangement between an approved sponsor and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled in an approved health plan provided or sponsored by the sponsor.

SEC. 9005. PROFILING PATTERNS OF PRACTICE OF QUALIFIED PROVIDERS.

(a) PROFILING OF PATTERNS OF PRACTICE; OPPORTUNITIES FOR QUALITY IMPROVEMENT.—

(1) MODEL ADOPTION.—The Secretary shall develop models for profiling the patterns of clinical practice of qualified providers and approved sponsors (to the extent that such sponsors provide health benefits in the form of items and services to enrollees).

(2) DISSEMINATION.—The Secretary shall disseminate to approved quality improvement organizations, approved sponsors, and approved States the models adopted under paragraph (1).

(3) OPPORTUNITIES FOR QUALITY IMPROVEMENT.—The Secretary shall develop and disseminate to approved quality improvement organizations models for improving quality of care where opportunities are identified through profiling and other means so as to assure the quality of health care services provided in the United States.

(4) DEADLINE.—The Secretary shall develop the models under this subsection not later than 18 months after the date of the enactment of this Act.

(b) IMPLEMENTATION BY QUALITY IMPROVEMENT ORGANIZATIONS.—

(1) IN GENERAL.—An approved quality improvement organization shall implement, on an ongoing basis, the models developed under subsection (a) with respect to—

(A) qualified providers who are licensed by a State that is in a geographic area for which the organization is responsible; and

(B) approved sponsors providing health benefits in the form of items and services to enrollees in a State—

(i) in which the sponsor provides or sponsors an approved health plan; and

(ii) that is in a geographic area for which the organization is responsible.

(2) POPULATION-BASED MONITORING.—The duties of an approved quality improvement organization under the preceding sentence shall include population-based monitoring of the patterns of clinical practice described in subsection (a)(1) for the purpose of promoting community-based quality improvement.

(3) QUALITY-RELATED PROFILING DATA.—In implementing a model for profiling patterns of clinical practice, an approved quality improvement organization shall use the quality-related profiling data transmitted to the organization under section 9006.

(c) LIMITATION ON LIABILITY.—Notwithstanding any other provision of law, a person providing information to any approved quality improvement organization may not be held, by reason of having provided such information, to have violated any criminal law, or to be civilly liable under any law of the United States or of any State (or political subdivision thereof) unless—

(1) such information is unrelated to the performance of the contract of such organization with the Secretary under section 9009;

(2) such information is transmitted in violation of section 9006; or

(3) such information is false and the person providing it knew, or had reason to believe, that such information was false.

SEC. 9006. QUALITY-RELATED PROFILING DATA.

(a) TRANSMISSION.—

(1) APPROVED SPONSORS.—An approved sponsor that provides health benefits in the form of items and services to enrollees shall transmit to each approved quality improvement organization for a geographic area that includes a State in which the sponsor provides or sponsors an approved health plan the set of quality-related profiling data established by the Secretary under subsection (b).

(2) PROVIDERS.—A qualified provider shall transmit to each approved quality improvement organization for a geographic area that includes a State in which the provider is licensed the set of quality-related profiling data established by the Secretary under subsection (b).

(3) APPLICATION OF SUBTITLE B.—Subsections (b), (c), and (d) of section 9104 and section 9107 shall apply to the transmission of data under this subsection.

(b) ESTABLISHMENT OF DATA SETS.—

(1) IN GENERAL.—The Secretary shall establish a set of quality-related profiling data to be transmitted by approved sponsors and qualified providers to approved quality improvement organizations in order to permit such organizations to carry out section 9005(b). The set of quality-related profiling data may only include data that are part of a set of health information established by the Secretary under paragraph (1) or (2) of section 9103(b). The set may only include data that an approved quality improvement organization is authorized to receive under subtitle C. The Secretary shall also specify the frequency with which approved sponsors and qualified providers are required to transmit the quality-related profiling data set.

(2) NO UNDUE BURDEN.—With respect to data developed or collected by an approved sponsor or a qualified provider under this section, the Secretary shall, in order to assure the utility, accuracy, and sufficiency of such data, establish guidelines for uniform methods of developing and collecting such data. Such guidelines shall include specifications ensuring that any set of quality-related profiling data to be transmitted under this section may be developed or collected using the least burdensome method consistent with the efficient and effective administration of this part.

(c) FREEDOM OF INFORMATION ACT.—An approved quality improvement organization, in carrying out its functions under a contract entered into under section 9009, shall not be considered a Federal agency for purposes of section 552 of title 5, United States Code.

(d) USE AND DISCLOSURE OF DATA.—The Secretary shall establish standards concerning the purposes for which, and the proce-

dures by which, data that is transmitted to, and collected by, an approved quality improvement organization under this section or section 9009 may be used and disclosed by the organization. The standards established under this subsection shall be consistent with subtitle C and section 1160(b) of the Social Security Act. Such standards shall include standards regarding the aggregation of data in a manner that does not reveal data that identifies or can readily be associated with the identity of an individual.

(e) REQUIREMENT ON ORGANIZATIONS.—An approved quality improvement organization shall comply with the standards established by the Secretary under subsection (c).

(f) DEADLINE.—Not later than 18 months after the date of the enactment of this Act, the Secretary—

(1) shall establish the set of quality-related profiling data under subsection (b); and

(2) shall establish the standards under subsection (c).

SEC. 9007. COMPLIANCE MONITORING BY APPROVED STATES.

(a) MONITORING.—An approved State shall monitor periodically, but not less than annually, compliance with requirements applicable to approved sponsors and qualified providers under this part by—

(1) approved sponsors providing or sponsoring an approved health plan in the State; and

(2) qualified providers licensed by the State.

(b) ENFORCEMENT.—

(1) APPROVED SPONSORS.—

(A) IN GENERAL.—If an approved State finds that an approved sponsor providing or sponsoring an approved health plan in the State engages in a pattern or practice of failing to fulfill a requirement applicable to the sponsor under this part, the State shall enforce the requirement by—

(i) prohibiting the sponsor from providing coverage under the plan in the State under section 5502; or

(ii) imposing a civil money penalty not to exceed $10,000 on the sponsor in accordance with the procedures described in section 5503(a)(2).

(B) PUBLIC INFORMATION.—An approved State shall make available to the public the following information with respect to an enforcement action under subparagraph (A), if such information is applicable with respect to the action:

(i) Information disclosing that the action has resulted in a penalty being imposed on an approved sponsor under clause (i) or (ii) of subparagraph (A).

(ii) Information disclosing that a national quality standard under section 9004 was found to have been violated by an approved sponsor through the action.

(iii) Any other information relating to the action that is required to be made available to the public under State law.

(2) QUALIFIED PROVIDERS.—If an approved State finds that a qualified provider that is licensed by the State engages in a pattern or practice of failing to fulfill a requirement applicable to the provider under this part, or failing to cooperate with an approved quality improvement organization to the extent the organization is carrying out a function under section 9009(c)(2), the State shall ensure that the appropriate State board or boards responsible for licensing, accrediting, and disciplining the provider are notified.

SEC. 9008. GUIDELINE DEVELOPMENT AND RESEARCH ON HEALTH CARE QUALITY.

(a) RESEARCH SUPPORT.—Section 902(a) of the Public Health Service Act is amended—

(1) in paragraph (7), by striking "; and" and inserting a semicolon;

(2) in paragraph (8), by striking the period and inserting "; and"; and

(3) by inserting after paragraph (8) the following:

"(9) effective and efficient dissemination of information, standards, and guidelines.".

(b) DEVELOPMENT OF PEDIATRIC PRACTICE GUIDELINES.—Section 912(b) of the Public Health Service Act is amended—

(1) in paragraph (3), by striking "; and" and inserting a semicolon;

(2) in paragraph (4), by striking "; and" and inserting a semicolon;

(3) in paragraph (5), by striking the period and inserting "; and"; and

(4) by inserting after paragraph (5) the following:

"(6) include pediatric practice guidelines for the medical treatment of individuals under the age of 18.".

(c) LIMITATION OF LIABILITY.—Section 913 of the Public Health Service Act is amended by inserting after subsection (c) the following:

"(d) LIMITATION OF LIABILITY.—A member of a panel convened under this section, or an entity having a contract under this section, may not be held, by reason of the performance of any duty, function, or activity required or authorized pursuant to this part or a valid contract entered into under this section, to have violated any criminal law or to be civilly liable under any law of the United States or of any State (or political subdivision thereof), if the member or entity exercised good faith in the performance of such duty, function, or activity.".

(d) DISSEMINATION OF GUIDELINES.—Section 914(c) of the Public Health Service Act is amended by—

(1) striking "912(a)." and inserting "912(a) or certified under section 915."; and

(2) striking "bodies," and inserting "bodies, States, approved quality improvement organizations (as defined in section 9013(2) of the Guaranteed Health Insurance Act of 1994),".

(d) EVALUATION, CERTIFICATION, AND DISSEMINATION OF GUIDELINES.—Part B of title IX of the Public Health Service Act is amended by adding at the end the following:

"SEC. 915. EVALUATION, CERTIFICATION, AND DISSEMINATION OF GUIDELINES.

"(a) EVALUATION AND CERTIFICATION.—Not later than 18 months after the date of the enactment of the Guaranteed Health Insurance Act of 1994, the Administrator shall establish a procedure by which individuals and entities may submit practice guidelines of the type described in section 912(a)(1) to the Administrator for evaluation and certification by the Administrator.

"(b) GUIDELINE CLEARINGHOUSE.—The Administrator shall establish and oversee a clearinghouse and dissemination program for practice guidelines that are certified under this section.".

(e) AUTHORIZATION OF APPROPRIATIONS.—Section 1142(i) of the Social Security Act is amended—

(1) in paragraph (1)—

(A) in subparagraph (D), by striking "and";

(B) in subparagraph (E), by striking the period and inserting "; and"; and

(C) by inserting after subparagraph (E) the following:

"(F) $6,000,000 for each of the fiscal years 1995 through 2000."; and

(2) in paragraph (2), by striking "and 1994" and inserting "through 2000".

SEC. 9009. QUALITY IMPROVEMENT ORGANIZATIONS.

(a) IN GENERAL.—

(1) CONTRACTS.—Subject to subsection (e), and using competitive contracting procedures, the Secretary shall enter into contracts with quality improvement organizations to perform

the functions specified in subsection (c) for the geographic areas established under subsection (d)(1).

(2) COMMENCEMENT.—The Secretary may not enter into a contract under this section before the date that is 18 months after the date of the enactment of this Act or October 1, 1997, whichever occurs later.

(b) DEFINITION.—For purposes of this part, the term "quality improvement organization" means a private nonprofit entity that—

(1) has a governing body that is broadly representative of consumers of health care, purchasers of health care, qualified providers, and representatives of academia, including experts in quality improvement;

(2) has a governing body that, to the greatest extent feasible, reflects the racial, ethnic, and gender composition of the population of the United States;

(3) has a staff that includes individuals with expertise in the fields of quality improvement, public health, patient outcome assessment, risk adjustment, clinical practice guidelines, health services data analysis, and provider and consumer education; and

(4) is able, in the judgment of the Secretary, to satisfy the requirements in paragraphs (1) and (2) of subsection (c).

(c) FUNCTIONS.—

(1) IN GENERAL.—A quality improvement organization entering into a contract with the Secretary under this section—

(A) shall fulfill each requirement that is set forth in sections 9002 through 9008 and that is applicable to quality improvement organizations;

(B) shall assist in the development of innovative programs to improve the quality of health care services, including provider education programs;

(C) shall collaborate with, and provide technical assistance to, approved sponsors and qualified providers in ongoing efforts to improve the quality of care;

(D) shall develop programs in lifetime learning;

(E) shall disseminate information about quality improvement programs;

(F) shall disseminate and encourage the appropriate application of guidelines developed, updated, or certified pursuant to title IX of the Public Health Service Act or other guidelines;

(G) shall maintain such records, make such reports (including expenditure reports), and cooperate with such audits, as the Secretary finds necessary to determine the compliance of the organization with the requirements of this part; and

(H) shall perform such duties and functions, assume such responsibilities, and comply with such other requirements as the Secretary may require under regulations promulgated to carry out this part.

(2) REFERRAL.—

(A) EVALUATION OF PRACTICES.—If a quality improvement organization entering into a contract with the Secretary under this section finds that the pattern of practice of a qualified provider or an approved sponsor that provides health benefits in the form of items and services to enrollees suggests deficiencies in the quality of care being provided by the provider or sponsor that could impair patient health or safety, the organization shall evaluate the practices that may have lead to the suggestion of deficiencies.

(B) ASSISTANCE IN ELIMINATING DEFICIENCIES.—If a quality improvement organization finds, after conducting an evaluation under subparagraph (A), that the quality of the practices of a qualified provider or an approved sponsor referred to in such subparagraph is deficient, the organization shall work

with the provider to assist the provider to eliminate the deficiencies.

(C) NO SUBSTANTIAL IMPROVEMENT.—If a quality improvement organization finds, after affording reasonable opportunities for improvement, that substantial improvement in the quality of the practices of a qualified provider or an approved plan sponsor referred to in subparagraph (B) has not occurred, the organization shall determine whether the deficiencies in the quality of such practices pose a danger to patient health or safety. If the organization finds that such practices do pose such a danger, the organization shall notify the appropriate State board or boards responsible for licensing, accrediting, and disciplining the provider or sponsor.

(d) CONTRACT SPECIFICATIONS.—

(1) ESTABLISHMENT OF GEOGRAPHIC AREAS.—The Secretary shall establish throughout the United States geographic areas with respect to which contracts under this section will be made. In establishing such areas, the Secretary shall take into account the following criteria:

(A) STATE AREAS.—Each State shall generally be designated as a geographic area for purposes of this paragraph.

(B) MULTI-STATE AREAS.—The Secretary may establish geographic areas comprised of multiple contiguous States rather than State areas only where the volume of activity or other relevant factors (as determined by the Secretary) warrant such an establishment.

(2) ORGANIZATIONS ENTITLED TO CONTRACT WITH SECRETARY.—

(A) IN GENERAL.—The Secretary shall enter into a contract with a quality improvement organization for each area established under paragraph (1) if a qualified organization is available in such area and such organization and the Secretary have negotiated a proposed contract which the Secretary determines will be carried out by such organization in a manner consistent with the efficient and effective administration of this part.

(B) LIMITATION ON AFFILIATIONS WITH PAYERS.—The Secretary may not enter into a contract under this section with any entity which is, or is affiliated with (through management, ownership, or common control), an entity (other than a self-insured employer) which directly or indirectly makes payments to any qualified provider whose health care services are reviewed by such entity or would be reviewed by such entity if it entered into a contract with the Secretary under this section.

(C) LIMITATION ON AFFILIATIONS WITH PROVIDERS.—The Secretary may not enter into a contract under this section with any entity which is, or is affiliated with (through management, ownership, or common control), a qualified provider, or association of such providers, within the area served by such entity or which would be served by such entity if it entered into a contract with the Secretary under this part. For purposes of this subparagraph, an entity shall not be considered to be affiliated with a qualified provider or association of providers by reason of management, ownership, or common control if the management, ownership, or common control consists only of not more than 20 percent of the members of the governing board of the entity being affiliated (through management, ownership, or common control) with one or more of such providers or associations.

(3) TERMS OF CONTRACT.—Each contract with an organization under this section shall provide that—

(A) the organization shall perform the functions set forth in subsection (c) or may subcontract for the perform-

ance of all or some of such functions (and for purposes of subparagraphs (B) and (C) paragraph (2), a subcontract under this subparagraph shall not constitute an affiliation with a subcontractor);

(B) the Secretary shall have the right to evaluate the quality and effectiveness of the organization in carrying out the functions specified in the contract;

(C) the contract shall be for an initial term of 3 years and shall be renewable for an additional term of 2 years thereafter without a competitive selection process based upon evidence of successful quality improvement activities;

(D) if the Secretary intends not to renew a contract, the Secretary shall notify the organization of the decision at least 90 days prior to the expiration of the contract term, and shall provide the organization an opportunity to present data, interpretations of data, and other information pertinent to its performance under the contract, which shall be reviewed in a timely manner by the Secretary;

(E) the organization may terminate the contract upon 90 days notice to the Secretary;

(F) the Secretary may terminate the contract prior to the expiration of the contract term upon 90 days notice to the organization if the Secretary determines that—

(i) the organization does not substantially meet the requirements of this section; or

(ii) the organization has failed substantially to carry out the contract or is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part, but only after such organization has had an opportunity to submit data and have such data reviewed by the panel established under paragraph (4).

(4) EVALUATION OF PERFORMANCE.—In evaluating the performance of quality improvement organizations under contracts under this section, the Secretary shall place emphasis on the performance of such organizations in improving the quality of health care services and educating qualified providers and approved sponsors concerning the process being used by the organization and the criteria being applied by the organization.

(5) CONTRACTING AUTHORITY OF SECRETARY.—The contracting authority of the Secretary under this section may be carried out without regard to any provision of law relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the purposes of this part. The Secretary may use different contracting methods with respect to different geographical areas.

(6) TERMINATION NOT SUBJECT TO JUDICIAL REVIEW.—Any determination by the Secretary to terminate or not to renew a contract under this section shall not be subject to judicial review.

(e) ASSUMPTION OF RESPONSIBILITIES BY SECRETARY.—If the Secretary determines that there is no qualified entity available for an area with which the Secretary can enter into a contract under this section, the Secretary shall take such steps as are necessary to perform in the area the duties applicable to approved quality improvement organizations under this part. Any information required under this part to be transmitted by any person to an approved quality improvement organization for an area shall be transmitted to the Secretary in the case where there is no qualified entity available for an area with which the Secretary can enter into a contract under this section.

(f) LIMITATION OF LIABILITY.—A quality improvement organization having a contract with the Secretary under this section, a person who is employed by, or who has a fiduciary relationship with, any such organization, and a person who furnishes professional

services to such organization, may not be held, by reason of the performance of any duty, function, or activity required or authorized pursuant to this part or to a valid contract entered into under this section, to have violated any criminal law or to be civilly liable under any law of the United States or of any State (or political subdivision thereof), if the organization or person exercised good faith in the performance of such duty, function, or activity.

SEC. 9010. QUALITY MANAGEMENT GRANTS.

(a) IN GENERAL.—

(1) GRANTS.—The Secretary shall make a grant to each State that satisfies the requirements of this section.

(2) COMMENCEMENT.—The Secretary may not make a grant under this section before the date that is 18 months after the date of the enactment of this Act or October 1, 1997, whichever occurs later.

(b) APPLICATIONS.—

(1) SUBMISSION.—To apply for a grant under this section for any fiscal year, a State shall submit an application to the Secretary in accordance with the procedures established by the Secretary. The Secretary shall establish a deadline for the submission of applications under this paragraph for each fiscal year.

(2) CRITERIA FOR APPROVAL.—The Secretary may not approve an application submitted under paragraph (1) unless the application includes assurances satisfactory to the Secretary that—

(A) the State has a State regulatory program approved under section 5502(b) of the Social Security Act;

(B) the State is willing and able to fulfill each requirement that is set forth in sections 9002 through 9008 that is applicable to an approved State;

(C) the State will enforce the requirements set forth in sections 9002 through 9008 that are applicable to an approved sponsor or a qualified provider with respect to each approved sponsor that provides or sponsors an approved health plan in the State and each qualified provider licensed by the State, except in the case where another individual or entity is charged with such enforcement under this part;

(D) the State will maintain such records, make such reports (including expenditure reports), and cooperate with such audits, as the Secretary finds necessary to determine the compliance of the State (and persons regulated by the State) with the requirements of this part;

(E) the State will carry out a plan, that has been submitted to the Secretary in a form and manner specified by the Secretary, to make specific improvements, in accordance with standards established by the Secretary for this purpose, in the health status of populations in the State that—

(i) experience a disproportionately high rate of morbidity and mortality; or

(ii) are historically underserved; and

(F) funds received under this section will be used for consumer protection and quality oversight activities.

(3) PETITIONS FOR RECONSIDERATION AND REAPPLICATIONS.—

(A) IN GENERAL.—With respect to an application submitted under paragraph (1) that is disapproved under this subsection, the applicant may submit to the Secretary—

(i) a petition for reconsideration of the application; and

(ii) an application that conforms to the requirements of this subsection.

(B) DEADLINES.—The Secretary shall establish a deadline for the submission of petitions for reconsideration and

reapplications under this paragraph for each fiscal year. The Secretary shall approve or disapprove each such petition and reapplication before the termination of the 60-day period beginning on the date of such submission.

(c) ABILITY TO SATISFY REQUIREMENTS THROUGH ARRANGEMENTS.—A State may satisfy a requirement that is set forth in any of sections 9002 through 9008 directly or through arrangements with individuals or entities approved by the State that demonstrate to the satisfaction of the State that the individual or entity—

(1) has the ability to fulfill any duty delegated to the individual or entity by the State; and

(2) does not have a relationship with an approved sponsor or a qualified provider that would interfere with the ability of the individual or entity to fulfill any duty of a participating State under this part.

(d) PERIODIC REVIEW.—The Secretary shall periodically review the compliance by States that receive a grant under this section with the terms of the award of the grant.

(e) FEDERAL ASSUMPTION OF STATE RESPONSIBILITIES.—

(1) IN GENERAL.—In the case of a State that does not receive a grant under this section on or before January 1, 1999, or that substantially fails to satisfy a term of an award of such a grant, the Secretary shall take such steps as are necessary—

(A) to perform in the State the duties specified in sections 9002 through 9008 as duties of approved States;

(B) to enforce in the State the requirements set forth in sections 9002 through 9008 that are applicable to an approved sponsor or a qualified provider in the same manner as an approved State would be required to enforce such requirements under subsection (b)(2)(C).

