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

(ii) ADDITIONAL RULES.—If a code set is modified under this subsection, 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 and cost of complying with such modification.

(d) EVALUATION OF STANDARDS.—The Secretary may establish a process to measure or verify the consistency of standards adopted or modified under this subtitle. Such process may include demonstration projects and analysis of the cost of implementing such standards and modifications.

PART 3—REQUIREMENTS WITH RESPECT TO CERTAIN TRANSACTIONS AND INFORMATION

SEC. 5121. REQUIREMENTS WITH RESPECT TO CERTAIN TRANSACTIONS AND INFORMATION.

(a) REQUIREMENTS ON PLANS AND PROVIDERS RELATING TO FINANCIAL AND ADMINISTRATIVE TRANSACTIONS.—If a health care provider or a health plan conducts any of the following transactions, such transactions shall be standard transactions and the information transmitted or received in connection with such transaction shall be in the form of standard data elements:

(1) Claims submission (including coordination of benefits).

(2) Claims attachments.

(3) Responses to research inquiries by a health researcher.

(4) Other transactions determined appropriate by the Secretary consistent with the goals of improving the functions of the health care system and reducing administrative costs.

(b) REQUIREMENT ONLY ON PLANS RELATING TO FINANCIAL AND ADMINISTRATIVE TRANSACTIONS.—If a person desires to conduct any of the following transactions with a health plan as a standard transaction, the health plan shall conduct such standard transaction and the in-

formation transmitted or received in connection with such transaction shall be in the form of standard data elements:

(1) Enrollment and disenrollment.

(2) Eligibility.

(3) Payment and remittance advice.

(4) Premium payments.

(5) First report of injury.

(6) Claims status.

(7) Referral certification and authorization.

(8) Other transactions determined appropriate by the Secretary consistent with the goals of improving the functions of the health care system and reducing administrative costs.

(c) REQUIREMENT ON PLANS RELATING TO QUALITY INFORMATION.—Any information required to be submitted by a health plan to a State under section 1020 shall be in the form of standard data elements and the transmission of such data shall be in the form of a standard transaction.

(d) REQUIREMENT WITH RESPECT TO DISCLOSURE OF INFORMATION.—

(1) IN GENERAL.—A health plan or health care provider shall ensure that the standard data elements transmitted or received by such plan or provider in connection with the transactions described

in subsections (a), (b), and (c) or acquired under section 5164(a) can be disclosed through the health information network.

(2) SPECIAL RULE.—In the case of a health care provider that does not file claims, such provider shall ensure that standard data elements for encounter information can be disclosed through the health information network.

(3) CONSTRUCTION.—Nothing in this subsection shall be construed as requiring a health care provider or health plan to disclose any health information unless such disclosure is required by law.

(e) SATISFACTION OF REQUIREMENTS.—A health care provider or health plan may satisfy the requirement imposed on such provider or plan under subsection (a), (b), (c), or (d) by—

(1) directly transmitting standard data elements;

(2) submitting nonstandard data elements to a health information network service certified under section 5141 for processing into standard data elements and transmission; or

(3) in the case of a provider, submitting data elements to a plan which satisfies the requirements imposed on such provider on the provider's behalf.

(f) TIMELINESS.—A health care provider or health plan shall be determined to have satisfied a requirement imposed under this section only if the action required is completed in a timely manner, as determined by the Secretary. In setting standards for timeliness, the Secretary shall take into consideration the age and the amount of information being requested.

SEC. 5122. TIMETABLES FOR COMPLIANCE WITH REQUIREMENTS.

(a) INITIAL COMPLIANCE.—

(1) IN GENERAL.—Not later than 12 months after the date on which standards are adopted under part 2 with respect to a type of transaction or data elements for a type of health information, a health plan or health care provider shall comply with the requirements of this subtitle with respect to such transaction or information.

(2) ADDITIONAL DATA ELEMENTS.—Not later than 12 months after the date on which the Secretary adopts an addition to a set of data elements for health information under part 2, a health plan or health care provider shall comply with the requirements of this subtitle using such data elements.

(b) COMPLIANCE WITH MODIFIED STANDARDS.—

(1) IN GENERAL.—If the Secretary adopts a modified standard under part 2, a health plan or health care provider shall be required to comply with the modified standard at such time as the Secretary determines appropriate taking into account the time needed to comply due to the nature and extent of the modification.

(2) SPECIAL RULE.—In the case of modifications to standards that do not occur within the 12-month period beginning on the date such standards are adopted, the time determined appropriate by the Secretary under paragraph (1) shall be no sooner than the last day of the 90-day period beginning on the date such modified standard is adopted and no later than the last day of the 12 month period beginning on the date such modified standard is adopted.

PART 4—ACCESSING HEALTH INFORMATION

SEC. 5131. ACCESSING HEALTH INFORMATION FOR AUTHORIZED PURPOSES.