(2) DATA TRANSMISSION.—Any information required under this part to be transmitted by any person to an approved State shall be transmitted to the Secretary in the case of a State described in paragraph (1).

SEC. 9011. AUTHORIZATION OF APPROPRIATIONS FOR CONTRACTS AND GRANTS.

There are authorized to be appropriated $300,000,000 for each of the fiscal years 1998 through 2002 for contracts under section 9009 and for grants under section 9010.

SEC. 9012. HEALTH CARE QUALITY ADVISORY COMMISSION.

(a) ESTABLISHMENT.—The Secretary shall provide for the appointment of a Health Care Quality Advisory Commission, to be composed of individuals from the public and private sectors with expertise in the fields of public health, financing and delivery of health care, health services research, health care quality, and privacy of health information and representatives of consumers appointed by the Secretary. To the greatest extent feasible, the membership of the Commission shall reflect the racial, ethnic, and gender composition of the population of the United States.

(b) DUTIES.—The Commission shall provide recommendations to the Secretary with respect to the—

(1) development and selection of the national measures of quality performance under section 9003, after consulting with appropriate interested parties, including the Administrator for Health Care Policy and Research, States, the National Association of Insurance Commissioners, approved sponsors, qualified providers, experts in quality measurement, nationally recognized accrediting bodies, other Federal advisory bodies, and consumers of health care services;

(2) establishment of an appropriate sequence for the interim sets of national measures of quality performance under section 9003(a)(4);

(3) development of national goals of quality performance;

(4) design and execution of consumer surveys under section 9002;

(5) standard format for performance reports under section 9003(g);

(6) establishment and functioning approved quality improvement organizations under section 9009; and

(7) impact of the implementation of the National Quality Management Program.

(c) MEMBERSHIP.—The Commission shall be composed of 15 members. Members of the Commission shall first be appointed not later than 6 months after the date of the enactment of this Act for a term of 3 years, except that the Secretary may provide initially for such shorter terms as will ensure that (on a continuing basis) the terms of not more than 4 member expire in any one year.

(d) DURATION.—Notwithstanding section 14(a) of the Federal Advisory Committee Act, the Commission shall continue in existence until otherwise provided by law.

(e) REPORT.—The Commission shall submit to the Congress an annual report not later than May 1 of each year concerning the activities of the Commission under this part during the preceding year.

SEC. 9013. DEFINITIONS.

For purposes of this part:

(1) APPROVED HEALTH PLAN.—The term "approved health plan" means an insured health benefit plan or a self-insured health benefit plan, as described in title V.

(2) APPROVED QUALITY IMPROVEMENT ORGANIZATION.—The term "approved quality improvement organization" means a quality improvement organization that has a contract with the Secretary under section 9009. When used with respect to a geographic area, such term means a quality improvement organization that is responsible under such a contract for carrying out the responsibilities of approved quality improvement organizations under this part in a geographic area established under section 9009(d)(1).

(3) APPROVED SPONSOR.—The term "approved sponsor" means—

(A) a carrier providing an insured health benefit plan, as described in title V; or

(B) a sponsor of a self-insured health benefit plan, as described in such title.

(4) APPROVED STATE.—The term "approved State" means a State that receives a grant under section 9010.

(5) HEALTH INSTITUTION.—The term "health institution" means a qualified provider that is not a network provider with respect to any approved health plan and is—

(A) a hospital (as defined in section 1861(e) of the Social Security Act);

(B) a psychiatric hospital (as defined in section 1861(f) of such Act);

(C) an institution (or a distinct part of an institution) which is primarily engaged in providing skilled nursing care and related services to residents who require medical or nursing care or rehabilitation services to residents for rehabilitation with respect to an illness, injury, disorder, or other health condition (regardless of whether the institution meets the requirements of section 1819 of such Act for receiving payment for items and services furnished under title 18 of such Act);

(D) an ambulatory surgical center (regardless of whether the center meets the health, safety, and other standards promulgated by the Secretary under section 1832(a)(2)(F)(i) of such Act);

(E) a provider of intensive residential services (as defined in section 1861(qq) of such Act); and

(F) a provider of intensive community-based services (as defined in section 1861(ff) of such Act).

(6) NETWORK PROVIDER.—The term "network provider", when used with respect to an approved health plan, means a qualified provider who is member of a plan network of the plan.

(7) PLAN NETWORK.—The term "plan network" means, with respect to an approved health plan, qualified providers who have entered into an agreement with the plan under which such providers are obligated to provide items and services covered under the plan to individuals enrolled in the plan, or have an agreement to provide services on a fee-for-service basis.

(8) QUALIFIED PROVIDER.—The term "qualified provider" means a health professional who, or a health facility that, is authorized to provide an item or service in the guaranteed national benefit package.

SEC. 9014. REFERENCES TO MEDICARE PROVISIONS.

In this part, any references to provisions of title XVIII of the Social Security Act are deemed to be references to such provisions as in effect on the day after the date of the enactment of this Act, taking into account the amendments made to such title by this Act as if the effective date of such amendments were January 1, 1997.

SEC. 9015. EFFECTIVE DATES.

(a) IN GENERAL.—Except as provided in subsection (b), the provisions of this part shall take effect on January 1, 1998.

(b) PROVISIONS EFFECTIVE IMMEDIATELY.—

(1) SECRETARIAL RESPONSIBILITIES.—The following provisions imposing a duty on the Secretary shall take effect on the date of the enactment of this Act:

(A) Section 9001.
(B) Section 9002.
(C) Subsections (a), (b), (c), and (j) of section 9003.
(D) Section 9004.
(E) Section 9005(a).
(F) Subsections (b), (c), and (e) of section 9006.
(G) Sections 9008, 9009, 9010, 9012, 9013, and 9014.

(2) AUTHORIZATION OF APPROPRIATIONS.—Section 9011 shall take effect on the date of the enactment of this Act.

PART 2—CONSUMER RESOURCES

SEC. 9021. CONSULTATION REQUIREMENTS REGARDING ADMINISTRATION OF PROGRAM.

The Secretary of Health and Human Services shall consult with the Secretary of Labor in carrying out part O of title III of the Public Health Service Act (relating to consumer resources regarding health plans).

Subtitle B—Information Systems and Administrative Simplification

SEC. 9101. REQUIREMENTS FOR HEALTH SECURITY CARDS AND PERSONAL IDENTIFIERS.

(a) HEALTH SECURITY CARDS.—

(1) REQUIREMENT.—Each administered health plan sponsor shall issue a health security card that meets the requirements of subsection (c) for each individual who is entitled to benefits under an administered health plan provided or sponsored by the sponsor, if the plan provides for coverage of the guaranteed national benefit package. Such card shall be issued to the individual involved or, in the case of an individual enrolled as a dependent of another individual, to that other individual.

(2) DEADLINE FOR APPLICATION OF REQUIREMENT.—The deadline specified under this paragraph for the requirement under paragraph (1) is January 1, 1997.

(b) ENFORCEMENT THROUGH CIVIL MONEY PENALTIES.—

(1) IN GENERAL.—In the case of an administered health plan sponsor that fails to issue a health security card in accordance with subsection (a)(1), the sponsor is subject to a civil money penalty of not to exceed $100 for each such violation. The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to a civil money penalty under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) of such Act.

(2) EFFECTIVE DATE.—No penalty may be imposed under paragraph (1) for any failure occurring before the deadline specified in subsection (a)(2).

(c) STANDARDS FOR CARDS.—

(1) IN GENERAL.—The Secretary shall establish standards consistent with this subsection respecting the form and information to be contained on health security cards (for purposes of subsection (a)).

(2) PERMISSIBLE USES OF CARD.—A health security card that is issued to an individual who is entitled to benefits under an administered health plan may be used by an individual or entity, in accordance with regulations promulgated by the Secretary consistent with subtitle C, only for the purpose of providing to the individual entitled to benefits, or assisting the individual in obtaining, an item or service that is covered under such plan.

(3) ELECTRONIC.—

(A) IN GENERAL.—Subject to subparagraph (B), the card shall be in a form similar to that of a credit card and shall have, encoded in electronic or magnetic form—

(i) the identity of the individual entitled to health benefits;

(ii) the administered health plan providing for coverage of the guaranteed national benefit package in which the individual is enrolled;

(iii) the identity of each principal insured (as defined by the Secretary) for the family that includes the individual, in the case of an individual who is enrolled under a family class of enrollment;

(iv) the telephone number or numbers (or other electronic equivalent) to be used for the submission electronically of claims under the plan; and

(v) information relating to organ donation.

(B) USE OF ELECTRONIC READ-AND-WRITE CARDS.—The Secretary may provide for cards in an electronic form that permits information on the card to be readily changed. Such information may include information relating to the health coverage status of the individual and the medical history of the individual.

(C) PERSONAL IDENTIFIER.—For purposes of subparagraph (A), and for purposes of the transactions described in section 9104(a), the Social Security account number assigned to the individual by the Secretary under section 205(c)(2) of the Social Security Act or, in the case of an infant or other individual to whom such a number has not been issued, such a Social Security account number of a parent or guardian or other number as the Secretary shall specify, shall be used as the personal identifier for the individual.

(4) ADDITIONAL INFORMATION.—The card shall include such additional information, in electronic or other form, as the Secretary may require to carry out the purposes of this Act. In addition, the administered health plan sponsor issuing the card may include such additional information on the card as the sponsor desires, subject to such limitations as the Secretary may provide.

(5) DEADLINE.—The Secretary shall first establish the standards for health security cards under this subsection by not later than 18 months after the date of the enactment of this Act.

(d) MISUSE OF CARDS.—

(1) IN GENERAL.—An individual or entity may not collect, disseminate, request or require presentation of, or otherwise use (by electronic or other means) a health security card except as authorized under this section.

(2) PRIVATE RIGHT OF ACTION.—A person who is aggrieved by a violation of paragraph (1) may, in a civil action, obtain appropriate relief, including actual, compensatory, and punitive damages and equitable relief, against any appropriate party.

(3) ATTORNEY'S FEES AND COSTS.—In any action under paragraph (2) in which the plaintiff substantially prevails, the court shall award the plaintiff reasonable attorney's fees (at generally prevailing hourly rates), reasonable expert witness fees, and other reasonable costs, unless the court finds that such award would not be appropriate.

(4) PENALTIES.—

(A) MISUSE OF INFORMATION.—The provisions of section 208(a) of the Social Security Act in relation to violations described in paragraphs (7) and (8) thereof shall apply with respect to the health security card and any information contained or encoded on such card in the same manner and to the same extent as such provisions apply with respect to the social security card and to the social security account number or other information contained or encoded on the social security card, except that, in applying such provisions, any reference therein to the Commissioner of Social Security shall be deemed a reference to the Secretary.

(B) MISUSE OF SYMBOLS, EMBLEMS, OR NAMES.—Section 1140 of the Social Security Act shall apply with respect to the health security card in the same manner and to the same extent as such section applies with respect to the social security card.

(5) CIVIL MONEY PENALTY.—Any person who the Secretary determines has failed to comply with paragraph (1) shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $1,000 for each such failure. The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) of such Act.

(7) PROTECTION AGAINST DELAY OR DENIAL OF SERVICES.—An individual may not have health services delayed or denied for inability or failure to produce a health security card.

SEC. 9102. NATIONAL ENROLLMENT VERIFICATION SYSTEMS.

(a) ESTABLISHMENT.—The Secretary shall establish national enrollment verification systems for the verification of an individual's enrollment in an administered health plan and entitlement to benefits under such plan. The systems shall assist in the identification of, and collection from, parties responsible for the payment for health care items and services furnished to individuals enrolled under an administered health plan.

(b) INFORMATION IN SYSTEMS.—The enrollment verification systems shall contain such information submitted by administered health plan sponsors, the Civilian Health and Medical Program of the Uniformed Services under chapter 55 of title 10, United States Code, employers, and other individuals and entities specified by the Secretary as the Secretary shall determine in standards established under this section. The information shall be submitted in a form and manner specified by the Secretary. The information shall include the following with respect to each individual enrolled in an

administered health plan (regardless of whether the individual is enrolled under an individual or a family class of enrollment):

(1) The name, address, and personal identifier of the individual and the identity of each principal insured (as defined by the Secretary under section 9101(c)(3)(A)(iii)) for the family that includes the individual, in the case of an individual who is enrolled under a family class of enrollment.

(2) The name, address, and telephone number (or other electronic equivalent) of each administered health plan in which the individual is enrolled.

(3) The type of coverage elected.

(4) Race and ethnicity data.

(5) The period for which such coverage is elected.

(6) The status of individuals with respect to deductibles, copayments, coinsurance, or out-of-pocket limits on cost sharing.

(7) Coordination of benefit information appropriate in determining liability in cases in which benefits may be payable under 2 or more administered health plans.

(c) PERIODICITY OF SUBMISSIONS.—The standards established by the Secretary under this subsection shall require the submission of information to the national enrollment verification systems on a periodic basis (as determined by the Secretary) in order to report applicable changes with respect to the information described in subsection (b).

(d) FORM OF INQUIRY.—The verification systems shall be capable of accepting inquiries from health care providers, administered health plan sponsors, the Civilian Health and Medical Program of the Uniformed Services under chapter 55 of title 10, United States Code, (and any other individual or entity determined appropriate by the Secretary) in a variety of electronic and other forms.

(e) FORM OF RESPONSE.—The systems shall be capable of responding to inquiries under subsection (d) in a variety of electronic and other forms.

(f) LIMITS ON DISCLOSURE OF INFORMATION REPORTED.—The disclosure of information reported to the national enrollment verification systems shall be restricted by the Secretary under standards established by the Secretary that are consistent with subtitle C.

(g) FEES.—The Secretary shall establish a schedule of fees for the acceptance of, and response to, inquiries to the verification systems. The Secretary may impose appropriate fees, according to the schedule, for such inquiries and responses.

(h) PUBLIC DOMAIN SOFTWARE TO PROVIDERS.—The Secretary shall provide for the development, and shall make available without charge to health care providers, a variety of forms of computer software to enable such providers to make inquiries to, and receive responses from, the national enrollment verification systems in electronic form.

(i) DEADLINE.—The Secretary shall establish the system and standards under this section (and shall develop and make available the software under subsection (h)) by not later than January 1, 1996.

(j) CIVIL MONEY PENALTY.—In the case of a failure of an individual or entity to report information to the enrollment verification system under a standard established by the Secretary under this section, the individual or entity shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $1000 for each day in which such failure persists. The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to a civil money penalty under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) of such Act.

SEC. 9103. STANDARDS FOR HEALTH INFORMATION AND INFORMATION TRANSACTIONS.

(a) STANDARDS TO ENSURE COMPARABILITY OF INFORMATION.—

(1) IN GENERAL.—The Secretary shall establish standards necessary to make a set of health information described in subsection (b) that is created by an administered health plan sponsor or a health provider comparable with the same set of information created by another such sponsor or provider.

(2) DATA ELEMENTS.—The standards shall specifically define the data elements that comprise each set of health information described in subsection (b).

(3) FORMAT.—The standards shall include uniform presentation and format requirements for the arrangement of data elements.

(4) ELECTRONIC.—The standards under paragraph (1) shall require that health information described in such paragraph be in electronic or magnetic form.

(5) UNIQUE IDENTIFIERS.—The Secretary shall establish a system to provide for a unique identifier for each employer, administered health plan, administered health plan sponsor, group practice, and health provider. In the case of a health provider that has a unique identifier issued for purposes of the medicare program, the 2 unique identifiers shall be identical.

(6) CODE SETS.—The Secretary, in consultation with experts from the private sector and Federal agencies—

(A) shall select code sets for appropriate data elements from among the code sets that have been developed by private and public entities; or

(B) shall establish code sets for appropriate data elements if no code set for the data elements has been developed by such entities.

(b) SETS OF HEALTH INFORMATION.—

(1) PLAN AND PROVIDER TRANSACTIONS.—The Secretary shall establish a separate set of health information that is appropriate for transmission in connection with each transaction described in section 9104(a).

(2) ENCOUNTER INFORMATION.—The Secretary shall establish a set of encounter information derived from inpatient and outpatient clinical encounters that the Secretary determines—

(A) is appropriate for creation by—

(i) an administered health plan sponsor to the extent the sponsor provides health benefits in the form of items and services to enrollees; or

(ii) a network provider with respect to an administered health plan sponsored or provided by an administered health plan sponsor, but only if the sponsor does not—

(I) provide health benefits in the form of payments based on claims; or

(II) create the set of encounter information; and

(B) is necessary to provide information regarding the operation of an administered health plan sponsor described in subparagraph (A)(i), or a network provider described in subparagraph (A)(ii), that is equivalent to information derived from claims.

(3) PATIENT MEDICAL RECORD INFORMATION.—The Secretary shall establish a set of patient medical record information.

(4) ADDITIONS TO SETS.—The Secretary may make additions to a set of health information established under paragraph (1), (2), or (3) as the Secretary determines appropriate in a manner that minimizes the disruption to, and costs of compliance incurred by, an administered health plan sponsor or a health provider that is required to comply with section 9104.

(c) STANDARDS FOR INFORMATION TRANSACTIONS.—

(1) IN GENERAL.—The Secretary shall establish standards relating to technical aspects of the procedure and method by which an administered health plan sponsor or a health provider that is required to comply with section 9104 may transmit electronically health information that is included in a set of health information described in subsection (b). The standards shall include standards with respect to the format in which such information shall be transmitted under such section.

(2) CHAIN OF CUSTODY.—The standards under paragraph (1) shall ensure the suitability of health information that is included in a set of health information described in subsection (b) in a court of law.

(3) RECORD KEEPING.—The standards shall include instructions on record keeping in support of claims for benefits under an administered health plan.

(4) STANDARDS FOR CLAIMS FOR CLINICAL LABORATORY TESTS.—The standards shall provide that claims for clinical laboratory tests for which benefits are provided under an administered health plan shall be submitted directly by the person or entity that performed (or supervised the performance of) the tests to the plan in a manner consistent with (and subject to such exceptions as are provided under) the requirement for direct submission of such claims under the medicare program.

(5) ENSURING ACCOUNTABILITY FOR CLAIMS SUBMITTED ELECTRONICALLY.—In establishing the standards, the Secretary, in consultation with appropriate agencies, shall include such methods of ensuring health provider responsibility and accountability for claims submitted electronically that are designed to control fraud and abuse in the submission of such claims.

(6) SPECIAL RULE FOR COORDINATION OF BENEFITS.—Any standards adopted by the Secretary under paragraph (1) that relate to coordination of benefits shall provide, to the maximum extent practicable, that a claim for reimbursement for health services furnished is tested by an algorithm specified by the Secretary against appropriate records of enrollment and eligibility for the individual who received such services to determine any primary and secondary obligors for payment.

(d) GENERAL REQUIREMENTS.—In establishing standards under this section, the Secretary shall, to the maximum extent practicable—

(1) establish standards that are consistent with the objective of reducing the costs of providing and paying for health care;

(2) incorporate standards that are in use and generally accepted, or developed, by standard setting or standard development organizations; and

(3) consult with experts and professional organizations in the field of information management.

(e) TIMETABLES FOR STANDARDS.—

(1) INITIAL STANDARDS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), not later than January 1, 1996, the Secretary shall establish standards under subsections (a) and (c) with respect to each set of health information described in subsection (b).

(B) EXCEPTIONS.—

(i) IN GENERAL.—Not later than January 1, 1997, the Secretary shall establish standards under subsections (a) and (c) with respect to—

(I) health information that is appropriate for transmission in connection with the submission of a claim attachment; and

(II) the set of patient medical record information established under subsection (b)(3).

(ii) ADDITIONS.—The Secretary shall establish standards under subsection (a) and (c) with respect to health information that is added to a set of health information under subsection (b)(4) in conjunction with making such addition.

(2) MODIFICATIONS TO STANDARDS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall review the standards established under this section and shall modify such standards as determined appropriate, but not more frequently than once every 6 months. Any modification under this subparagraph shall be made in a manner that minimizes the disruption to, and costs of compliance incurred by, a health information plan sponsor or a health provider that is required to comply with section 9104.

(B) SPECIAL RULES.—

(i) MODIFICATIONS DURING FIRST 12-MONTH PERIOD.—The Secretary may not modify a standard established under this section during the 12-month period beginning on the date the standard is established unless the Secretary determines that a modification is necessary in order to permit a health information plan sponsor or a health provider to comply with section 9104.

(ii) ADDITIONS AND MODIFICATIONS TO CODE SETS.—

(I) IN GENERAL.—The Secretary shall ensure that procedures exist for the enhancement of code sets to accommodate changes in public health, biomedical science, and health care delivery.

(II) ADDITIONAL RULES.—If a code set is modified under this clause, the modified code set shall include instructions on how data elements that were encoded prior to the modification are to be converted or translated so as to preserve the value of the data elements. Any modification to a code set under this subsection shall be implemented in a manner that minimizes the disruption to, and costs of compliance incurred by, a health information plan sponsor or a health provider that is required to comply with section 9104.

(f) EVALUATION OF STANDARDS.—The Secretary may establish a process to measure or verify the consistency of standards established or modified under this section. The process may include demonstration projects and analyses of the cost of implementing such standards and modifications.

(g) DISTRIBUTION OF CODE SETS.—The Secretary shall establish efficient and low-cost procedures for the distribution of code sets that are selected, established, or modified under this section.

SEC. 9104. REQUIREMENTS ON SPONSORS AND PROVIDERS.

(a) TRANSACTIONS BY SPONSORS.—

(1) TRANSACTIONS WITH PROVIDERS.—If an administered health plan sponsor conducts any of the transactions described in paragraph (3) with a health provider—

(A) the transaction shall be a standard transaction; and

(B) the health information transmitted by the sponsor to the provider or by the provider to the sponsor in connection with the transaction shall be standard health information.

(2) TRANSACTIONS WITH SPONSORS.—If an administered health plan sponsor or a workers' compensation carrier conducts any of the transactions described in paragraph (3) with an administered health plan sponsor or a workers' compensation carrier—

(A) the transaction shall be a standard transaction; and

(B) the health information transmitted by any such sponsor or any such carrier in connection with the transaction shall be standard health information.

(3) TRANSACTIONS.—The transactions referred to in paragraphs (1) and (2) are the following:

(A) Verification of eligibility for benefits.
(B) First report of injury.
(C) Coordination of benefits.
(D) Claim submission.
(E) Claim attachment submission.
(F) Claim status notification.
(G) Claim status verification.
(H) Claim adjudication.
(I) Payment and remittance advice.

(b) DISCLOSURE OF INFORMATION.—

(1) TRANSACTION INFORMATION.—If an administered health plan sponsor or a health provider discloses health information that was transmitted or received by the sponsor or provider in connection with a transaction described in subsection (a) to a State, a Federal or State agency, a grantee of a State or the Federal Government, or a party to a contract entered into by a State or the Federal Government, and the disclosure is made in order to fulfill a requirement under this Act—

(A) the health information disclosed shall be standard health information; and

(B) the disclosure shall be made through an electronic transmission consistent with—

(i) the standards under section 9103(c); and
(ii) subtitle C.

(2) ENCOUNTER INFORMATION.—If an administered health plan sponsor or a health provider discloses health information that is included in the set of encounter information established by the Secretary under section 9103(b)(2) to a State, a Federal or State agency, a grantee of a State or the Federal Government, or a party to a contract entered into by a State or the Federal Government, and the disclosure is made in order to fulfill a requirement under this Act—

(A) the health information disclosed shall be standard health information; and

(B) the disclosure shall be made through an electronic transmission consistent with—

(i) the standards under section 9103(c); and
(ii) subtitle C.

(3) REQUIREMENT ON GOVERNMENT AGENTS.—A State, a Federal or State agency, a grantee of a State or the Federal Government, or a party to a contract entered into by a State or the Federal Government may not impose a requirement on an administered health plan sponsor or a health provider that is inconsistent with paragraph (1) or (2).

(c) USE OF HEALTH INFORMATION NETWORK SERVICES.—A health information plan sponsor or a health provider may comply with any provision of this section by entering into an agreement or other arrangement with a health information network service certified under section 9106 pursuant to which the service undertakes the duties applicable to the sponsor or provider under the provision.

(d) TIMETABLES FOR COMPLIANCE.—

(1) INITIAL COMPLIANCE.—

(A) IN GENERAL.—A health information plan sponsor or health provider shall comply with the requirements of this section not later than January 1, 1997.

(B) ADDITIONAL HEALTH INFORMATION.—Not later than 6 months after the date on which the Secretary makes an addition to a set of health information under section

9103(b)(4), a health information plan sponsor or health provider shall comply with the requirements of this section with respect to the additional information.

(2) COMPLIANCE WITH MODIFIED STANDARDS.—

(A) IN GENERAL.—If the Secretary modifies a standard established under section 9103, a health information plan sponsor or health provider shall comply with the modified standard at such time as the Secretary determines appropriate, taking into account the nature and intent of the modification.

(B) SPECIAL RULE.—In the case of a modification to a standard under subparagraph (A) that does not occur within the 12-month period beginning on the date the standard is established, the time determined appropriate by the Secretary under subparagraph (A) may not be—

(i) earlier than the last day of the 90-day period beginning on the date the modified standard is established; or

(ii) later than the last day of the 12-month period beginning on the date the standard is established.

SEC. 9105. IMPOSITION OF ADDITIONAL REQUIREMENTS.

(a) ACCEPTANCE OF CLAIMS.—An administered health plan sponsor may not reject a claim for payment submitted by any individual or entity under an administered health plan provided or sponsored by the sponsor on the basis of the form or manner in which the claim is submitted if the claim—

(1) contains the standard health information in the set of health information with respect to claims submission established by the Secretary under section 9103(b)(1); and

(2) is submitted in accordance with the standards established under section 9103(c).

(b) ACCEPTANCE OF ATTACHMENTS.—An administered health plan sponsor may not reject a claim attachment submitted by any individual or entity in connection with a claim for payment under an administered health plan provided or sponsored by the sponsor on the basis of the form or manner in which the attachment is submitted if the attachment—

(1) contains the standard health information in the set of health information with respect to claims attachment submission established by the Secretary under section 9103(b)(1); and

(2) is submitted in accordance with the standards established under section 9103(c).

(c) LIMITATION ON OTHER TRANSACTIONS.—An administered health plan sponsor or a health provider may not require, as a condition of conducting a transaction described in section 9104(a), that any individual or entity—

(A) provide any health information that is not in the set of health information established by the Secretary under section 9103(b)(1) with respect to the transaction; or

(B) transmit any such health information in a manner inconsistent with the standards established under section 9103(c).

(d) EXCEPTIONS.—Subsections (a), (b), and (c) do not apply if—

(1) the individual or entity on whom the administered health plan sponsor or the health provider is imposing a requirement otherwise prohibited under the subsections voluntarily agrees to the imposition of the requirement; or

(2) a waiver is granted under subsection (e) to impose a requirement otherwise prohibited under such subsections.

(e) CONDITIONS FOR WAIVERS.—

(1) IN GENERAL.—An administered health plan sponsor or health provider may request a waiver from the Secretary, in order to impose on an individual or entity a requirement otherwise prohibited under subsection (a), (b), or (c).

(2) CONSIDERATION OF WAIVER REQUESTS.—A waiver may not be granted under this subsection to impose an otherwise

prohibited requirement unless the Secretary determines that the value of any additional information to be provided under the requirement for research or other purposes significantly outweighs the administrative cost of the imposition of the requirement, taking into account the burden of the timing of the imposition of the requirement.

(3) ANONYMOUS REPORTING.—If an administered health plan sponsor or a health provider attempts to impose on an individual or entity a requirement prohibited under subsection (a), (b), or (c), the individual or entity may contact the Secretary. The Secretary shall develop a procedure under which an individual or entity that contacts the Secretary under the preceding sentence shall remain anonymous. The Secretary shall notify the sponsor or provider imposing the requirement that the requirement may not be imposed unless the other sponsor or provider voluntarily agrees to such requirement or a waiver is obtained under this subsection.

(f) TIMETABLES FOR COMPLIANCE.—An administered health plan sponsor or a health provider shall comply with the requirements of this section not later than January 1, 1997.

SEC. 9106. STANDARDS AND CERTIFICATION FOR HEALTH INFORMATION NETWORK SERVICES.

(a) STANDARDS FOR OPERATIONS.—The Secretary shall establish standards with respect to the operation of health information network services, including standards ensuring that such services—

(1) develop, operate, and cooperate with one another to form a health information network;

(2) meet all of the requirements under subtitle C that are applicable to such services;

(3) make public information concerning their performance, as measured by uniform indicators such as accessibility, transaction responsiveness, administrative efficiency, reliability, dependability, and any other indicator determined appropriate by the Secretary; and

(4) have the highest security procedures that are practicable with respect to the processing and handling of health information.

(b) CERTIFICATION BY SECRETARY.—

(1) ESTABLISHMENT OF PROCEDURE.—Not later than 12 months after the date of the enactment of this Act, the Secretary shall establish a certification procedure for health information network services which ensures that services certified under this section are qualified—

(A) to meet the requirements of this part and the standards established by the Secretary under this section; and

(B) to ensure the confidentiality of protected health information (as defined in section 9200(a)) as required under subtitle C.

(2) DEEMED CERTIFICATION.—The Secretary may designate private individuals or entities to conduct the certification procedure established by the Secretary under this subsection. A health information network service certified by such an individual or entity in accordance with such designation shall be considered to be certified by the Secretary under this subsection.

(3) APPLICATION FOR CERTIFICATION.—Each entity desiring to be certified as a health information network service shall apply to the Secretary for certification in a form and manner determined appropriate by the Secretary.

(4) AUDITS AND REPORTS.—The procedure established under paragraph (1) shall provide for audits by the Secretary and reports by an entity certified under this section as the Secretary determines appropriate in order to monitor the compli-

ance by the entity with the requirements of this part and the standards established by the Secretary under this section.

(5) RECERTIFICATION.—A health information network service shall be recertified under this subsection not less than every 3 years.

(c) LOSS OF CERTIFICATION.—

(1) MANDATORY TERMINATION.—If a health information network service violates a provision of subtitle C, the certification of the service under this section shall be terminated unless the Secretary determines that appropriate corrective action has been taken.

(2) DISCRETIONARY TERMINATION.—If a health information service violates a requirement or standard under this part and a penalty has been imposed under section 9107, the Secretary shall review the certification of the service and may terminate the certification.

(d) HEALTH INFORMATION CONTINUITY.—If a health information network service is decertified or ceases to function, in a manner that would threaten the continued availability of the standard health information held by the service, the service shall transfer the standard health information to a health information network service that is certified under this section and designated by the Secretary to receive the information.

SEC. 9107. CIVIL MONEY PENALTY.

(a) IN GENERAL.—Any person who the Secretary determines is required, but has failed, to comply with a requirement or standard imposed under this part shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $1,000 for each such failure.

(b) PROCESS.—The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to a civil money penalty under subsection (a) in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) of such Act.

SEC. 9108. EFFECT ON STATE LAW.

(a) PREEMPTION OF STATE QUILL PEN LAWS.—

(1) IN GENERAL.—Any provision of State law that requires medical or health insurance records (including billing information) to be maintained in written, rather than electronic, form is deemed to be satisfied if the records are maintained in an electronic form that meets standards established by the Secretary under paragraph (2).

(2) SECRETARIAL AUTHORITY.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall issue regulations to carry out paragraph (1). The regulations shall provide for an electronic substitute that is in the form of a unique identifier (assigned to each authorized individual) that serves the functional equivalent of a signature. The regulations may provide for such exceptions to paragraph (1) as the Secretary determines to be necessary to prevent fraud and abuse, to prevent the illegal distribution of controlled substances, and in such other cases as the Secretary deems appropriate.

(b) PUBLIC HEALTH REPORTING.—Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.

SEC. 9109. DEFINITIONS.

For purposes of this subtitle:

(1) ADMINISTERED HEALTH PLAN.—The term "administered health plan" has the meaning given the term "health benefit plan" in section 5504(3), but includes—

(A) the medicare program, medicare supplemental health insurance, medicare part C, the medicaid program,

the wrap-around benefit program under part B of title XXII of the Social Security Act; and

(B) except as the Secretary may provide, other Federal or State programs or arrangements that provide health benefits (other than coverage or insurance described in clause (i) or clauses (iii) through (ix) of section 5504(3)(B)).

(2) ADMINISTERED HEALTH PLAN SPONSOR.—The term "administered health plan sponsor" has the meaning given the term "sponsor" in section 5504(13) in relation to an administered health plan (as defined in paragraph (1)).

(3) CODE SET.—The term "code set" means any set of codes used for encoding data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes.

(4) COORDINATION OF BENEFITS.—The term "coordination of benefits" means determining and coordinating the financial obligations of administered health plan sponsors and workers' compensation carriers when health care benefits are payable by more than one such sponsor or carrier.

(5) HEALTH INFORMATION.—The term "health information" means any information that relates to the past, present, or future physical or mental health or condition or functional status of an individual, the provision of health care to an individual, or payment for the provision of health care to an individual.

(6) HEALTH INFORMATION NETWORK SERVICE.—The term "health information network service" means a private entity or an entity operated by a State that enters into contracts—

(A) to process or facilitate the processing of nonstandard health information into standard health information;

(B) to provide the means by which individuals and entities transmit and receive standard health information to satisfy the requirements of this part; or

(C) to provide other information processing services, such as automated coordination of benefits or claim routing.

(7) HEALTH PROVIDER.—The term "health provider" includes a provider of services (as defined in section 1861(u) of the Social Security Act), a provider of medical or other health services (as defined in section 1861(s) of such Act), and any other person (other than an administered health plan sponsor) furnishing health care items or services.

(8) NETWORK PROVIDER.—The term "network provider", when used with respect to an administered health plan, means a health provider who is member of a plan network of the plan.

(9) PLAN NETWORK.—The term "plan network" means, with respect to an administered health plan, health providers who have entered into an agreement with the plan under which such providers are obligated to provide items and services covered under the plan to individuals enrolled in the plan, or have an agreement to provide services on a fee-for-service basis.

(10) STANDARD.—The term "standard", when used with reference to health information or a transaction involving such information, means that the information or transaction meets any standard established by the Secretary under section 9103 that applies to the information or transaction.

(11) WORKERS' COMPENSATION CARRIER.—The term "workers compensation carrier" has the meaning given such term in section 13000(4).

Subtitle C—Fair Health Information Practices

SEC. 9200. DEFINITIONS.

(a) DEFINITIONS RELATING TO PROTECTED HEALTH INFORMATION.—For purposes of this subtitle:

(1) DISCLOSE.—The term "disclose", when used with respect to protected health information that is held by a health information trustee, means to provide access to the information, but only if such access is provided by the trustee to a person other than—

(A) the trustee or an officer or employee of the trustee;

(B) an affiliated person of the trustee; or

(C) a protected individual who is a subject of the information.

(2) DISCLOSURE.—The term "disclosure" means the act or an instance of disclosing.

(3) PROTECTED HEALTH INFORMATION.—The term "protected health information" means any information, whether oral or recorded in any form or medium—

(A) that is created or received in a State by—

(i) a health care provider;

(ii) a health plan sponsor;

(iii) a health oversight agency;

(iv) a health information service organization; or

(v) a public health authority;

(B) that—

(i) relates in any way to—

(I) the past, present, or future physical or mental health or condition or functional status of a protected individual;

(II) the provision of health care to a protected individual;

(III) any cause or circumstance underlying the provision of such care; or

(IV) payment for the provision of such care; or

(ii) is received by a health care provider in the course of the provision of health care; and

(C) that—

(i) identifies the individual; or

(ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

(4) PROTECTED INDIVIDUAL.—The term "protected individual" means an individual who, with respect to a date—

(A) is living on the date; or

(B) has died within the 2-year period ending on the date.

(5) USE.—The term "use", when used with respect to protected health information that is held by a health information trustee, means—

(A) to use, or provide access to, the information in any manner that does not constitute a disclosure; or

(B) any act or instance of using, or providing access, described in subparagraph (A).

(b) DEFINITIONS RELATING TO HEALTH INFORMATION TRUSTEES.—For purposes of this subtitle:

(1) CARRIER.—The term "carrier" has the meaning given such term in section 5504(2).

(2) HEALTH PLAN.—The term "health plan" has the meaning given such term in section 5504(4).

(3) HEALTH PLAN SPONSOR.—The term "health plan sponsor" means a person who, with respect to a specific item of pro-

tected health information, receives, creates, uses, maintains, or discloses the information while acting in whole or in part in the capacity of—

(A) a carrier providing an insured health plan;

(B) a public or private entity sponsoring any other health plan; or

(C) an officer or employee of a person described in subparagraph (A) or (B).

(4) HEALTH CARE PROVIDER.—The term "health care provider" means a person who, with respect to a specific item of protected health information, receives, creates, uses, maintains, or discloses the information while acting in whole or in part in the capacity of—

(A) a person who is licensed, certified, registered, or otherwise authorized by law to provide an item or service that constitutes health care in the ordinary course of business or practice of a profession;

(B) a Federal or State program that directly provides items or services that constitute health care to beneficiaries; or

(C) an officer or employee of a person described in subparagraph (A) or (B).

(5) HEALTH INFORMATION SERVICE ORGANIZATION.—The term "health information service organization" means a person who, with respect to a specific item of protected health information, receives, creates, uses, maintains, or discloses the information while acting in whole or in part in the capacity of—

(A) a person, other than an affiliated person, who performs specific functions for which the Secretary has authorized (by means of a designation or certification) the person to receive access to health care information in electronic or magnetic form that is regulated by this Act; or

(B) an officer or employee of a person described in subparagraph (A).

(6) HEALTH INFORMATION TRUSTEE.—The term "health information trustee" means—

(A) a health care provider;

(B) a health information service organization;

(C) a health oversight agency;

(D) a health plan sponsor;

(E) a public health authority;

(F) a health researcher;

(G) a person who, with respect to a specific item of protected health information, is not described in subparagraphs (A) through (F) but receives the information—

(i) pursuant to—

(I) section 9227 (relating to emergency circumstances);

(II) section 9228 (relating to judicial and administrative purposes);

(III) section 9229 (relating to law enforcement); or

(IV) section 9230 (relating to subpoenas, warrants, and search warrants); or

(ii) while acting in whole or in part in the capacity of an officer or employee of a person described in clause (i).

(7) HEALTH OVERSIGHT AGENCY.—The term "health oversight agency" means a person who, with respect to a specific item of protected health information, receives, creates, uses, maintains, or discloses the information while acting in whole or in part in the capacity of—

(A) a person who performs or oversees the performance of an assessment, evaluation, determination, or investigation relating to the licensing, accreditation, or certification of health care providers;

(B) a person who—

(i) performs or oversees the performance of an audit, assessment, evaluation, determination, or investigation relating to the effectiveness of, compliance with, or applicability of, legal, fiscal, medical, quality, or scientific standards or aspects of performance related to the delivery of, or payment for, health care; and

(ii) is a public agency, acting on behalf of a public agency, acting pursuant to a requirement of a public agency, or carrying out activities under a State or Federal statute regulating the assessment, evaluation, determination, or investigation; or

(C) an officer or employee of a person described in subparagraph (A) or (B).

(8) HEALTH RESEARCHER.—The term "health researcher" means a person who, with respect to a specific item of protected health information, receives the information—

(A) pursuant to section 9226 (relating to health research); or

(B) while acting in whole or in part in the capacity of an officer or employee of a person described in subparagraph (A).

(9) PUBLIC HEALTH AUTHORITY.—The term "public health authority" means a person who, with respect to a specific item of protected health information, receives, creates, uses, maintains, or discloses the information while acting in whole or in part in the capacity of—

(A) an authority of the United States, a State, or a political subdivision of a State that is responsible for public health matters;

(B) a person acting under the direction of such an authority; or

(C) an officer or employee of a person described in subparagraph (A) or (B).

(c) OTHER DEFINITIONS.—For purposes of this subtitle:

(1) AFFILIATED PERSON.—The term "affiliated person" means a person who—

(A) is not a health information trustee;

(B) is a contractor, subcontractor, associate, or subsidiary of a person who is a health information trustee; and

(C) pursuant to an agreement or other relationship with such trustee, receives, creates, uses, maintains, or discloses protected health information.

(2) APPROVED HEALTH RESEARCH PROJECT.—The term "approved health research project" means a biomedical, epidemiological, or health services research or statistics project, or a research project on behavioral and social factors affecting health, that has been approved by a certified institutional review board.

(3) CERTIFIED INSTITUTIONAL REVIEW BOARD.—The term "certified institutional review board" means a board—

(A) established by an entity to review research involving protected health information and the rights of protected individuals conducted at or supported by the entity;

(B) established in accordance with regulations of the Secretary under section 9226(e)(1); and

(C) certified by the Secretary under section 9226(e)(2).

(4) HEALTH CARE.—The term "health care"—

(A) means—

(i) any preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, counseling, service, or procedure—

(I) with respect to the physical or mental condition, or functional status, of an individual; or

(II) affecting the structure or function of the human body or any part of the human body, in-

cluding banking of blood, sperm, organs, or any other tissue; or

(ii) any sale or dispensing of a drug, device, equipment, or other item to an individual, or for the use of an individual, pursuant to a prescription; but

(B) does not include any item or service that is not furnished for the purpose of maintaining or improving the health of an individual.

(5) LAW ENFORCEMENT INQUIRY.—The term "law enforcement inquiry" means a lawful investigation or official proceeding inquiring into a violation of, or failure to comply with, any criminal or civil statute or any regulation, rule, or order issued pursuant to such a statute.

(6) PERSON.—The term "person" includes an authority of the United States, a State, or a political subdivision of a State.

PART 1—DUTIES OF HEALTH INFORMATION TRUSTEES

SEC. 9201. INSPECTION OF PROTECTED HEALTH INFORMATION.

(a) IN GENERAL.—Except as provided in subsection (b), a health information trustee described in subsection (g)—

(1) shall permit a protected individual to inspect any protected health information about the individual that the trustee maintains, any accounting with respect to such information required under section 9204, and any copy of an authorization required under section 9222 that pertains to such information;

(2) shall provide the protected individual with a copy of the information upon request by the individual and subject to any conditions imposed by the trustee under subsection (d);

(3) shall permit a person who has been designated in writing by the protected individual to inspect the information on behalf of the individual or to accompany the individual during the inspection; and

(4) may offer to explain or interpret information that is inspected or copied under this subsection.

(b) EXCEPTIONS.—A health information trustee is not required by this section to permit inspection or copying of protected health information by a protected individual if any of the following conditions apply:

(1) MENTAL HEALTH TREATMENT NOTES.—The information consists of psychiatric, psychological, or mental health treatment notes about the individual, the trustee determines in the exercise of reasonable professional judgment that inspection or copying of the notes would cause sufficient harm to the protected individual so as to outweigh the desirability of permitting access, and the trustee does not disclose the notes to any person not directly engaged in treating the individual, except with the authorization of the individual or under compulsion of law.

(2) INFORMATION ABOUT OTHERS.—The information relates to an individual, other than the protected individual or a health care provider, and the trustee determines in the exercise of reasonable professional judgment that inspection or copying of the information would cause sufficient harm to one or both of the individuals so as to outweigh the desirability of permitting access.

(3) ENDANGERMENT TO LIFE OR SAFETY.—Inspection or copying of the information could reasonably be expected to endanger the life or physical safety of an individual.

(4) CONFIDENTIAL SOURCE.—The information identifies or could reasonably lead to the identification of an individual (other than a health care provider) who provided information under a promise of confidentiality to a health care provider concerning a protected individual who is a subject of the information.

(5) ADMINISTRATIVE PURPOSES.—The information—

(A) is used by the trustee solely for administrative purposes and not in the provision of health care to a protected individual who is a subject of the information; and

(B) is not disclosed by the trustee to any person.

(6) DUPLICATIVE INFORMATION.—The information duplicates information available for inspection under subsection (a).

(7) INFORMATION COMPILED IN ANTICIPATION OF LITIGATION.—The information is compiled principally—

(A) in anticipation of a civil, criminal, or administrative action or proceeding; or

(B) for use in such an action or proceeding.

(c) INSPECTION AND COPYING OF SEGREGABLE PORTION.—A health information trustee shall permit inspection and copying under subsection (a) of any reasonably segregable portion of a record after deletion of any portion that is exempt under subsection (b).

(d) CONDITIONS.—A health information trustee may—

(1) require a written request for the inspection and copying of protected health information under this section; and

(2) charge a reasonable cost-based fee for—

(A) permitting inspection of information under this section; and

(B) providing a copy of protected health information under this section.

(e) STATEMENT OF REASONS FOR DENIAL.—If a health information trustee denies in whole or in part a request for inspection or copying under this section, the trustee shall provide the protected individual who made the request with a written statement of the reasons for the denial.

(f) DEADLINE.—A health information trustee shall comply with or deny a request for inspection or copying of protected health information under this section within the 30-day period beginning on the date the trustee receives the request.

(g) APPLICABILITY.—This section applies to a health information trustee who is—

(1) a health plan sponsor;

(2) a health care provider;

(3) a health information service organization;

(4) a health oversight agency; or

(5) a public health authority.

SEC. 9202. AMENDMENT OF PROTECTED HEALTH INFORMATION.

(a) IN GENERAL.—A health information trustee described in subsection (f) shall, within the 45-day period beginning on the date the trustee receives from a protected individual about whom the trustee maintains protected health information a written request that the trustee correct or amend the information, complete the duties described in one of the following paragraphs:

(1) CORRECTION OR AMENDMENT AND NOTIFICATION.—The trustee shall—

(A) make the correction or amendment requested;

(B) inform the protected individual of the amendment or correction that has been made;

(C) make reasonable efforts to inform any person who is identified by the protected individual, who is not an employee of the trustee, and to whom the uncorrected or unamended portion of the information was previously disclosed of the correction or amendment that has been made; and

(D) at the request of the individual, make reasonable efforts to inform any known source of the uncorrected or unamended portion of the information about the correction or amendment that has been made.

(2) REASONS FOR REFUSAL AND REVIEW PROCEDURES.—The trustee shall inform the protected individual of—

(A) the reasons for the refusal of the trustee to make the correction or amendment;

(B) any procedures for further review of the refusal; and

(C) the individual's right to file with the trustee a concise statement setting forth the requested correction or amendment and the individual's reasons for disagreeing with the refusal of the trustee.

(b) STANDARDS FOR CORRECTION OR AMENDMENT.—A trustee shall correct or amend protected health information in accordance with a request made under subsection (a) if the trustee determines that the information is not accurate, relevant, timely, or complete for the purposes for which the information may be used or disclosed by the trustee.

(c) STATEMENT OF DISAGREEMENT.—After a protected individual has filed a statement of disagreement under subsection (a)(2)(C), the trustee, in any subsequent disclosure of the disputed portion of the information, shall include a copy of the individual's statement and may include a concise statement of the trustee's reasons for not making the requested correction or amendment.

(d) CONSTRUCTION.—This section may not be construed to require a health information trustee to conduct a hearing or proceeding concerning a request for a correction or amendment to protected health information the trustee maintains.

(e) CORRECTION.—For purposes of subsection (a), a correction is deemed to have been made to protected health information when—

(1) information that is not timely, accurate, relevant, or complete is clearly marked as incorrect; or

(2) supplementary correct information is made part of the information and adequately cross-referenced.

(f) APPLICABILITY.—This section applies to a health information trustee who is—

(1) a health plan sponsor;

(2) a health care provider;

(3) a health information service organization;

(4) a health oversight agency; or

(5) a public health authority.

SEC. 9203. NOTICE OF INFORMATION PRACTICES.

(a) PREPARATION OF NOTICE.—A health information trustee described in subsection (d) shall prepare a written notice of information practices describing the following:

(1) The rights under this subtitle of a protected individual who is the subject of protected health information, including the right to inspect and copy such information and the right to seek amendments to such information, and the procedures for authorizing disclosures of protected health information and for revoking such authorizations.

(2) The procedures established by the trustee for the exercise of such rights.

(3) The uses and disclosures of protected health information that are authorized under this subtitle.

(b) DISSEMINATION OF NOTICE.—A health information trustee—

(1) shall, upon request, provide any person with a copy of the trustee's notice of information practices (described in subsection (a)); and

(2) shall make reasonable efforts to inform persons in a clear and conspicuous manner of the existence and availability of such notice.

(c) MODEL NOTICES.—Not later than July 1, 1996, the Secretary, after notice and opportunity for public comment, shall develop and disseminate model notices of information practices for use by health information trustees under this section.

(d) APPLICABILITY.—This section applies to a health information trustee who is—

(1) a health plan sponsor;

(2) a health care provider;

(3) a health information service organization; or
(4) a health oversight agency.

SEC. 9204. ACCOUNTING FOR DISCLOSURES.

(a) IN GENERAL.—Except as provided in subsection (b) and section 9224, each health information trustee shall create and maintain, with respect to any protected health information the trustee discloses, a record of—
(1) the date and purpose of the disclosure;
(2) the name of the person to whom the disclosure was made;
(3) the address of the person to whom the disclosure was made or the location to which the disclosure was made; and
(4) where practicable, a description of the information disclosed.

(b) REGULATIONS.—Not later than July 1, 1996, the Secretary shall promulgate regulations that exempt a health information trustee from maintaining a record under subsection (a) with respect to protected health information disclosed by the trustee for purposes of peer review, licensing, certification, accreditation, and similar activities.

SEC. 9205. SECURITY.

(a) IN GENERAL.—Each health information trustee who receives or creates protected health information that is subject to this subtitle shall maintain reasonable and appropriate administrative, technical, and physical safeguards—
(1) to ensure the integrity and confidentiality of the information;
(2) to protect against any reasonably anticipated—
(A) threats or hazards to the security or integrity of the information; and
(B) unauthorized uses or disclosures of the information; and
(3) otherwise ensure compliance with this subtitle by the trustee and the officers and employees of the trustee.

(b) GUIDELINES.—Not later than July 1, 1996, the Secretary, after notice and opportunity for public comment, shall develop and disseminate guidelines for the implementation of this section. The guidelines shall take into account—
(1) the technical capabilities of record systems used to maintain protected health information;
(2) the costs of security measures;
(3) the need for training persons who have access to protected health information; and
(4) the value of audit trails in computerized record systems.

PART 2—USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

SEC. 9221. GENERAL LIMITATIONS ON USE AND DISCLOSURE.

(a) USE.—Except as otherwise provided under this subtitle, a health information trustee may use protected health information only for a purpose—
(1) that is compatible with and directly related to the purpose for which the information—
(A) was collected; or
(B) was received by the trustee; or
(2) for which the trustee is authorized to disclose the information under this subtitle.

(b) DISCLOSURE.—A health information trustee may disclose protected health information only as authorized under this subtitle.

(c) SCOPE OF USES AND DISCLOSURES.—
(1) IN GENERAL.—A use or disclosure of protected health information by a health information trustee shall be limited, when practicable, to the minimum amount of information nec-

essary to accomplish the purpose for which the information is used or disclosed.

(2) GUIDELINES.—Not later than July 1, 1996, the Secretary, after notice and opportunity for public comment, shall issue guidelines to implement paragraph (1), which shall take into account the technical capabilities of the record systems used to maintain protected health information and the costs of limiting use and disclosure.

(d) IDENTIFICATION OF DISCLOSED INFORMATION AS PROTECTED INFORMATION.—Except with respect to protected health information that is disclosed under section 9224 (relating to next of kin and directory information), a health information trustee may disclose protected health information only if the recipient has been notified that the information is protected health information that is subject to this subtitle.

(e) AGREEMENT TO LIMIT USE OR DISCLOSURE.—A health information trustee who receives protected health information from any person pursuant to a written agreement to restrict use or disclosure of the information to a greater extent than otherwise would be required under this subtitle shall comply with the terms of the agreement, except where use or disclosure of the information in violation of the agreement is required by law. A trustee who fails to comply with the preceding sentence shall be subject to section 9261 (relating to civil actions) with respect to such failure.

(f) NO GENERAL REQUIREMENT TO DISCLOSE.—Nothing in this subtitle shall be construed to require a health information trustee to disclose protected health information not otherwise required to be disclosed by law.

SEC. 9222. AUTHORIZATIONS FOR DISCLOSURE OF PROTECTED HEALTH INFORMATION.

(a) WRITTEN AUTHORIZATIONS.—A health information trustee, other than a health information service organization, may disclose protected health information pursuant to an authorization executed by the protected individual who is the subject of the information, if each of the following requirements is satisfied:

(1) WRITING.—The authorization is in writing, signed by the individual, and dated on the date of such signature.

(2) SEPARATE FORM.—The authorization is not on a form used to authorize or facilitate the provision of, or payment for, health care.

(3) TRUSTEE DESCRIBED.—The trustee is specifically named or generically described in the authorization as authorized to disclose such information.

(4) RECIPIENT DESCRIBED.—The person to whom the information is to be disclosed is specifically named or generically described in the authorization as a person to whom such information may be disclosed.

(5) STATEMENT OF INTENDED USES AND DISCLOSURES RECEIVED.—The authorization contains an acknowledgment that the individual has received a statement described in subsection (b) from such person.

(6) INFORMATION DESCRIBED.—The information to be disclosed is described in the authorization.

(7) AUTHORIZATION TIMELY RECEIVED.—The authorization is received by the trustee during a period described in subsection (c)(1).

(8) DISCLOSURE TIMELY MADE.—The disclosure occurs during a period described in subsection (c)(2).

(b) STATEMENT OF INTENDED USES AND DISCLOSURES.—

(1) IN GENERAL.—A person who wishes to receive from a health information trustee protected health information about a protected individual pursuant to an authorization executed by the individual shall supply the individual, in writing and on a form that is distinct from the authorization, with a statement of the uses for which the person intends the information and the disclosures the person intends to make of the information.

Such statement shall be supplied before the authorization is executed.

(2) ENFORCEMENT.—If the person uses or discloses the information in a manner that is inconsistent with such statement, the person shall be subject to section 9261 (relating to civil actions) with respect to such failure, except where such use or disclosure is required by law.

(3) MODEL STATEMENTS.—Not later than July 1, 1996, the Secretary, after notice and opportunity for public comment, shall develop and disseminate model statements of intended uses and disclosures of the type described in paragraph (1).

(c) TIME LIMITATIONS ON AUTHORIZATIONS.—

(1) RECEIPT BY TRUSTEE.—For purposes of subsection (a)(7), an authorization is timely received if it is received by the trustee during—

(A) the 1-year period beginning on the date that the authorization is signed under subsection (a)(1), if the authorization permits the disclosure of protected health information to—

(i) a health plan sponsor;

(ii) a health care provider;

(iii) a health oversight agency;

(iv) a public health authority;

(v) a health researcher; or

(vi) a person who provides counseling or social services to individuals; or

(B) the 30-day period beginning on the date that the authorization is signed under subsection (a)(1), if the authorization permits the disclosure of protected health information to a person other than a person described in subparagraph (A).

(2) DISCLOSURE BY TRUSTEE.—For purposes of subsection (a)(8), a disclosure is timely made if it occurs before—

(A) the date or event (if any) specified in the authorization upon which the authorization expires; and

(B) the expiration of the 6-month period beginning on the date the trustee receives the authorization.

(d) REVOCATION OR AMENDMENT OF AUTHORIZATION.—

(1) IN GENERAL.—A protected individual in writing may revoke or amend an authorization described in subsection (a), in whole or in part, at any time, except insofar as—

(A) disclosure of protected health information has been authorized to permit validation of expenditures based on health condition by a government authority; or

(B) action has been taken in reliance on the authorization.

(2) NOTICE OF REVOCATION.—A health information trustee who discloses protected health information in reliance on an authorization that has been revoked shall not be subject to any liability or penalty under this subtitle if—

(A) the reliance was in good faith;

(B) the trustee had no notice of the revocation; and

(C) the disclosure was otherwise in accordance with the requirements of this section.

(e) ADDITIONAL REQUIREMENTS OF TRUSTEE.—A health information trustee may impose requirements for an authorization that are in addition to the requirements in this section.

(f) COPY.—A health information trustee who discloses protected health information pursuant to an authorization under this section shall maintain a copy of the authorization.

(g) CONSTRUCTION.—This section may not be construed—

(1) to require a health information trustee to disclose protected health information; or

(2) to limit the right of a health information trustee to charge a fee for the disclosure or reproduction of protected health information.

(h) SUBPOENAS, WARRANTS, AND SEARCH WARRANTS.—If a health information trustee discloses protected health information pursuant to an authorization in order to comply with an administrative subpoena or warrant or a judicial subpoena or search warrant, the authorization—

(1) shall specifically authorize the disclosure for the purpose of permitting the trustee to comply with the subpoena, warrant, or search warrant; and

(2) shall otherwise meet the requirements in this section.

SEC. 9223. TREATMENT, PAYMENT, AND OVERSIGHT.

(a) DISCLOSURES BY PLANS, PROVIDERS, AND OVERSIGHT AGENCIES.—A health information trustee described in subsection (d) may disclose protected health information to a health plan sponsor, health care provider, or health oversight agency if the disclosure is—

(1) for the purpose of providing health care and a protected individual who is a subject of the information has not previously objected to the disclosure in writing;

(2) for the purpose of providing for the payment for health care furnished to an individual; or

(3) for use by a health oversight agency for a purpose that is described in subparagraph (A) or (B)(i) of section 9200(b)(7).

(b) SENSITIVE CLAIMS INFORMATION.—Not later than July 1, 1996, the Secretary shall establish standards consistent with this subtitle with respect to the disclosure, to any person other than a health plan sponsor, of protected health information created or received by a health care provider or a health plan sponsor in connection with a claim for benefits under a health plan, where such information—

(1) pertains to a diagnosis, item, or service; and

(2) is disclosed—

(A) concurrent with the filing of the claim; or

(B) after the claim is filed.

(c) USE IN ACTION AGAINST INDIVIDUAL.—A person who receives protected health information about a protected individual through a disclosure under this section may not use or disclose the information in any administrative, civil, or criminal action or investigation directed against the individual, except an action or investigation arising out of and related to receipt of health care or payment for health care.

(d) APPLICABILITY.—A health information trustee referred to in subsection (a) is any of the following:

(1) A health plan sponsor.

(2) A health care provider.

(3) A health oversight agency.

(4) A health information service organization.

SEC. 9224. NEXT OF KIN AND DIRECTORY INFORMATION.

(a) NEXT OF KIN.—A health information trustee who is a health care provider, who received protected health information pursuant to section 9227 (relating to emergency circumstances), or who is an officer or employee of such a recipient may orally disclose protected health information about a protected individual to the next of kin of the individual (as defined under State law), or to a person with whom the individual has a close personal relationship, if—

(1) the trustee has no reason to believe that the individual would consider the information especially sensitive;

(2) the individual has not previously objected to the disclosure;

(3) the disclosure is consistent with good medical or other professional practice; and

(4) the information disclosed is limited to information about health care that is being provided to the individual at or about the time of the disclosure.

(b) DIRECTORY INFORMATION.—

(1) IN GENERAL.—A health information trustee who is a health care provider, who received protected health information pursuant to section 9227 (relating to emergency circumstances), or who is an officer or employee of a such a recipient may disclose to any person the information described in paragraph (2) if—

(A) a protected individual who is a subject of the information has not objected in writing to the disclosure;

(B) the disclosure is otherwise consistent with good medical and other professional practice; and

(C) the information does not reveal specific information about the physical or mental condition or functional status of a protected individual or about the health care provided to a protected individual.

(2) INFORMATION DESCRIBED.—The information referred to in paragraph (1) is the following:

(A) The name of an individual receiving health care from a health care provider on a premises controlled by the provider.

(B) The location of the individual on such premises.

(C) The general health status of the individual, described in terms of critical, poor, fair, stable, satisfactory, or terms denoting similar conditions.

(c) NO ACCOUNTING REQUIRED.—A health information trustee who discloses protected health information under this section is not required to maintain an accounting of the disclosure under section 9204.

(d) RECIPIENTS.—A person to whom protected health information is disclosed under this section shall not, by reason of such disclosure, be subject to any requirement under this subtitle.

SEC. 9225. PUBLIC HEALTH.

(a) IN GENERAL.—A health information trustee who is a health care provider or a public health authority may disclose protected health information to—

(1) a public health authority for use in legally authorized—

(A) disease or injury reporting;

(B) public health surveillance; or

(C) public health investigation or intervention; or

(2) an individual who is authorized by law to receive the information in a public health intervention.

(b) USE IN ACTION AGAINST INDIVIDUAL.—A public health authority who receives protected health information about a protected individual through a disclosure under this section may not use or disclose the information in any administrative, civil, or criminal action or investigation directed against the individual, except where the use or disclosure is authorized by law for protection of the public health.

(c) INDIVIDUAL RECIPIENTS.—An individual to whom protected health information is disclosed under subsection (a)(2) shall not, by reason of such disclosure, be subject to any requirement under this subtitle.

SEC. 9226. HEALTH RESEARCH.

(a) IN GENERAL.—A health information trustee described in subsection (d) may disclose protected health information to a person if—

(1) the person is conducting an approved health research project;

(2) the information is to be used in the project; and

(3) the project has been determined by a certified institutional review board to be—

(A) of sufficient importance so as to outweigh the intrusion into the privacy of the protected individual who is the subject of the information that would result from the disclosure; and

(B) impracticable to conduct without the information.

(b) DISCLOSURES BY HEALTH INFORMATION SERVICE ORGANIZATIONS.—A health information service organization may disclose protected health information under subsection (a) only if the certified institutional review board referred to in subsection (a)(3) has been certified as being qualified to make determinations under such subsection with respect to disclosures by such organizations.

(c) LIMITATIONS ON USE AND DISCLOSURE; OBLIGATIONS OF RECIPIENT.—A health researcher who receives protected health information about a protected individual pursuant to subsection (a)—

(1) may use the information solely for purposes of an approved health research project;

(2) may not use or disclose the information in any administrative, civil, or criminal action or investigation directed against the individual; and

(3) shall remove or destroy, at the earliest opportunity consistent with the purposes of the approved health research project in connection with which the disclosure was made, information that would enable an individual to be identified, unless a certified institutional review board has determined that there is a health or research justification for retention of such identifiers and there is an adequate plan to protect the identifiers from use and disclosure that is inconsistent with this subtitle.

(d) APPLICABILITY.—A health information trustee referred to in subsection (a) is any health information trustee other than a person who, with respect to the specific protected health information to be disclosed under such subsection, received the information—

(1) pursuant to—

(A) section 9228 (relating to judicial and administrative purposes);

(B) paragraph (1), (2), or (3) of section 9229(a) (relating to law enforcement); or

(C) section 9230 (relating to subpoenas, warrants, and search warrants); or

(2) while acting in whole or in part in the capacity of an officer or employee of a person described in paragraph (1).

(e) REQUIREMENTS FOR INSTITUTIONAL REVIEW BOARDS.—

(1) REGULATIONS.—Not later than July 1, 1996, the Secretary, after opportunity for notice and comment, shall promulgate regulations establishing requirements for certified institutional review boards under this subtitle. The regulations shall be based on regulations promulgated under section 491(a) of the Public Health Service Act and shall ensure that certified institutional review boards are qualified to assess and protect the confidentiality of research subjects. The regulations shall include specific requirements for certified institutional review boards that make determinations under subsection (a)(3) with respect to disclosures by health information service organizations. To the greatest extent feasible, the membership of a certified institutional review board shall reflect the racial, ethnic, and gender composition of the population of the United States.

(2) CERTIFICATION.—The Secretary shall certify that an institutional review board satisfies the requirements of the regulations promulgated under paragraph (1).

SEC. 9227. EMERGENCY CIRCUMSTANCES.

(a) IN GENERAL.—A health information trustee may disclose protected health information if the trustee believes, on reasonable grounds, that the disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of an individual.

(b) USE IN ACTION AGAINST INDIVIDUAL.—A person who receives protected health information about a protected individual through a disclosure under this section may not use or disclose the information in any administrative, civil, or criminal action or investigation directed against the individual, except an action or investigation arising out of and related to receipt of health care or payment for health care.

SEC. 9228. JUDICIAL AND ADMINISTRATIVE PURPOSES.

(a) IN GENERAL.—A health information trustee described in subsection (d) may disclose protected health information—

(1) pursuant to the Federal Rules of Civil Procedure, the Federal Rules of Criminal Procedure, or comparable rules of other courts or administrative agencies in connection with litigation or proceedings to which a protected individual who is a subject of the information is a party and in which the individual has placed the individual's physical or mental condition or functional status in issue;

(2) if directed by a court in connection with a court-ordered examination of an individual; or

(3) to assist in the identification of a dead individual.

(b) WRITTEN STATEMENT.—A person seeking protected health information about a protected individual held by health information trustee under—

(1) subsection (a)(1)—

(A) shall notify the protected individual or the attorney of the protected individual of the request for the information;

(B) shall provide the trustee with a signed document attesting—

(i) that the protected individual is a party to the litigation or proceedings for which the information is sought;

(ii) that the individual has placed the individual's physical or mental condition or functional status in issue; and

(iii) the date on which the protected individual or the attorney of the protected individual was notified under subparagraph (A); and

(C) shall not accept any requested protected health information from the trustee until the termination of the 10-day period beginning on the date notice was given under subparagraph (A); or

(2) subsection (a)(3) shall provide the trustee with a written statement that the information is sought to assist in the identification of a dead individual.

(c) USE AND DISCLOSURE.—A person to whom protected health information is disclosed under this section may use and disclose the information only to accomplish the purpose for which the disclosure was made.

(d) APPLICABILITY.—A health information trustee referred to in subsection (a) is any of the following:

(1) A health plan sponsor.

(2) A health care provider.

(3) A health oversight agency.

(4) A person who, with respect to the specific protected health information to be disclosed under such subsection, received the information—

(A) pursuant to—

(i) section 9227 (relating to emergency circumstances); or

(ii) section 9230 (relating to subpoenas, warrants, and search warrants); or

(B) while acting in whole or in part in the capacity of an officer or employee of a person described in subparagraph (A).

SEC. 9229. LAW ENFORCEMENT.

(a) IN GENERAL.—A health information trustee, other than a health information service organization, may disclose protected health information to a law enforcement agency, other than a health oversight agency—

(1) if the information is disclosed for use in an investigation or prosecution of a health information trustee;

(2) in connection with criminal activity committed against the trustee or an affiliated person of the trustee or on premises controlled by the trustee; or

(3) if the information is needed to determine whether a crime has been committed and the nature of any crime that may have been committed (other than a crime that may have been committed by the protected individual who is the subject of the information).

(b) ADDITIONAL AUTHORITY OF CERTAIN TRUSTEES.—A health information trustee who is not a health information service organization, a public health authority, or a health researcher may disclose protected health information to a law enforcement agency (other than a health oversight agency)—

(1) to assist in the identification or location of a victim or witness in a law enforcement inquiry;

(2) pursuant to a law requiring the reporting of specific health care information to law enforcement authorities; or

(3) if the information is specific health information described in paragraph (2) and the trustee is operated by a Federal agency;

(c) CERTIFICATION.—Where a law enforcement agency requests a health information trustee to disclose protected health information under subsection (a) or (b)(1), the agency shall provide the trustee with a written certification that—

(1) is signed by a supervisory official of a rank designated by the head of the agency;

(2) specifies the information requested; and

(3) states that the information is needed for a lawful purpose under this section.

(d) RESTRICTIONS ON DISCLOSURE AND USE.—A person who receives protected health information about a protected individual through a disclosure under this section may not use or disclose the information—

(1) in any administrative, civil, or criminal action or investigation directed against the individual, except an action or investigation arising out of and directly related to the action or investigation for which the information was obtained; and

(2) otherwise unless the use or disclosure is necessary to fulfill the purpose for which the information was obtained and is not prohibited by any other provision of law.

SEC. 9230. SUBPOENAS, WARRANTS, AND SEARCH WARRANTS.

(a) IN GENERAL.—A health information trustee described in subsection (g) may disclose protected health information if the disclosure is pursuant to any of the following:

(1) A subpoena issued under the authority of a grand jury and the trustee is provided a written certification by the grand jury that the grand jury has complied with the applicable access provisions of section 9241.

(2) An administrative subpoena or warrant or a judicial subpoena or search warrant and the trustee is provided a written certification by the person seeking the information that the person has complied with the applicable access provisions of section 9241 or 9243(a).

(3) An administrative subpoena or warrant or a judicial subpoena or search warrant and the disclosure otherwise meets the conditions of one of sections 9223 through 9229.

(b) AUTHORITY OF ALL TRUSTEES.—Any health information trustee may disclose protected health information if the disclosure is pursuant to subsection (a)(3).

(c) RESTRICTIONS ON USE AND DISCLOSURE.—Protected health information about a protected individual that is disclosed by a health information trustee pursuant to—

(1) subsection (a)(2) may not be otherwise used or disclosed by the recipient unless the use or disclosure is necessary to fulfill the purpose for which the information was obtained; and

(2) subsection (a)(3) may not be used or disclosed by the recipient unless the recipient complies with the conditions and restrictions on use and disclosure with which the recipient would have been required to comply if the disclosure by the trustee had been made under the section referred to in subsection (a)(3) the conditions of which were met by the disclosure.

(d) RESTRICTIONS ON GRAND JURIES.—Protected health information that is disclosed by a health information trustee under subsection (a)(1)—

(1) shall be returnable on a date when the grand jury is in session and actually presented to the grand jury;

(2) shall be used only for the purpose of considering whether to issue an indictment or report by that grand jury, or for the purpose of prosecuting a crime for which that indictment or report is issued, or for a purpose authorized by rule 6(e) of the Federal Rules of Criminal Procedure or a comparable State rule;

(3) shall be destroyed or returned to the trustee if not used for one of the purposes specified in paragraph (2); and

(4) shall not be maintained, or a description of the contents of such information shall not be maintained, by any government authority other than in the sealed records of the grand jury, unless such information has been used in the prosecution of a crime for which the grand jury issued an indictment or presentment or for a purpose authorized by rule 6(e) of the Federal Rules of Criminal Procedure or a comparable State rule.

(e) USE IN ACTION AGAINST INDIVIDUAL.—A person who receives protected health information about a protected individual through a disclosure under this section may not use or disclose the information in any administrative, civil, or criminal action or investigation directed against the individual, except an action or investigation arising out of and directly related to the inquiry for which the information was obtained.

(f) CONSTRUCTION.—Nothing in this section shall be construed as authority for a health information trustee to refuse to comply with a valid administrative subpoena or warrant or a valid judicial subpoena or search warrant that meets the requirements of this subtitle.

(g) APPLICABILITY.—A health information trustee referred to in subsection (a) is any trustee other than the following:

(1) A health information service organization.

(2) A public health authority.

(3) A health researcher.

SEC. 9231. HEALTH INFORMATION SERVICE ORGANIZATIONS.

A health information trustee may disclose protected health information to a health information service organization for the purpose of permitting the organization to perform a function for which the Secretary has authorized (by means of a designation or certification) the organization to receive access to health care information in electronic or magnetic form that is regulated by this Act.

PART 3—ACCESS PROCEDURES AND CHALLENGE RIGHTS

SEC. 9241. ACCESS PROCEDURES FOR LAW ENFORCEMENT SUBPOENAS, WARRANTS, AND SEARCH WARRANTS.

(a) PROBABLE CAUSE REQUIREMENT.—A government authority may not obtain protected health information about a protected individual from a health information trustee under paragraph (1) or (2) of section 9230(a) for use in a law enforcement inquiry unless there is probable cause to believe that the information is relevant to a legitimate law enforcement inquiry being conducted by the government authority.

(b) WARRANTS AND SEARCH WARRANTS.—A government authority that obtains protected health information about a protected individual from a health information trustee under circumstances described in subsection (a) and pursuant to a warrant or search warrant shall, not later than 30 days after the date the warrant was served on the trustee, serve the individual with, or mail to the last known address of the individual, a copy of the warrant.

(c) SUBPOENAS.—Except as provided in subsection (d), a government authority may not obtain protected health information about a protected individual from a health information trustee under circumstances described in subsection (a) and pursuant to a subpoena unless a copy of the subpoena has been served by hand delivery upon the individual, or mailed to the last known address of the individual, on or before the date on which the subpoena was served on the trustee, together with a notice (published by the Secretary under section 9245(1)) of the individual's right to challenge the subpoena in accordance with section 9242, and—

(1) 30 days have passed from the date of service, or 30 days have passed from the date of mailing, and within such time period the individual has not initiated a challenge in accordance with section 9242; or

(2) disclosure is ordered by a court under section 9242.

(d) APPLICATION FOR DELAY.—

(1) IN GENERAL.—A government authority may apply to an appropriate court to delay (for an initial period of not longer than 90 days) serving a copy of a subpoena and a notice otherwise required under subsection (c) with respect to a law enforcement inquiry. The government authority may apply to the court for extensions of the delay.

(2) REASONS FOR DELAY.—An application for a delay, or extension of a delay, under this subsection shall state, with reasonable specificity, the reasons why the delay or extension is being sought.

(3) EX PARTE ORDER.—The court shall enter an ex parte order delaying, or extending the delay of, the notice and an order prohibiting the trustee from revealing the request for, or the disclosure of, the protected health information being sought if the court finds that—

(A) the inquiry being conducted is within the lawful jurisdiction of the government authority seeking the protected health information;

(B) there is probable cause to believe that the protected health information being sought is relevant to a legitimate law enforcement inquiry being conducted by the government authority;

(C) the government authority's need for the information outweighs the privacy interest of the protected individual who is the subject of the information; and

(D) there are reasonable grounds to believe that receipt of a notice by the individual will result in—

(i) endangering the life or physical safety of any individual;

(ii) flight from prosecution;

(iii) destruction of or tampering with evidence or the information being sought; or

(iv) intimidation of potential witnesses.

(4) SERVICE OF APPLICATION ON INDIVIDUAL.—Upon the expiration of a period of delay of notice under this subsection, the government authority shall serve upon the individual, with the service of the subpoena and the notice, a copy of any applications filed and approved under this subsection.

SEC. 9242. CHALLENGE PROCEDURES FOR LAW ENFORCEMENT SUBPOENAS.

(a) MOTION TO QUASH SUBPOENA.—Within 30 days of the date of service, or 30 days of the date of mailing, of a subpoena of a government authority seeking protected health information about a

protected individual from a health information trustee under paragraph (1) or (2) of section 9230(a) (except a subpoena to which section 9243 applies), the individual may file (without filing fee) a motion to quash the subpoena—

(1) in the case of a State judicial subpoena, in the court which issued the subpoena;

(2) in the case of a subpoena issued under the authority of a State that is not a State judicial subpoena, in a court of competent jurisdiction;

(3) in the case of a subpoena issued under the authority of a Federal court, in any court of the United States of competent jurisdiction; or

(4) in the case of any other subpoena issued under the authority of the United States, in—

(A) the United States district court for the district in which the individual resides or in which the subpoena was issued; or

(B) another United States district court of competent jurisdiction.

(b) COPY.—A copy of the motion shall be served by the individual upon the government authority by delivery of registered or certified mail.

(c) AFFIDAVITS AND SWORN DOCUMENTS.—The government authority may file with the court such affidavits and other sworn documents as sustain the validity of the subpoena. The individual may file with the court, within 5 days of the date of the authority's filing, affidavits and sworn documents in response to the authority's filing. The court, upon the request of the individual, the government authority, or both, may proceed in camera.

(d) PROCEEDINGS AND DECISION ON MOTION.—The court may conduct such proceedings as it deems appropriate to rule on the motion. All such proceedings shall be completed, and the motion ruled on, within 10 calendar days of the date of the government authority's filing.

(e) EXTENSION OF TIME LIMITS FOR GOOD CAUSE.—The court, for good cause shown, may at any time in its discretion enlarge the time limits established by subsections (c) and (d).

(f) STANDARD FOR DECISION.—A court may deny a motion under subsection (a) if it finds that there is probable cause to believe that the protected health information being sought is relevant to a legitimate law enforcement inquiry being conducted by the government authority, unless the court finds that the individual's privacy interest outweighs the government authority's need for the information. The individual shall have the burden of demonstrating that the individual's privacy interest outweighs the need established by the government authority for the information.

(g) SPECIFIC CONSIDERATIONS WITH RESPECT TO PRIVACY INTEREST.—In determining under subsection (f) whether an individual's privacy interest outweighs the government authority's need for the information, the court shall consider—

(1) the particular purpose for which the information was collected by the trustee;

(2) the degree to which disclosure of the information will embarrass, injure, or invade the privacy of the individual;

(3) the effect of the disclosure on the individual's future health care;

(4) the importance of the inquiry being conducted by the government authority, and the importance of the information to that inquiry; and

(5) any other factor deemed relevant by the court.

(h) ATTORNEY'S FEES.—In the case of any motion brought under subsection (a) in which the individual has substantially prevailed, the court, in its discretion, may assess against a government authority a reasonable attorney's fee and other litigation costs (including expert fees) reasonably incurred.

(i) NO INTERLOCUTORY APPEAL.—A court ruling denying a motion to quash under this section shall not be deemed a final order and no interlocutory appeal may be taken therefrom by the individual. An appeal of such a ruling may be taken by the individual within such period of time as is provided by law as part of any appeal from a final order in any legal proceeding initiated against the individual arising out of or based upon the protect health information disclosed.

SEC. 9243. ACCESS AND CHALLENGE PROCEDURES FOR OTHER SUBPOENAS.

(a) IN GENERAL.—A person (other than a government authority seeking protected health information under circumstances described in section 9241(a)) may not obtain protected health information about a protected individual from a health information trustee pursuant to a subpoena under section 9230(a)(2) unless—

(1) a copy of the subpoena has been served upon the individual or mailed to the last known address of the individual on or before the date on which the subpoena was served on the trustee, together with a notice (published by the Secretary under section 9245(2)) of the individual's right to challenge the subpoena, in accordance with subsection (b); and

(2) either—

(A) 30 days have passed from the date of service or 30 days have passed from the date of the mailing and within such time period the individual has not initiated a challenge in accordance with subsection (b); or

(B) disclosure is ordered by a court under such subsection.

(b) MOTION TO QUASH.—Within 30 days of the date of service or 30 days of the date of mailing of a subpoena seeking protected health information about a protected individual from a health information trustee under subsection (a), the individual may file (without filing fee) in any court of competent jurisdiction, a motion to quash the subpoena, with a copy served on the person seeking the information. The individual may oppose, or seek to limit, the subpoena on any grounds that would otherwise be available if the individual were in possession of the information.

(c) STANDARD FOR DECISION.—The court shall grant an individual's motion under subsection (b) if the person seeking the information has not sustained the burden of demonstrating that—

(1) there are reasonable grounds to believe that the information will be relevant to a lawsuit or other judicial or administrative proceeding; and

(2) the need of the person for the information outweighs the privacy interest of the individual.

(d) SPECIFIC CONSIDERATIONS WITH RESPECT TO PRIVACY INTEREST.—In determining under subsection (c) whether the need of the person for the information outweighs the privacy interest of the individual, the court shall consider—

(1) the particular purpose for which the information was collected by the trustee;

(2) the degree to which disclosure of the information will embarrass, injure, or invade the privacy of the individual;

(3) the effect of the disclosure on the individual's future health care;

(4) the importance of the information to the lawsuit or proceeding; and

(5) any other factor deemed relevant by the court.

(e) ATTORNEY'S FEES.—In the case of any motion brought under subsection (b) by an individual against a person in which the individual has substantially prevailed, the court, in its discretion, may assess against the person a reasonable attorney's fee and other litigation costs (including expert fees) reasonably incurred.

SEC. 9244. CONSTRUCTION OF PART; SUSPENSION OF STATUTE OF LIMITATIONS.

(a) IN GENERAL.—Nothing in this part shall affect the right of a health information trustee to challenge a request for protected health information. Nothing in this part shall entitle a protected individual to assert the rights of a health information trustee.

(b) EFFECT OF MOTION ON STATUTE OF LIMITATIONS.—If an individual who is the subject of protected health information files a motion under this part which has the effect of delaying the access of a government authority to such information, the period beginning on the date such motion was filed and ending on the date on which the motion is decided shall be excluded in computing any period of limitations within which the government authority may commence any civil or criminal action in connection with which the access is sought.

SEC. 9245. RESPONSIBILITIES OF SECRETARY.

Not later than July 1, 1996, the Secretary, after notice and opportunity for public comment, shall develop and disseminate brief, clear, and easily understood model notices—

(1) for use under subsection (c) of section 9241, detailing the rights of a protected individual who wishes to challenge, under section 9242, the disclosure of protected health information about the individual under such subsection; and

(2) for use under subsection (a) of section 9243, detailing the rights of a protected individual who wishes to challenge, under subsection (b) of such section, the disclosure of protected health information about the individual under such section.

PART 4—MISCELLANEOUS PROVISIONS

SEC. 9251. PAYMENT CARD AND ELECTRONIC PAYMENT TRANSACTIONS.

(a) PAYMENT FOR HEALTH CARE THROUGH CARD OR ELECTRONIC MEANS.—If a protected individual pays a health information trustee for health care by presenting a debit, credit, or other payment card or account number, or by any other electronic payment means, the trustee may disclose to a person described in subsection (b) only such protected health information about the individual as is necessary for the processing of the payment transaction or the billing or collection of amounts charged to, debited from, or otherwise paid by, the individual using the card, number, or other electronic payment means.

(b) TRANSACTION PROCESSING.—A person who is a debit, credit, or other payment card issuer, is otherwise directly involved in the processing of payment transactions involving such cards or other electronic payment transactions, or is otherwise directly involved in the billing or collection of amounts paid through such means, may only use or disclose protected health information about a protected individual that has been disclosed in accordance with subsection (a) when necessary for—

(1) the authorization, settlement, billing or collection of amounts charged to, debited from, or otherwise paid by, the individual using a debit, credit, or other payment card or account number, or by other electronic payment means;

(2) the transfer of receivables, accounts, or interest therein;

(3) the audit of the credit, debit, or other payment card account information;

(4) compliance with Federal, State, or local law; or

(5) a properly authorized civil, criminal, or regulatory investigation by Federal, State, or local authorities.

SEC. 9252. ACCESS TO PROTECTED HEALTH INFORMATION OUTSIDE OF THE UNITED STATES.

(a) IN GENERAL.—Notwithstanding the provisions of part 2, and except as provided in subsection (b), a health information trustee may not permit any person who is not in a State to have

access to protected health information about a protected individual unless one or more of the following conditions exist:

(1) SPECIFIC AUTHORIZATION.—The individual has specifically consented to the provision of such access outside of the United States in an authorization that meets the requirements of section 9222.

(2) EQUIVALENT PROTECTION.—The provision of such access is authorized under this subtitle and the Secretary has determined that there are fair information practices for protected health information in the jurisdiction where the access will be provided that provide protections for individuals and protected health information that are equivalent to the protections provided for by this subtitle.

(3) ACCESS REQUIRED BY LAW.—The provision of such access is required under—

(A) a Federal statute; or

(B) a treaty or other international agreement applicable to the United States.

(b) EXCEPTIONS.—Subsection (a) does not apply where the provision of access to protected health information—

(1) is to a foreign public health authority;

(2) is authorized under section 9224 (relating to next of kin and directory information), 9226 (relating to health research), or 9227 (relating to emergency circumstances); or

(3) is necessary for the purpose of providing for payment for health care that has been provided to an individual.

SEC. 9253. STANDARDS FOR ELECTRONIC DOCUMENTS AND COMMUNICATIONS.

(a) STANDARDS.—Not later than July 1, 1996, the Secretary, after notice and opportunity for public comment and in consultation with appropriate private standard-setting organizations and other interested parties, shall establish standards with respect to the creation, transmission, receipt, and maintenance, in electronic and magnetic form, of each type of written document specifically required or authorized under this subtitle. Where a signature is required under any other provision of this subtitle, such standards shall provide for an electronic or magnetic substitute that serves the functional equivalent of a signature.

(b) TREATMENT OF COMPLYING DOCUMENTS AND COMMUNICATIONS.—An electronic or magnetic document or communication that satisfies the standards established under subsection (a) with respect to such document or communication shall be treated as satisfying the requirements of this subtitle that apply to an equivalent written document.

SEC. 9254. DUTIES AND AUTHORITIES OF AFFILIATED PERSONS.

(a) REQUIREMENTS ON TRUSTEES.—

(1) PROVISION OF INFORMATION.—A health information trustee may provide protected health information to a person who, with respect to the trustee, is an affiliated person and may permit the affiliated person to use such information, only for the purpose of conducting, supporting, or facilitating an activity that the trustee is authorized to undertake.

(2) NOTICE TO AFFILIATED PERSON.—A health information trustee shall notify a person who, with respect to the trustee, is an affiliated person of any duties under this subtitle that the affiliated person is required to fulfill and of any authorities under this subtitle that the affiliated person is authorized to exercise.

(b) DUTIES OF AFFILIATED PERSONS.—

(1) IN GENERAL.—An affiliated person shall fulfill any duty under this subtitle that—

(A) the health information trustee with whom the person has an agreement or relationship described in section 9200(c)(1)(C) is required to fulfill; and

(B) the person has undertaken to fulfill pursuant to such agreement or relationship.

(2) CONSTRUCTION OF OTHER PARTS.—With respect to a duty described in paragraph (1) that an affiliated person is required to fulfill, the person shall be considered a health information trustee for purposes of this subtitle. The person shall be subject to part 5 (relating to enforcement) with respect to any such duty that the person fails to fulfill.

(3) EFFECT ON TRUSTEE.—An agreement or relationship with an affiliated person does not relieve a health information trustee of any duty or liability under this subtitle.

(b) AUTHORITIES OF AFFILIATED PERSONS.—

(1) IN GENERAL.—An affiliated person may only exercise an authority under this subtitle that the health information trustee with whom the person is affiliated may exercise and that the person has been given by the trustee pursuant to an agreement or relationship described in section 9200(c)(1)(C). With respect to any such authority, the person shall be considered a health information trustee for purposes of this subtitle. The person shall be subject to part 5 (relating to enforcement) with respect to any act that exceeds such authority.

(2) EFFECT ON TRUSTEE.—An agreement or relationship with an affiliated person does not affect the authority of a health information trustee under this subtitle.

SEC. 9255. AGENTS AND ATTORNEYS.

(a) IN GENERAL.—Except as provided in subsections (b) and (c), a person who is authorized by law (on grounds other than an individual's minority), or by an instrument recognized under law, to act as an agent, attorney, proxy, or other legal representative for a protected individual or the estate of a protected individual, or otherwise to exercise the rights of the individual or estate, may, to the extent authorized, exercise and discharge the rights of the individual or estate under this subtitle.

(b) HEALTH CARE POWER OF ATTORNEY.—A person who is authorized by law (on grounds other than an individual's minority), or by an instrument recognized under law, to make decisions about the provision of health care to an individual who is incapacitated may exercise and discharge the rights of the individual under this subtitle to the extent necessary to effectuate the terms or purposes of the grant of authority.

(c) NO COURT DECLARATION.—If a health care provider determines that an individual, who has not been declared to be legally incompetent, suffers from a medical condition that prevents the individual from acting knowingly or effectively on the individual's own behalf, the right of the individual to authorize disclosure under section 9222 may be exercised and discharged in the best interest of the individual by—

(1) a person described in subsection (b) with respect to the individual;

(2) a person described in subsection (a) with respect to the individual, but only if a person described in paragraph (1) cannot be contacted after a reasonable effort;

(3) the next of kin of the individual, but only if a person described in paragraph (1) or (2) cannot be contacted after a reasonable effort; or

(4) the health care provider, but only if a person described in paragraph (1), (2), or (3) cannot be contacted after a reasonable effort.

SEC. 9256. MINORS.

(a) INDIVIDUALS WHO ARE 18 OR LEGALLY CAPABLE.—In the case of an individual—

(1) who is 18 years of age or older, all rights of the individual shall be exercised by the individual, except as provided in section 9255; or

(2) who, acting alone, has the legal capacity under State law to apply for and obtain health care and has sought such care, the individual shall exercise all rights of an individual

under this subtitle with respect to protected health information relating to such care.

(b) INDIVIDUALS UNDER 18.—Except as provided in subsection (a)(2), in the case of an individual who is—

(1) under 14 years of age, all the individual's rights under this subtitle shall be exercised through the parent or legal guardian of the individual; or

(2) 14, 15, 16, or 17 years of age, the right of inspection (under section 9201), the right of amendment (under section 9202), and the right to authorize disclosure of protected health information (under section 9222) of the individual may be exercised either by the individual or by the parent or legal guardian of the individual.

SEC. 9257. MAINTENANCE OF CERTAIN PROTECTED HEALTH INFORMATION.

(a) IN GENERAL.—The Secretary shall establish a process under which the protected health information described in subsection (b) that is maintained by a person described in subsection (c) is delivered to, and maintained by, an individual or entity designated by the Secretary (which may include a State).

(b) INFORMATION DESCRIBED.—The protected health information referred to in subsection (a) is protected health information that—

(1) is recorded in any form or medium;

(2) is created by—

(A) a health care provider; or

(B) a health plan sponsor that provides health benefits in the form of items and services to enrollees and not in the form of reimbursement for items and services; and

(3) relates in any way to the past, present, or future physical or mental health or condition or functional status of a protected individual or the provision of health care to a protected individual.

(c) PERSONS DESCRIBED.—A person referred to in subsection (a) is any of the following:

(A) A health care facility that has closed.

(B) A professional practice operated by a health care provider that has closed.

(C) A health plan sponsor that—

(i) previously provided health benefits in the form of items and services to enrollees; and

(ii) has ceased to do business.

PART 5—ENFORCEMENT

SEC. 9261. CIVIL ACTIONS.

(a) IN GENERAL.—Any individual whose right under this subtitle has been knowingly or negligently violated—

(1) by a health information trustee, or any other person, who is not described in paragraph (2), (3), (4), or (5) may maintain a civil action for actual damages and for equitable relief against the health information trustee or other person;

(2) by an officer or employee of the United States while the officer or employee was acting within the scope of the office or employment may maintain a civil action for actual damages and for equitable relief against the United States;

(3) by an officer or employee of any government authority of a State that has waived its sovereign immunity to a claim for damages resulting from a violation of this subtitle while the officer or employee was acting within the scope of the office or employment may maintain a civil action for actual damages and for equitable relief against the State government;

(4) by an officer or employee of a government of a State that is not described in paragraph (3) may maintain a civil action for actual damages and for equitable relief against the officer or employee; or

(5) by an officer or employee of a government authority while the officer or employee was not acting within the scope of the office or employment may maintain a civil action for actual damages and for equitable relief against the officer or employee.

(b) KNOWING VIOLATIONS.—Any individual entitled to recover actual damages under this section because of a knowing violation of a provision of this subtitle (other than subsection (c) or (d) of section 9221) shall be entitled to recover the amount of the actual damages demonstrated or $5000, whichever is greater.

(c) ACTUAL DAMAGES.—For purposes of this section, the term "actual damages" includes damages paid to compensate an individual for nonpecuniary losses such as physical and mental injury as well as damages paid to compensate for pecuniary losses.

(d) PUNITIVE DAMAGES; ATTORNEY'S FEES.—In any action brought under this section in which the complainant has prevailed because of a knowing violation of a provision of this subtitle (other than subsection (c) or (d) of section 9221), the court may, in addition to any relief awarded under subsections (a) and (b), award such punitive damages as may be warranted. In such an action, the court, in its discretion, may allow the prevailing party a reasonable attorney's fee (including expert fees) as part of the costs, and the United States shall be liable for costs the same as a private person.

(e) LIMITATION.—A civil action under this section may not be commenced more than 2 years after the date on which the aggrieved individual discovered the violation or the date on which the aggrieved individual had a reasonable opportunity to discover the violation, whichever occurs first.

(f) INSPECTION AND AMENDMENT.—If a health information trustee has established a formal internal procedure that allows an individual who has been denied inspection or amendment of protected health information to appeal the denial, the individual may not maintain a civil action in connection with the denial until the earlier of—

(1) the date the appeal procedure has been exhausted; or

(2) the date that is 4 months after the date on which the appeal procedure was initiated.

(g) NO LIABILITY FOR PERMISSIBLE DISCLOSURES.—A health information trustee who makes a disclosure of protected health information about a protected individual that is permitted by this subtitle and not otherwise prohibited by State or Federal statute shall not be liable to the individual for the disclosure under common law.

(h) NO LIABILITY FOR INSTITUTIONAL REVIEW BOARD DETERMINATIONS.—If the members of a certified institutional review board have in good faith determined that an approved health research project is of sufficient importance so as to outweigh the intrusion into the privacy of an individual pursuant to section 9226(a)(1), the members, the board, and the parent institution of the board shall not be liable to the individual as a result of such determination.

(i) GOOD FAITH RELIANCE ON CERTIFICATION.—A health information trustee who relies in good faith on a certification by a government authority or other person and discloses protected health information about an individual in accordance with this subtitle shall not be liable to the individual for such disclosure.

SEC. 9262. CIVIL MONEY PENALTIES.

(a) VIOLATION.—Any health information trustee who the Secretary determines has demonstrated a pattern or practice of failure to comply with the provisions of this subtitle shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $10,000 for each such failure. In determining the amount of any penalty to be assessed under the procedures established under subsection (b), the Secretary shall take into account the previous record of compliance of the person being assessed with the applicable requirements of this subtitle and the gravity of the violation.

(b) PROCEDURES FOR IMPOSITION OF PENALTIES.—The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to the imposition of a civil monetary penalty under this section in the same manner as such provisions apply with respect to the imposition of a penalty under section 1128A of such Act.

SEC. 9263. ALTERNATIVE DISPUTE RESOLUTION.

(a) IN GENERAL.—Not later than July 1, 1996, the Secretary shall, by regulation, develop alternative dispute resolution methods for use by individuals, health information trustees, and other persons in resolving claims under section 9261. Such regulations may not require an individual to pursue an alternative dispute resolution method.

(b) SUSPENSION OF STATUTE OF LIMITATIONS.—The regulations established by the Secretary under subsection (a) may provide that a period in which an individual who alleges that a right of the individual under this subtitle has been violated pursues (as defined by the Secretary) an alternative dispute resolution method under this section shall be excluded in computing the period of limitations under section 9261(e).

(c) METHODS.—The methods under subsection (a) shall include at least the following:

(1) ARBITRATION.—The use of arbitration.

(2) MEDIATION.—The use of mediation.

(3) EARLY OFFERS OF SETTLEMENT.—The use of a process under which parties make early offers of settlement.

(d) STANDARDS FOR ESTABLISHING METHODS.—In developing alternative dispute resolution methods under subsection (a), the Secretary shall ensure that the methods promote the resolution of claims in a manner that—

(1) is affordable for the parties involved;

(2) provides for timely and fair resolution of claims; and

(3) provides for reasonably convenient access to dispute resolution for individuals.

SEC. 9264. AMENDMENTS TO CRIMINAL LAW.

(a) IN GENERAL.—Title 18, United States Code, is amended by inserting after chapter 89 the following:

"CHAPTER 90—PROTECTED HEALTH INFORMATION

"Sec.
"1831. Definitions.
"1832. Obtaining protected health information under false pretenses.
"1833. Monetary gain from obtaining protected health information under false pretenses.
"1834. Knowing and unlawful obtaining of protected health information.
"1835. Monetary gain from knowing and unlawful obtaining of protected health information.
"1836. Knowing and unlawful use or disclosure of protected health information.
"1837. Monetary gain from knowing and unlawful sale, transfer, or use of protected health information.

"§ 1831. Definitions

"As used in this chapter—

"(1) the term 'health information trustee' has the meaning given such term in section 9200(b)(6) of the Guaranteed Health Insurance Act of 1994;

"(2) the term 'protected health information' has the meaning given such term in section 9200(a)(3) of such Act; and

"(3) the term 'protected individual' has the meaning given such term in section 9200(a)(4) of such Act.

"§ 1832. Obtaining protected health information under false pretenses

"Whoever under false pretenses—

"(1) requests or obtains protected health information from a health information trustee; or

"(2) obtains from a protected individual an authorization for the disclosure of protected health information about the individual maintained by a health information trustee;

shall be fined under this title or imprisoned not more than 5 years, or both.

"§ 1833. Monetary gain from obtaining protected health information under false pretenses

"Whoever under false pretenses—

"(1) requests or obtains protected health information from a health information trustee with the intent to sell, transfer, or use such information for profit or monetary gain; or

"(2) obtains from a protected individual an authorization for the disclosure of protected health information about the individual maintained by a health information trustee with the intent to sell, transfer, or use such authorization for profit or monetary gain;

and knowingly sells, transfers, or uses such information or authorization for profit or monetary gain shall be fined under this title or imprisoned not more than 10 years, or both.

"§ 1834. Knowing and unlawful obtaining of protected health information

"Whoever knowingly obtains protected health information from a health information trustee in violation of subtitle C of title IX of the Guaranteed Health Insurance Act of 1994, knowing that such obtaining is unlawful, shall be fined under this title or imprisoned not more than 5 years, or both.

"§ 1835. Monetary gain from knowing and unlawful obtaining of protected health information

"Whoever knowingly—

"(1) obtains protected health information from a health information trustee in violation of subtitle C of title IX of the Guaranteed Health Insurance Act of 1994, knowing that such obtaining is unlawful and with the intent to sell, transfer, or use such information for profit or monetary gain; and

"(2) knowingly sells, transfers, or uses such information for profit or monetary gain;

shall be fined under this title or imprisoned not more than 10 years, or both.

"§ 1836. Knowing and unlawful use or disclosure of protected health information

"Whoever knowingly uses or discloses protected health information in violation of subtitle C of title IX of the Guaranteed Health Insurance Act of 1994, knowing that such use or disclosure is unlawful, shall be fined under this title or imprisoned not more than 5 years, or both.

"§ 1837. Monetary gain from knowing and unlawful sale, transfer, or use of protected health information

"Whoever knowingly sells, transfers, or uses protected health information in violation of subtitle C of title IX of the Guaranteed Health Insurance Act of 1994, knowing that such sale, transfer, or use is unlawful, shall be fined under this title or imprisoned not more than 10 years, or both."

(b) CLERICAL AMENDMENT.—The table of chapters for part I of title 18, United States Code, is amended by inserting after the item relating to chapter 89 the following:

"90. Protected health information ..... 1831".

PART 6—AMENDMENTS TO TITLE 5, UNITED STATES CODE

SEC. 9271. AMENDMENTS TO TITLE 5, UNITED STATES CODE.

(a) NEW SUBSECTION.—Section 552a of title 5, United States Code, is amended by adding at the end the following:

"(w) MEDICAL EXEMPTIONS.—The head of an agency that is a health information trustee (as defined in section 9200(b)(6) of the Guaranteed Health Insurance Act of 1994) shall promulgate rules, in accordance with the requirements (including general notice) of subsections (b)(1), (b)(2), (b)(3), (c), and (e) of section 553 of this title, to exempt a system of records within the agency, to the extent that the system of records contains protected health information (as defined in section 9200(a)(3) of such Act), from all provisions of this section except subsections (e)(1), (e)(2), subparagraphs (A) through (C) and (E) through (I) of subsection (e)(4), and subsections (e)(5), (e)(6), (e)(9), (e)(12), (l), (n), (o), (p), (q), (r), and (u).".

(b) REPEAL.—Section 552a(f)(3) of title 5, United States Code, is amended by striking "pertaining to him," and all that follows through the semicolon and inserting "pertaining to the individual;".

PART 7—REGULATIONS, RESEARCH, AND EDUCATION; EFFECTIVE DATES; APPLICABILITY; AND RELATIONSHIP TO OTHER LAWS

SEC. 9281. REGULATIONS; RESEARCH AND EDUCATION.

(a) REGULATIONS.—Not later than July 1, 1996, the Secretary shall prescribe regulations to carry out this subtitle.

(b) RESEARCH AND TECHNICAL SUPPORT.—The Secretary may sponsor—

(1) research relating to the privacy and security of protected health information;

(2) the development of consent forms governing disclosure of such information; and

(3) the development of technology to implement standards regarding such information.

(c) EDUCATION.—The Secretary shall establish education and awareness programs—

(1) to foster adequate security practices by health information trustees;

(2) to train personnel of health information trustees respecting the duties of such personnel with respect to protected health information; and

(3) to inform individuals and employers who purchase health care respecting their rights with respect to such information.

SEC. 9282. EFFECTIVE DATES.

(a) IN GENERAL.—Except as provided in subsection (b), this subtitle, and the amendments made by this subtitle, shall take effect on January 1, 1997.

(b) PROVISIONS EFFECTIVE IMMEDIATELY.—A provision of this subtitle shall take effect on the date of the enactment of this Act if the provision—

(1) imposes a duty on the Secretary to develop, establish, or promulgate regulations, guidelines, notices, statements, or education and awareness programs;

(2) authorizes the Secretary to sponsor research or the development of forms or technology; or

(3) defines a term.

SEC. 9283. APPLICABILITY.

(a) PROTECTED HEALTH INFORMATION.—Except as provided in subsections (b) and (c), the provisions of this subtitle shall apply to any protected health information that is received, created, used,

maintained, or disclosed by a health information trustee in a State on or after January 1, 1997, regardless of whether the information existed or was disclosed prior to such date.

(b) EXCEPTION.—

(1) IN GENERAL.—The provisions of this subtitle shall not apply to a trustee described in paragraph (2), except with respect to protected health information that is received by the trustee on or after January 1, 1997. With respect to protected health information that is received by such a trustee before such date, other applicable law shall continue to apply.

(2) APPLICABILITY.—A trustee referred to in paragraph (1) is—

(A) a health researcher; or

(B) a person who, with respect to specific protected health information, received the information—

(i) pursuant to—

(I) section 9227 (relating to emergency circumstances);

(II) section 9228 (relating to judicial and administrative purposes);

(III) section 9229 (relating to law enforcement); or

(IV) section 9230 (relating to subpoenas, warrants, and search warrants); or

(ii) while acting in whole or in part in the capacity of an officer or employee of a person described in clause (i).

(c) AUTHORIZATIONS FOR DISCLOSURES.—An authorization for the disclosure of protected health information about a protected individual that is executed by the individual before January 1, 1997, and is recognized and valid under State law on December 31, 1996, shall remain valid and shall not be subject to the requirements of section 9222 until January 1, 1998, or the occurrence of the date or event (if any) specified in the authorization upon which the authorization expires, whichever occurs earlier.

SEC. 9284. RELATIONSHIP TO OTHER LAWS.

(a) STATE LAW.—Except as otherwise provided in subsections (b), (c), (d), and (f), a State may not establish, continue in effect, or enforce any State law to the extent that the law is inconsistent with, or imposes additional requirements with respect to, any of the following:

(1) A duty of a health information trustee under this subtitle.

(2) A provision of part 3 (relating to access procedures and challenge rights) or part 4 (miscellaneous provisions).

(b) LAWS RELATING TO AUTHORIZED DISCLOSURES.—This part does not preempt, supersede, or modify the operation of any State law to the extent that the law prohibits or regulates a disclosure of protected health information that is authorized under this part.

(c) CRIMINAL PENALTIES.—A State may establish and enforce criminal penalties with respect to a failure to comply with a provision of this part.

(d) PRIVILEGES.—A privilege that a person has under law in a court of a State or the United States or under the rules of any agency of a State or the United States may not be diminished, waived, or otherwise affected by—

(1) the execution by a protected individual of an authorization for disclosure of protected health information under this part, if the authorization is executed for the purpose of receiving health care or providing for the payment for health care; or

(2) any provision of this part that authorizes the disclosure of protected health information for the purpose of receiving health care or providing for the payment for health care.

(e) DEPARTMENT OF VETERANS AFFAIRS.—The limitations on use and disclosure of protected health information under this part

shall not be construed to prevent any exchange of such information within and among components of the Department of Veterans Affairs that determine eligibility for or entitlement to, or that provide, benefits under laws administered by the Secretary of Veterans Affairs.

(f) CERTAIN DUTIES UNDER STATE OR FEDERAL LAW.—This part shall not be construed to preempt, supersede, or modify the operation of any of the following:

(1) Any law that provides for the reporting of vital statistics such as birth or death information.

(2) Any law requiring the reporting of abuse or neglect information about any individual.

(3) Subpart II of part E of title XXVI of the Public Health Service Act (relating to notifications of emergency response employees of possible exposure to infectious diseases).

(4) The Americans with Disabilities Act of 1990.

(5) Any Federal or State statute that establishes a privilege for records used in health professional peer review activities.

(g) SECRETARIAL AUTHORITY.—

(1) SECRETARY OF HEALTH AND HUMAN SERVICES.—A provision of this part does not preempt, supersede, or modify the operation of section 543 of the Public Health Service Act, except to the extent that the Secretary of Health and Human Services determines through regulations promulgated by such Secretary that the provision provides greater protection for protected health information, and the rights of protected individuals, than is provided under such section 543.

(2) SECRETARY OF VETERANS AFFAIRS.—A provision of this part does not preempt, supersede, or modify the operation of section 7332 of title 38, United States Code, except to the extent that the Secretary of Veterans Affairs determines through regulations promulgated by such Secretary that the provision provides greater protection for protected health information, and the rights of protected individuals, than is provided under such section 7332.

Subtitle D—Remedies

TABLE OF CONTENTS OF SUBTITLE

PART 2—GENERAL CIVIL REMEDIES

PART 3—ANTI-DISCRIMINATION

SEC. 9300. DEFINITIONS.

For purposes of this subtitle—

(1) CERTIFIED HEALTH BENEFIT PLAN.—The term "certified health benefit plan" means—

(A) a health benefit plan (as defined in section 5504(3)) provided or sponsored by a private person (regardless of whether enrollment in such plan is facilitated by a purchasing cooperative or governmental program);

(B) a health benefit plan established or maintained by the government of a State or political subdivision thereof, or by any agency or instrumentality of such a government, for its employees; and

(C) a long-term care insurance policy (as defined in section 10111).

(2) CERTIFIED HEALTH BENEFIT PLAN SPONSOR.—The term "certified health benefit plan sponsor" has the meaning given the term "sponsor" in section 5504(13) in relation to a certified health benefit plan.

(3) DISABILITY.—The term "disability" has the meaning given such term in section 3(2) of the Americans with Disabilities Act of 1990.

(4) HEALTH PROVIDER.—The term "health provider" has the meaning given such term in section 9109(7).

(5) NETWORK PROVIDER.—The term "network provider" has the meaning given such term in section 9109(8).

(6) PLAN NETWORK.—The term "plan network" has the meaning given such term in section 9109(9).

(7) THIRD PARTY CONTRACTOR.—The term "third party contractor" means, in connection with a certified health benefit plan, any person (other than a certified health benefit plan sponsor with respect to the plan) who—

(A) administers or processes payments made under the plan pursuant to requests for payment for items and services but is not the provider of the items and services, or

(B) carries out any other duty of the certified health benefit plan sponsor under a direct or indirect contractual arrangement with the certified health benefit plan sponsor, other than providing the items and services.

PART 1—GRIEVANCE AND APPEALS PROCESS

Subpart A—Review of Refusals of Items and Services and Denials of Payment To Providers and Individuals

SEC. 9301. DETERMINATIONS BY CERTIFIED HEALTH BENEFIT PLAN SPONSORS PROVIDING ITEMS AND SERVICES.

(a) APPLICABILITY.—This section applies in the case of a certified health benefit plan to the extent it provides benefits in the form of items and services.

(b) EXPLANATION OF REASONS FOR CERTAIN REFUSALS OF ITEMS OR SERVICES.—

(1) IN GENERAL.—A certified health benefit plan sponsor shall provide any individual who is refused an item or service under the certified health benefit plan a written explanation for such refusal within three business days after a request for

such explanation is made by or on behalf of the individual. Such explanation shall set forth the specific reasons for the refusal and shall meet the requirements of section 9303(a). For purposes of this section, a refusal to provide an item or service at the time requested shall be treated as a refusal of a request for the item or service. For treatment in the complaint review office of refusals involving urgent requests for items and services, see section 9306(b)(4).

(2) EXPLANATION WITH RESPECT TO CERTAIN REFUSALS.—

(A) NOT COVERED UNDER COMPREHENSIVE BENEFIT PACKAGE.—If the refusal by a certified health benefit plan sponsor of an item or service is based in whole or in part on a determination that the item or service is not covered by the comprehensive benefit package, the explanation required under paragraph (1) shall include the specific factual basis for the individual determination.

(B) EXPERIMENTAL TREATMENTS OR INVESTIGATIVE PROCEDURES.—If the refusal by a certified health benefit plan sponsor of an item or service is based in whole or in part on exclusion of coverage with respect to a service because the service is determined to comprise an experimental treatment or investigatory procedure, the explanation required under paragraph (1) shall include the medical basis for the determination and a description of the process used in making the determination.

(C) INCONSISTENCY WITH PRACTICE GUIDELINES.—If the refusal by a certified health benefit plan sponsor of an item or service is based in whole or in part on a determination that a particular treatment is not medically necessary or appropriate or is inconsistent with the plan's practice guidelines, the explanation required under paragraph (1) shall include the medical basis for the determination, the guidelines used in making the determination, the basis for such guidelines, and a description of the process used in making the determination.

(c) REQUIREMENTS RELATING TO TERMINATED OR REDUCED ITEMS OR SERVICES.—

(1) WRITTEN EXPLANATION.—A certified health benefit plan sponsor shall provide to any individual a written explanation for any intended action that would result in termination or reduction of any item or service which has been provided in a course of treatment for such individual. Such explanation shall be provided not less than one business day before the action is to be taken by the certified health benefit plan sponsor. The written explanation shall set forth the specific reasons for such action and shall meet the requirements of section 9303(a). Subsection (b)(2) shall apply with respect to such written explanation.

(2) INTERIM RELIEF IN URGENT CASES IN COMPLAINT REVIEW OFFICE.—

(A) IN GENERAL.—Upon the filing of a complaint with the appropriate complaint review office under section 9304 with respect to any proposed action described in a written explanation received pursuant to paragraph (1), together with an attestation described in subparagraph (B), the item or service proposed to be terminated or reduced shall be continued until an initial decision on the complaint is made by the complaint review office.

(B) ATTESTATION.—An attestation described in this paragraph is an attestation, with respect to the individual on whose behalf the complaint is made—

(i) that failure to immediately provide the item or service could reasonably be expected to result in—

(I) placing the health of such individual (or, with respect to such an individual who is a preg-

nant woman, the health of the woman or her unborn child) in serious jeopardy,

(II) serious impairment to bodily functions, or

(III) serious dysfunction of any bodily organ or part,

or

(ii) that immediate provision of the item or service is necessary because such individual has made or is at serious risk of making an attempt to harm himself or herself or another individual.

(d) FAILURE TO MEET REQUIREMENTS ESTABLISHING RIGHT TO FILE COMPLAINT.—A refusal described in subsection (b)(1), a reduction or termination described in subsection (c), or a failure by a certified health benefit plan sponsor to comply with any requirement of this section with respect to any individual shall establish a right for the aggrieved individual to file a complaint with the complaint review office under section 9304.

SEC. 9302. DETERMINATIONS BY CERTIFIED HEALTH BENEFIT PLAN SPONSORS PROVIDING BENEFITS IN THE FORM OF PAYMENTS TO HEALTH PROVIDERS OR INDIVIDUALS FOR ITEMS AND SERVICES.

(a) APPLICABILITY.—This section applies in the case of a certified health benefit plan to the extent it provides benefits in the form of payments to health providers or individuals for items and services.

(b) TREATMENT OF REQUESTS FOR PAYMENTS FOR ITEMS AND SERVICES.—

(1) NOTICE REQUIREMENTS AND TIME LIMITS.—

(A) IN GENERAL.—In the case of a request presented to a certified health benefit plan sponsor by a health provider or individual for payment for any item or service provided to an individual, the certified health benefit plan sponsor shall provide to the health provider or individual a written notice of any denial, in whole or in part, of the payment within 20 business days after the date on which the request is presented in writing to the certified health benefit plan sponsor. Failure by any certified health benefit plan sponsor to respond to any such request within such period of 20 business days shall be treated as a final determination by the certified health benefit plan sponsor to deny the request.

(B) MATTERS TO BE INCLUDED IN NOTICE.—Such notice shall include a written explanation for such denial which sets forth the specific reasons therefor and which meets the requirements of section 9303(a).

(2) EXPLANATION WITH RESPECT TO CERTAIN DENIALS.—

(A) NOT COVERED UNDER COMPREHENSIVE BENEFIT PACKAGE.—If the denial by a certified health benefit plan sponsor of payment to a health provider or individual for an item or service is based in whole or in part on a determination that the item or service is not covered by the comprehensive benefit package, exceeds the maximum payment rate, if any, applicable to the class of service under title VI, or exceeds payment rates under any applicable fee schedule, the explanation required under paragraph (1) shall include the specific factual basis for the individual determination.

(B) EXPERIMENTAL TREATMENTS OR INVESTIGATIVE PROCEDURES.—If the denial by a certified health benefit plan sponsor of payment to a health provider or individual for an item or service is based in whole or in part on exclusion of coverage with respect to a service because the service is determined to comprise an experimental treatment or investigatory procedure, the explanation required under paragraph (1) shall include the medical basis for the determination and a description of the process used in making the determination.

(C) INCONSISTENCY WITH PRACTICE GUIDELINES.—If the denial by a certified health benefit plan sponsor of payment to a health provider or individual for an item or service is based in whole or in part on a determination that a particular treatment is not medically necessary or appropriate or is inconsistent with the plan's practice guidelines, the explanation required under paragraph (1) shall include the medical basis for the determination, the guidelines used in making the determination, the basis for such guidelines, and a description of the process used in making the determination.

(c) TREATMENT OF REQUESTS BY HEALTH PROVIDERS OR INDIVIDUALS FOR PREAUTHORIZATION OF PAYMENT FOR ITEMS AND SERVICES.—

(1) IN GENERAL.—Except as otherwise provided in this subsection, subsection (e)(1), and section 9306(b)(4), any request by a health provider or an individual for preauthorization of payment for any item or service under a certified health benefit plan shall be treated in the same manner as a request for payment for an item or service under subsection (b). In applying subsection (b)(1)(A) to such a request, each reference therein to "20 business days" shall be deemed a reference to "10 business days".

(2) TREATMENT OF URGENT REQUESTS FOR PREAUTHORIZATION.—

(A) APPLICABILITY.—This paragraph applies to any request for preauthorization of an item or service (other than an emergency service which may not be subject to preauthorization) which is accompanied by an attestation, with respect to the individual on whose behalf the request is made—

(i) that failure to immediately provide the item or service could reasonably be expected to result in—

(I) placing the health of such individual (or, with respect to such an individual who is a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

(II) serious impairment to bodily functions, or

(III) serious dysfunction of any bodily organ or part,

or

(ii) that immediate provision of the item or service is necessary because such individual has made or is at serious risk of making an attempt to harm himself or herself or another individual.

(B) SHORTENED TIME LIMIT FOR CONSIDERATION OF URGENT REQUESTS FOR PREAUTHORIZATION.—A certified health benefit plan sponsor shall approve or deny any request described in subparagraph (A) within 24 hours after the request is presented to the certified health benefit plan sponsor. Failure to comply with the requirements of this paragraph shall be treated as a final determination by the certified health benefit plan sponsor to deny the request.

(3) DENIAL OF PREVIOUSLY AUTHORIZED CLAIMS NOT PERMITTED.—In any case in which a certified health benefit plan sponsor approves a request for preauthorization of payment for any item or service submitted by a health provider or individual pursuant to this section, the certified health benefit plan sponsor may not subsequently deny payment for such item or service, unless the certified health benefit plan sponsor makes a showing of an intentional misrepresentation of a material fact by the person making the request.

(d) TREATMENT OF REQUESTS TO CERTIFIED HEALTH BENEFIT PLAN SPONSORS FOR CONTINUATION OR RESTORATION OF TERMINATED OR REDUCED PAYMENT FOR ITEMS OR SERVICES.—

(1) IN GENERAL.—A certified health benefit plan sponsor shall provide to a health provider or individual a written explanation for any intended action that would result in termination or reduction of payment to such health provider or individual for any item or service which has been provided in the course of treatment. Such explanation shall be provided not less than one business day before the certified health benefit plan sponsor intends to take such action, shall set forth the specific reasons for such action, and shall meet the requirements of section 9303(a). Subsection (b)(2) shall apply with respect to such explanation.

(2) INTERIM RELIEF IN COMPLAINT REVIEW OFFICE OF URGENT REQUESTS FOR CONTINUATION OF PAYMENT FOR ITEMS AND SERVICES.—Upon the filing of a complaint with the appropriate complaint review office under section 9304 with respect to any proposed action described in a written explanation received pursuant to paragraph (1), accompanied by an attestation meeting the requirements of subsection (c)(2), the payment for the items and services which is proposed to be terminated or reduced shall be continued until an initial decision on the complaint is made by the complaint review office under section 9306(b)(4).

(e) TIME LIMIT FOR DETERMINATION OF INCOMPLETENESS OF REQUESTS FOR PAYMENT.—For purposes of this section—

(1) Any urgent request referred to in subsection (c)(2) shall be treated as submitted in complete form.

(2) Any other request referred to in subsection (b), (c), or (d) and any other written request by a health provider or individual to the certified health benefit plan sponsor regarding payment for an item or service provided thereunder shall be treated as filed in complete form as of 10 business days after the date of the submission thereof, unless the certified health benefit plan sponsor provides to the health provider or individual, within such period, a written explanation of any required matter remaining to be filed in order to complete the presentation of the request. Such explanation shall meet the requirements of section 9303(a).

(f) FAILURE TO MEET REQUIREMENTS ESTABLISHING RIGHT TO FILE COMPLAINT.—A denial in whole or in part by a plan of a request for payment described in subsection (b), (c), or (d) or a failure by a certified health benefit plan sponsor to comply with any requirement of this section with respect to any individual shall establish a right for such individual to file a complaint with the complaint review office under section 9304.

SEC. 9303. NOTICES; WAIVER OF RIGHTS PROHIBITED.

(a) NOTICE REQUIREMENTS.—Each written notice or explanation required under section 9301 or 9302 shall include—

(1) the address and telephone number of the Consumer Health Advocacy Office (established pursuant to part O of title III of the Public Health Service Act, as added by title VII) serving the community-rating area in which the recipient of the notice or explanation resides or (in the case of a health provider) provides health care and the services available from such Office, and

(2) an explanation of the right of aggrieved individuals and health providers to obtain review of grievances against the certified health benefit plan sponsor in the complaint review office for the applicable community-rating area under section 9304.

Any such notice or explanation shall be written in language calculated to be understood by the average individual enrolled under the plan and shall be provided in a form which takes into account accessibility to the information by individuals whose primary language is not English and shall be provided in a manner consistent with the applicable requirements of the Americans with Disabilities Act of 1990.

(b) WAIVER OF RIGHTS PROHIBITED.—A certified health benefit plan sponsor may not require any party to waive any right under the plan or Federal or State law, except to the extent otherwise specified in a settlement agreement under section 9319 or in a settlement agreement obtained with representation of such party by an attorney.

SEC. 9304. REVIEW OF GRIEVANCES BASED ON ACTS OR PRACTICES BY CERTIFIED HEALTH BENEFIT PLAN SPONSORS.

(a) FILINGS OF COMPLAINTS BY AGGRIEVED PERSONS.—Each State shall establish a complaint review office for each community-rating area, unless such area is adequately served by another complaint review office established by the State. Any person may, pursuant to section 9301(d) or section 9302(f), file with the complaint review office a complaint against the certified health benefit plan sponsor (or a third party contractor with respect to a certified health benefit plan) not later than three years after the alleged violation occurs.

(b) NOTICE OF FILING.—The complaint review office shall serve by certified mail a copy of the complaint (including the date, place, and circumstances of the alleged violation) to the person or persons against whom the complaint is made within 10 days after the filing of the complaint.

SEC. 9305. INITIAL PROCEEDINGS IN COMPLAINT REVIEW OFFICES.

(a) ELECTIONS.—Whenever a complaint is brought to a complaint review office under section 9304, the complaint review office shall provide the complainant with an opportunity, in such form and manner as shall be prescribed in regulations of the Secretary, to elect one of the following:

(1) to submit the complaint as a dispute under the Early Resolution Program, if established pursuant to part 2,

(2) to proceed with the complaint to a hearing in the complaint review office under section 9306, or

(3) to forego further proceedings in the complaint review office and rely on remedies available in a court of competent jurisdiction, including remedies under section 9321.

(b) EFFECT OF PARTICIPATION IN EARLY RESOLUTION PROGRAM.—If the complainant makes an election to submit the complaint as a dispute under the Early Resolution Program under subsection (a)(1) and the proceedings under the Program with respect to the dispute are terminated without settlement or resolution of the dispute with respect to such matter, the complainant may proceed to an election under subsection (a)(2) or (a)(3).

SEC. 9306. HEARINGS BEFORE HEARING OFFICERS IN COMPLAINT REVIEW OFFICES.

(a) ASSIGNMENT OF COMPLAINTS TO HEARING OFFICERS AND NOTICE TO PARTIES.—

(1) IN GENERAL.—In the case of an election under section 9305(a)(2) the complaint review office shall assign the complaint to a hearing officer employed by the State in the office who shall conduct a hearing on the compliant under this section.

(2) QUALIFICATIONS FOR HEARING OFFICERS.—The hearing officer shall be qualified and shall not have any official, financial, or personal conflict of interest.

(b) HEARINGS.—

(1) DE NOVO HEARING.—Hearings under this section shall be de novo. In any such hearing, the hearing officer shall provide for—

(A) full review of the applicable law and facts,

(B) no deference to factual findings, legal findings, or plan interpretations of the decisionmaker below, and

(C) admission of any new evidence and new witnesses provided by all parties to the extent relevant to any issue being considered.

(2) RECORDED TESTIMONY.—The testimony taken by the hearing officer shall be recorded.

(3) AUTHORITY OF HEARING OFFICERS.—The hearing officer may compel, by subpoena, the attendance of witnesses and the production of evidence at any designated place or hearing. In case of contumacy or refusal to obey a subpoena lawfully issued under this paragraph and upon application of the hearing officer, the hearing officer may seek enforcement of the subpoena in an appropriate district court of the United States or in a State court of competent jurisdiction.

(4) EXPEDITED HEARINGS.—Notwithstanding section 9025 and the preceding provisions of this section, upon receipt of a complaint relating to a refusal or denial referred to in section 9301 or 9302 which is accompanied by an attestation equivalent to the attestation described in section 9301(c)(2)(B) or 9302(c)(2)(A), the complaint review office shall promptly provide the complainant with the opportunity to make an election under section 9305(a)(2) and assignment to a hearing on the complaint before a hearing officer. The complaint review office shall ensure that such a hearing commences not later than 24 hours after receipt of the complaint by the complaint hearing office and that the hearing is completed and the decision is rendered within three business days after the date on which the complaint is received.

(c) DECISION OF HEARING OFFICER.—

(1) IN GENERAL.—Within 60 days after the close of the hearing, the hearing officer shall make a decision with respect to each allegation in the complaint. The hearing officer shall decide the extent to which any party against whom the complaint is brought has acted or failed to act in violation of the terms of the certified health benefit plan or Federal or State law. Each such decision—

(A) shall be supported by substantial evidence on the record considered as a whole,

(B) shall include the hearing officer's findings of fact, and

(C) shall constitute the hearing officer's final disposition of the proceedings.

The burden of proof shall be on the party against whom the complaint is filed.

(2) DECISIONS FINDING IN FAVOR OF COMPLAINANT.—If the hearing officer rules in favor of the complainant—

(A) the hearing officer may order the party against whom the complaint is brought, as a remedy for such violation—

(i) to cease and desist from such violation,

(ii) to provide items and services under the plan, or payment requested, and to otherwise comply with the terms of the plan and the applicable requirements of Federal and State law,

(iii) to pay to the complainant actual and compensatory damages, except punitive damages, and

(iv) to pay to the complainant prejudgment interest on the actual costs incurred in obtaining the items and services, or payment therefor, at issue in the complaint, and

(B) if the complainant substantially prevails, the hearing officer shall award the complainant reasonable attorney's fees (at generally prevailing hourly rates), reasonable expert witness fees, and other reasonable costs, unless the court finds that such award would not be appropriate.

(3) FINALITY OF DECISION.—The decision of the hearing officer shall be final, unless review is sought under subsection (d).

(d) REVIEW.—

(1) IN GENERAL.—Any party to the complaint may, within 60 days after service of the decision by the complaint review office, seek review of the decision in a court of competent juris-

diction. In any such proceeding in which the plaintiff substantially prevails, the court shall award the plaintiff reasonable attorney's fees (at generally prevailing hourly rates), reasonable expert witness fees, and other reasonable costs, unless the court finds that such award would not be appropriate.

(2) SCOPE OF REVIEW.—The court shall set aside or modify the decision of the hearing officer if—

(A) the decision is not supported by substantial evidence on the record considered as a whole,

(B) in the case of any interpretation by the hearing officer of contractual terms (irrespective of the extent to which extrinsic evidence was considered), the determination is not supported by a preponderance of the evidence, or

(C) the decision is in excess of jurisdiction, without observance any procedure required by law, in violation of a statutory or constitutional right, or otherwise contrary to law.

(e) COURT ENFORCEMENT OF ORDERS.—If the complainant prevails and the order is not appealed, the complainant may petition any court of competent jurisdiction for enforcement of the order.

SEC. 9307. COORDINATION WITH OTHER PROVISIONS OF LAW.

Nothing under any provision of the Employee Retirement Income Security Act of 1974 or any other Federal law (other than this Act) shall be construed as limiting any right or remedy provided under this Act.

Subpart B—Early Resolution Programs

SEC. 9311. ESTABLISHMENT OF EARLY RESOLUTION PROGRAMS IN COMPLAINT REVIEW OFFICES.

(a) ESTABLISHMENT OF PROGRAMS.—Each State may establish and maintain an Early Resolution Program in each complaint review office in such State in accordance with this subpart. Any such Program shall include the establishment and maintenance of forums for mediation of disputes in accordance with this subpart.

(b) DUTIES OF COMPLAINT REVIEW OFFICES.—Each State establishing an Early Resolution Program shall—

(1) administer the Early Resolution Program in each claims review office in accordance with regulations of the Secretary,

(2) develop Program policy and procedures,

(3) maintain a roster of facilitators for each claims review office to act under the Program in mediation proceedings between parties conducted under this subpart, and coordinate the recruitment, selection, and training of such facilitators,

(4) provide meeting sites, maintain records, and provide facilitators with administrative support staff,

(5) establish and maintain attorney referral panels, and

(6) monitor and evaluate the Program on an ongoing basis.

SEC. 9312. ELIGIBILITY OF CASES FOR SUBMISSION TO EARLY RESOLUTION PROGRAM.

(a) CASE CRITERIA.—A dispute may be submitted to the Early Resolution Program only if the dispute consists of an assertion by an individual (hereinafter in this subpart referred to as the 'claimant') of—

(1) a denial or refusal by the certified health benefit plan sponsor (or a third party contractor with respect to the certified health benefit plan), contrary to the provisions of the certified health benefit plan, this Act, or State law, of one or more items or services under the plan or payment therefor, or

(2) failure or refusal by the certified health benefit plan sponsor (or a third party contractor with respect to the certified health benefit plan) to comply with the claimant's request for information or documents the disclosure of which is required under the plan, this Act, or State law (including fail-

ure or refusal to comply with any claim of entitlement to disclosure based on colorable claims to rights to benefits under the plan).

(b) REPRESENTATION.—Any claimant may be secure representation by any person.

(c) NOTICE OF PROGRAM AVAILABILITY.—Each certified health benefit plan sponsor shall ensure that, as part of review procedures established pursuant to this subpart, claimants taking part in such procedure will be informed during such procedure of the availability of the Early Resolution Program.

SEC. 9313. FACILITATORS.

(a) RECRUITMENT.—The State shall recruit individuals to serve as facilitators under the Early Resolution Program from individuals who have the requisite expertise for such service.

(b) CRITERIA.—In selecting individuals to serve as facilitators, the State shall consider the following:

(1) the individual's experience in dispute resolution;

(2) the individual's ability to act impartially;

(3) the individual's ability to perform evaluations quickly and to present them in nontechnical terms; and

(4) the individual's experience in employee benefit law and the individual's expertise pertaining to medical or disability issues;

(c) TRAINING OF FACILITATORS.—The State shall provide a training program for all new facilitators. The curriculum shall include the procedures of the Program, relevant ethical obligations, and skills in arbitration, mediation, and conciliation necessary for effective alternative dispute resolution in the applicable proceedings. A facilitator may serve only upon completion of such training program.

(d) ASSIGNMENT OF FACILITATORS TO CASES.—Upon submission of a dispute to mediation proceedings under this subpart, the State shall appoint a facilitator (as appropriate) through a random selection procedure which shall be prescribed in regulations.

(e) COMPENSATION.—Facilitators serving in the Early Resolution Program may, at their election, serve on a pro bono basis or be compensated at a fixed fee to be established by the State. Each facilitator shall receive travel expenses, including per diem in lieu of subsistence.

SEC. 9314. INITIATION OF PROCEEDINGS.

(a) FILING OF ELECTION.—A claimant with a dispute which is eligible under section 9312 for submission to the Early Resolution Program may elect to participate in proceedings under the Program by means of filing with the appropriate complaint review office an election for mediation under the Program. An election to commence mediation proceedings under the Program shall be in such form and manner as the Secretary may prescribe.

(b) AGREEMENT TO PARTICIPATE.—

(1) ELECTION BY CLAIMANTS.—A claimant may elect participation in mediation proceedings under the Program only by entering into a written agreement (including an agreement to comply with the rules of the Program and consent for the State to contact the certified health benefit plan sponsor (and any third party contractor with respect to the plan) involved regarding the agreement) and by releasing plan records to the Program for the exclusive use of the facilitator assigned to the mediation. The State may charge the claimant a filing fee of not more than $100. The State shall provide for waiver of the fee in cases of hardship, under standards which shall be prescribed by the Secretary by regulation.

(2) PARTICIPATION BY CERTIFIED HEALTH BENEFIT PLAN SPONSORS AND THIRD PARTY CONTRACTORS.—Each party whose participation in the mediation proceedings has been elected by a claimant shall participate in, and cooperate fully, in the proceedings. The complaint review office shall provide each party with a copy of the participation agreement described in para-

graph (1), together with a written description of mediation under the Early Resolution Program. Each party shall submit a copy of the agreement, with the party's signature, to the complaint review office, and shall include a copy of the written record of any claims procedure completed by the plan pursuant to section 9301 or 9302 with respect to the dispute and all relevant plan documents. The State may charge each such party a filing fee of not more than $100. The relevant documents shall include all relevant medical records of the claimant and all documents under which the plan is or was administered or operated, including copies of any insurance contracts under which benefits are or were provided and any fee or reimbursement schedules for health providers requested by the facilitator.

SEC. 9315. THE MEDIATION PROCEEDINGS.

(a) IN GENERAL.—A mediation proceeding under the Early Resolution Program shall be conducted by facilitators recruited, trained, and assigned by the State under section 9313 and in accordance with fair and equitable procedures to be prescribed by the Secretary which shall be subject to the requirements of this subpart.

(b) PROCEDURAL RULES.—

(1) INAPPLICABILITY OF FORMAL RULES OF EVIDENCE.—Formal rules of evidence shall not apply to mediation proceedings under the Program. All statements made and evidence presented in the proceedings shall be admissible in such proceedings. The facilitator shall be the sole judge of the proper weight to be afforded to each submission.

(2) INAPPLICABILITY OF OATH REQUIREMENTS.—The parties to the mediation proceedings shall not be required to make statements or present evidence under oath.

(c) ANALYSIS STAGE.—In the commencement of the mediation proceedings with respect to any dispute, the facilitator assigned to the dispute shall—

(1) identify the necessary parties,

(2) confirm that the case is eligible for mediation under the Program,

(3) ensure that each party is informed of available legal representation, including such services as may be available free of charge under legal assistance programs,

(4) set a conference date,

(5) at the option of the facilitator, request position papers from the parties, if the facilitator determines that such papers are needed to clarify the parties' positions and issues in dispute, and

(6) analyze the record of any plan procedure conducted pursuant to subpart A and any position papers submitted by the parties, with appropriate legal assistance provided by the State, to determine if further case development is needed to clarify the legal and factual issues in dispute, and whether there is any need for additional information and documents, and request the parties to present any such needed information and documents.

(d) EVALUATION STAGE.—Upon completion of the procedures described in subsection (c), the mediation proceedings shall proceed as follows:

(1) COMMENCEMENT OF CONFERENCE.—The facilitator shall convene a conference between the parties. Each party shall be given the opportunity to make a statement summarizing the facts, issues, and arguments in support of such party's position, and present, or inform the facilitator of, any additional evidence such party considers to be relevant to the evaluation.

(2) NEUTRALITY OF FACILITATOR.—The facilitator shall maintain a neutral stance between the parties.

(3) PREPARATION OF SETTLEMENT AGREEMENT.—If settlement is reached, the facilitator shall assist in the preparation

of a written settlement agreement (which shall remain confidential at the option of the parties) and shall ensure that the parties understand the terms of the settlement.

(4) EVALUATION UPON INITIAL FAILURE TO REACH SETTLEMENT.—If no settlement is reached, the facilitator may evaluate for the parties the likely outcome of further administrative action or litigation, based on the facilitator's assessment of the relative strength of each party's position. Any such evaluation by the facilitator shall be treated as a proceeding communication to which section 9318 applies.

(5) FURTHER PROCEEDINGS.—The facilitator shall then encourage extension of the proceedings if it is likely to lead to settlement or a substantial narrowing of the issues.

SEC. 9316. APPLICABLE TIME LIMITS.

The mediation proceedings under the Early Resolution Program with respect to any dispute shall be completed within 60 days after the date of the election to participate. The parties may agree to one extension of the proceedings of not more than 30 days.

SEC. 9317. LEGAL EFFECT OF PARTICIPATION IN PROCEEDINGS.

(a) PROCESS NONBINDING.—Findings and conclusions made in the mediation proceedings under the Early Resolution Program shall be treated as advisory in nature and nonbinding. Except as provided in subsection (b), the rights of the parties under subpart A shall not be affected by participation in the mediation proceedings under the Program.

(b) RESOLUTION THROUGH SETTLEMENT AGREEMENT.—If a case is settled through participation in the mediation proceedings under the Program, the facilitator shall assist the parties in drawing up an agreement which shall constitute, upon signature of the parties, a binding contract between the parties, which shall be enforceable under section 9319, and which shall be enforceable under this subpart and State law as if the terms of such agreement were terms of the plan.

(c) PRESERVATION OF RIGHTS OF NON-PARTIES.—The settlement agreement shall not have the effect of waiving or otherwise affecting any rights to review under this part, State law, or any other right under this Act, State law, or the plan with respect to any person who is not a party to the settlement agreement.

SEC. 9318. CONFIDENTIALITY.

(a) FACILITATORS.—Except as provided in subsections (d) and (e), a facilitator in a mediation proceeding under the Early Resolution Program shall not voluntarily disclose or through discovery or compulsory process be required to disclose any information concerning any proceeding communication or any communication provided in confidence to the facilitator, unless—

(1) all parties to the proceeding and the facilitator consent in writing, and, if the proceeding communication was provided by a participating nonparty, that the participating nonparty also consents in writing,

(2) the proceeding communication has already been made public,

(3) the proceeding communication is required by statute to be made public, but a facilitator may make such communication public only if no other person is reasonably available to disclose the communication, or

(4) a court determines that such testimony or disclosure is necessary to—

(A) prevent a manifest injustice,

(B) help establish a violation of law, or

(C) prevent harm to the public health or safety,

of sufficient magnitude in the particular case to outweigh the integrity of the proceedings in general by reducing the confidence of parties in future cases that their communications will remain confidential.

(b) PARTIES.—A party to a mediation proceeding under the Early Resolution Program shall not voluntarily disclose or through discovery or compulsory process be required to disclose any information concerning any proceeding communication, unless—

(1) the communication was prepared by the party seeking disclosure,

(2) all parties to the proceeding consent in writing,

(3) the proceeding communication has already been made public,

(4) the proceeding communication is required by statute to be made public,

(5) a court determines that such testimony or disclosure is necessary to—

(A) prevent a manifest injustice,

(B) help establish a violation of law, or

(C) prevent harm to the public health or safety,

of sufficient magnitude in the particular case to outweigh the integrity of the proceedings in general by reducing the confidence of parties in future cases that their communications will remain confidential,

(6) the proceeding communication is relevant to determining the existence or meaning of an agreement or award that resulted from the proceeding or to the enforcement of such an agreement or award, or

(7) the proceeding communication was provided to or was available to all parties to the proceeding.

(c) INADMISSIBILITY OF DISCLOSED INFORMATION.—Any proceeding communication that is disclosed in violation of subsection (a) or (b) shall not be admissible in any proceeding relating to the issues in controversy with respect to which the communication was made.

(d) ALTERNATIVE PROCEDURES.—The parties may agree to alternative confidential procedures for disclosures by a facilitator. Upon such agreement the parties shall inform the facilitator before the commencement of the proceeding of any modifications to the provisions of subsection (a) that will govern the confidentiality of the proceeding. If the parties do not so inform the facilitator, subsection (a) shall apply.

(e) NOTICE OF DEMANDS FOR DISCLOSURE.—If a demand for disclosure, by way of discovery request or other legal process, is made upon a facilitator regarding a proceeding communication, the facilitator shall make reasonable efforts to notify the parties and any affected participating nonparties of the demand. In any case in which such disclosure would otherwise be in violation of this section, the facilitator may perform such disclosure in accordance with such demand only if each party and affected nonparty participant who receives such notice consents to such disclosure within 15 calendar days after the date of the issuance of such notification.

(f) EXCEPTIONS.—

(1) INFORMATION OTHERWISE DISCLOSABLE.—Nothing in this section shall prevent the discovery or admissibility of any evidence that is otherwise discoverable, merely because the evidence was presented in the course of a mediation proceeding under the Early Resolution Program.

(2) DOCUMENTATION OF AGREEMENTS OR ORDERS.—Subsections (a) and (b) shall have no effect on the information and data that are necessary to document an agreement reached or order issued pursuant to a mediation proceeding under the Early Resolution Program.

(3) RESEARCH OR EDUCATIONAL PURPOSES.—Subsections (a) and (b) shall not prevent the gathering of information for research or educational purposes so long as the parties and the specific issues in controversy are not identifiable.

(4) DISPUTES BETWEEN FACILITATOR AND A PARTY.—Subsections (a) and (b) shall not prevent use of a proceeding communication to resolve a dispute between the facilitator in a mediation proceeding under the Early Resolution Program and a

party to or participant in such proceeding, so long as such proceeding communication is disclosed only to the extent necessary to resolve such dispute.

(g) CIVIL REMEDIES.—

(1) CIVIL PENALTY.—The Secretary shall assess a civil penalty against any person who discloses information in violation of subsection (a) or (b) in the amount of three times the amount of the claim involved. The procedures described in section 1128A of the Social Security Act (other than subsections (a) and (b)) apply to civil money penalties under this paragraph under this section in the same manner as such provisions apply with respect to the imposition of a penalty under section 1128A of such Act.

(2) DISQUALIFICATION FROM SERVICE.—Any facilitator who discloses information in violation of subsection (a) shall be disqualified from further service as a facilitator under this subpart.

(h) DEFINITIONS.—For purposes of this section—

(1) PROCEEDING COMMUNICATION.—The term 'proceeding communication' means any oral or written communication prepared for the purposes of a mediation proceeding under the Early Resolution Program, including any memoranda, notes, or work product of the facilitator, parties, or participating nonparties, except that such term does not include a written agreement to enter into the proceeding or a final written agreement reached as a result of the proceeding.

(2) IN CONFIDENCE.—The term 'in confidence' means, with respect to information, that the information is provided—

(A) with the expressed intent of the source that it not be disclosed, or

(B) under circumstances that would create the reasonable expectation on behalf of the source that the information will not be disclosed.

SEC. 9319. ENFORCEMENT OF SETTLEMENT AGREEMENTS.

(a) CONFIRMATION; JURISDICTION; PROCEDURE.—At any time within one year after the date of a settlement agreement entered into in mediation proceeding under the Early Resolution Program, any party to the agreement may apply to the United States district court in and for the district within which such agreement was made for an order confirming the agreement. Upon such application, the court shall grant such an order unless the agreement is vacated, modified, or corrected as prescribed in subsection (b) or (c). Notice of the application shall be served upon the adverse party. Upon such notice, the court shall have jurisdiction of such adverse party as though such adverse party had appeared generally in the proceeding. If the adverse party is a resident of the district within which the award was made, such service shall be made upon the adverse party or such party's attorney as prescribed by law for service of notice of motion in any action in the same court. If the adverse party is a nonresident, the notice of the application shall be served by the marshal of any district within which the adverse party may be found in like manner as other process of the court.

(b) VACATION; GROUNDS; REHEARING.—The court may make an order vacating the settlement agreement upon the application of any party to the agreement if—

(1) the agreement was procured under duress or by corruption, fraud, or undue means, or

(2) there was evident partiality or corruption in the facilitator who assisted in the making of the agreement.

(c) MODIFICATION OR CORRECTION; GROUNDS; ORDER.—The court may make an order modifying or correcting the settlement agreement upon the application of any party to the agreement if—

(1) there was a material miscalculation of figures or a material mistake in the description of any person, thing, or property referred to in the agreement,

(2) the agreement relates to a matter not submitted in the conference proceedings, unless it is a matter not affecting the merits of the agreement upon the matter submitted, or

(3) the agreement is imperfect in matter of form not affecting the merits of the controversy.

The order may modify and correct the agreement, so as to effect the intent thereof and promote justice between the parties.

(d) NOTICE OF MOTIONS TO VACATE OR MODIFY; SERVICE; STAY OF PROCEEDINGS.—Notice of a motion to vacate, modify, or correct a settlement agreement made in mediation proceedings under the Early Resolution Program must be served upon the adverse party or the party's attorney within 90 days after the settlement agreement is made. If the adverse party is a resident of the district within which the agreement is made, such service shall be made upon the adverse party or the party's attorney as prescribed by law for service of notice of motion in an action in the same court. If the adverse party is a nonresident, the notice of the application shall be served by the marshal of any district within which the adverse party may be found in like manner as other process of the court. For the purposes of the motion any judge who may make an order to stay the proceedings in an action brought in the same court may make an order, to be served with the notice of motion, staying the proceedings of the adverse party to enforce the agreement.

(e) PAPERS FILED WITH ORDER ON MOTIONS; JUDGMENT; DOCKETING; FORCE AND EFFECT; ENFORCEMENT.—

(1) FILING OF PAPERS.—The party moving for an order confirming, modifying, or correcting a settlement agreement made in mediation proceedings under the Early Resolution Program shall, at the time such order is filed with the clerk for the entry of judgment thereon, also file the following papers with the clerk:

(A) the agreement, and

(B) each notice, affidavit, or other paper used upon an application to confirm, modify, or correct the agreement, and a copy of each order of the court upon such an application.

(2) DOCKETING OF JUDGMENT.—The judgment shall be docketed as if it were rendered in an action.

(3) FORCE AND EFFECT; ENFORCEMENT.—The judgment so entered shall have the same force and effect, in all respects, as a judgment in an action, and shall be subject to all the provisions of law relating to such a judgment. Such judgment, including the terms of the agreement (as confirmed, modified, or corrected), may be enforced as if it had been rendered in an action in the court in which it is entered.

(f) APPEALS.—An appeal may be taken from an order confirming or denying confirmation of a settlement agreement made in mediation proceedings under the Early Resolution Program or modifying, correcting, or vacating such an agreement.

(g) ATTORNEY'S FEES AND COSTS.—In any action for court enforcement of a settlement agreement under this section in which the plaintiff substantially prevails, the court shall award the plaintiff reasonable attorney's fees (at generally prevailing hourly rates), reasonable expert witness fees, and other reasonable costs, unless the court finds that such award would not be appropriate.

(h) ENFORCEMENT IN STATE COURT.—Any party to a settlement agreement made in mediation proceedings under the Early Resolution Program may also apply to a State court of competent jurisdiction for an order confirming the agreement.

PART 2—GENERAL CIVIL REMEDIES

SEC. 9321. RIGHT OF ACTION AGAINST CERTIFIED HEALTH BENEFIT PLAN SPONSORS AND THIRD PARTY CONTRACTORS.

(a) IN GENERAL.—An individual or health provider who is aggrieved by an act or failure to act by a certified health benefit plan

sponsor or a third party contractor in violation of the terms of a certified health benefit plan or Federal or State law may bring a civil action in a court of competent jurisdiction for the relief described in subsection (b).

(b) RELIEF.—In the case of any violation described in subsection (a), the certified health benefit plan sponsor, together with each third party contractor (if any) whose act or failure to act constitutes or contributes to the violation, shall be jointly and severally liable to the aggrieved individual or health provider for appropriate relief, including actual, compensatory, and punitive damages and equitable relief.

(c) ATTORNEY'S FEES AND COSTS.—In any action under this section in which the plaintiff substantially prevails, the court shall award the plaintiff reasonable attorney's fees (at generally prevailing hourly rates), reasonable expert witness fees, and other reasonable costs, unless the court finds that such award would not be appropriate.

SEC. 9322. GENERAL PRIVATE RIGHT OF ACTION AGAINST STATES.

(a) IN GENERAL.—Any person aggrieved by an act or omission of a State which constitutes a failure to comply with an applicable requirement of this Act may obtain appropriate relief from the State, including actual, compensatory, and punitive damages and equitable relief, in any court of competent jurisdiction.

(b) EXHAUSTION OF REMEDIES.—In an action under subsection (a), the court shall exercise jurisdiction without regard to whether the aggrieved person has exhausted any administrative or other remedies that may be provided by law.

(c) ATTORNEY'S FEES AND COSTS.—In any action under this section in which the plaintiff substantially prevails, the court shall award the plaintiff reasonable attorney's fees (at generally prevailing hourly rates), reasonable expert witness fees, and other reasonable costs, unless the court finds that such award would not be appropriate.

PART 3—ANTI-DISCRIMINATION

SEC. 9331. REQUIREMENTS RELATING TO STATES.

(a) IN GENERAL.—A State, or a person acting under the authority of a State, may not discriminate, or engage (directly or through contractual arrangements) in any activity that has the effect of discriminating, in carrying out any responsibility or in exercising any authority under this Act, against an individual or entity on the basis of race, age, gender, sexual orientation, language, religion, national origin, status of an eligible individual as a citizen of the United States, income, disability, perceived health status, or anticipated need for health services.

(b) BOUNDARIES.—In establishing boundaries for community rating areas or consumer purchasing cooperative areas, a State may not discriminate, engage (directly or through contractual arrangements) in any activity that has the effect of discriminating, or otherwise take into account, race, age, gender, sexual orientation, language, religion, national origin, status of an eligible individual as a citizen of the United States, income, disability, perceived health status, or anticipated need for health services.

(c) REMEDY.—A person who is aggrieved by a violation of subsection (a) or (b) may, in a civil action, obtain appropriate relief, including actual, compensatory, and punitive damages and equitable relief, against any appropriate party, including a State.

(d) ATTORNEY'S FEES AND COSTS.—In any action under subsection (c) in which the plaintiff substantially prevails, the court shall award the plaintiff reasonable attorney's fees (at generally prevailing hourly rates), reasonable expert witness fees, and other reasonable costs, unless the court finds that such award would not be appropriate.

SEC. 9332. REQUIREMENTS RELATING TO CONSUMER PURCHASING COOPERATIVES.

(a) ACTIVITIES RELATING TO PLANS.—A consumer purchasing cooperative may not discriminate, or engage (directly or through contractual arrangements) in any activity that has the effect of discriminating, against a certified health benefit plan sponsor providing or sponsoring a certified health benefit plan on the basis of—

(1) mix of health providers associated with the plan;

(2) organizational arrangement of the plan (except as specifically provided in this Act);

(3) personal characteristics of an individual enrolled in the plan or considering enrolling in the plan that are unrelated to whether the individual is eligible to enroll in the plan, such as race, age, gender, sexual orientation, language, religion, national origin, status of an eligible individual as a citizen of the United States, income, disability, perceived health status, or anticipated need for health services; or

(4) personal characteristics of a health provider who is a network provider with respect to the plan, such as race, age, gender, sexual orientation, language, religion, national origin, status of an eligible individual as a citizen of the United States, income, disability, perceived health status, or anticipated need for health services.

(b) OTHER ACTIVITIES.—A consumer purchasing cooperative may not discriminate, or engage (directly or through contractual arrangements) in any other activity that has the effect of discriminating, against an individual or entity on the basis of race, age, gender, sexual orientation, language, religion, national origin, income, disability, status of an eligible individual as a citizen of the United States, perceived health status, or anticipated need for health services.

(c) REMEDY.—A person who is aggrieved by a violation of subsection (a) or (b) may, in a civil action, obtain appropriate relief, including actual, compensatory, and punitive damages and equitable relief, against any appropriate party.

(d) ATTORNEY'S FEES AND COSTS.—In any action under subsection (c) in which the plaintiff substantially prevails, the court shall award the plaintiff reasonable attorney's fees (at generally prevailing hourly rates), reasonable expert witness fees, and other reasonable costs, unless the court finds that such award would not be appropriate.

(e) EXHAUSTION OF REMEDIES.—In an action under subsection (c), the court shall exercise jurisdiction without regard to whether the aggrieved person has exhausted any administrative or other remedies that may be provided by law.

SEC. 9333. REQUIREMENTS RELATING TO PLAN SPONSORS.

(a) UNDERWRITING.—A certified health benefit plan sponsor providing or sponsoring a certified health benefit plan may not engage in any practice that has the effect of attracting or limiting enrollees on the basis of personal characteristics that are unrelated to the eligibility of an individual to enroll in the plan, such as race, age, gender, sexual orientation, language, religion, national origin, status of an eligible individual as a citizen of the United States, income, disability, perceived health status, or anticipated need for health services.

(b) SELECTION OF NETWORK PROVIDERS.—In selecting among health providers for membership in a plan network, or in establishing the terms and conditions of such membership, a certified health benefit plan sponsor described in subsection (a) may not discriminate, or engage (directly or through contractual arrangements) in any activity that has the effect of discriminating, against a health provider—

(1) based on personal characteristics of the provider, such as race, age, gender, sexual orientation, language, religion, national origin, status of an eligible individual as a citizen of the