(a) IN GENERAL.—The Secretary shall adopt technical standards for appropriate persons, including health plans, health care providers, health information network services certified under section 5141, health researchers, and Federal and State agencies, to locate and access the health information that is available through the health in-

formation network due to the requirements of this subtitle. Such technical standards shall ensure that any request to locate or access information shall be authorized under subtitle C.

(b) PROCUREMENT RULE FOR GOVERNMENT AGENCIES.—

(1) IN GENERAL.—Health information protection organizations certified under section 5141 shall make available to a Federal or State agency pursuant to a Federal Acquisition Regulation (or an equivalent State system), any non-identifiable health information that is requested by such agency.

(2) CERTAIN INFORMATION AVAILABLE AT LOW COST.—If a health information protection organization described in paragraph (1) needs information from a health plan or health care provider in order to comply with a request of a Federal or State agency that is necessary to comply with a requirement under this Act, such plan or provider shall make such information available to such organization for a charge that does not exceed the reasonable cost of transmitting the information. If requested, a health information protection organization that receives information under the preceding sentence must make such information available to any other such organi-

zation that is certified under section 5141 for a charge that does not exceed the reasonable cost of transmitting the information.

(c) FUNCTIONAL SEPARATION.—The standards adopted by the Secretary under subsection (a) shall ensure that any health information disclosed under such subsection shall not, after such disclosure, be used or released for an administrative, regulatory, or law enforcement purpose unless such disclosure was made for such purpose.

(d) PUBLIC USE FUNCTIONS.—Nothing in this subtitle shall be construed to limit the authority of a Federal or State agency to make non-identifiable health information available for public use functions.

SEC. 5132. RESPONDING TO ACCESS REQUESTS.

(a) IN GENERAL.—The Secretary shall adopt, and modify as appropriate, standards under which a health care provider or health plan shall respond to requests for access to health information consistent with this subtitle and subtitle C.

(b) STANDARDS DESCRIBED.—The standards under subsection (a) shall provide—

(1) for a standard format under which a provider or plan will respond to each request either by satisfying the request or by responding with a nega-

tive response, which may include an explanation of the failure to satisfy the request; and

(2) that a plan or provider shall respond to a request in a timely manner taking into account the age and amount of the information being requested.

SEC. 5133. LENGTH OF TIME INFORMATION SHOULD BE ACCESSIBLE.

The Secretary shall adopt standards with respect to the length of time any standard data elements for a type of health information should be accessible through the health information network.

SEC. 5134. TIMETABLES FOR ADOPTION OF STANDARDS AND COMPLIANCE.

(a) INITIAL STANDARDS.—The Secretary shall adopt standards under this part not later than 9 months after the date of the enactment of this subtitle and such standards shall be effective upon adoption.

(b) MODIFICATIONS TO STANDARDS.—

(1) IN GENERAL.—Except as provided in paragraph (2), the Secretary shall review the standards adopted under this part and shall adopt modified standards as determined appropriate, but no more frequently than once every 6 months. Any modification to standards shall be completed in a manner which minimizes the disruption and cost of compli-

ance. Any modifications to standards adopted under this part shall be effective upon adoption.

(2) SPECIAL RULE.—The Secretary shall not adopt modifications to any standards adopted under this part during the 12-month period beginning on the date such standards are adopted unless the Secretary determines that a modification is necessary in order to permit compliance with the requirements of this part.

PART 5—STANDARDS AND CERTIFICATION FOR HEALTH INFORMATION NETWORK

SEC. 5141. STANDARDS AND CERTIFICATION FOR HEALTH INFORMATION NETWORK SERVICES.

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

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

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

(3) such services make public information concerning their performance, as measured by uniform indicators such as accessibility, transaction respon-

siveness, administrative efficiency, reliability, dependability, and any other indicator determined appropriate by the Secretary;

(4) such services have security procedures that are consistent with the privacy requirements under subtitle C, including secure methods of access to and transmission of data;

(5) such services, if they are part of a larger organization, have policies and procedures in place which isolate their activities with respect to processing information in a manner that prevents access to such information by such larger organization.

(b) CERTIFICATION BY THE SECRETARY.—

(1) ESTABLISHMENT.—Not later than 12 months after the date of the enactment of this subtitle, the Secretary shall establish a certification procedure for health information network services which ensures that certified services are qualified to meet the requirements of this subtitle and the standards established by the Secretary under this section. Such certification procedure shall be implemented in a manner that minimizes the costs and delays of operations for such services.

(2) APPLICATION.—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.

(3) 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 such entity's compliance with the requirements of this subtitle, subtitle C, and the standards established by the Secretary under this section.

(c) LOSS OF CERTIFICATION.—

(1) MANDATORY TERMINATION.—Except as provided in paragraph (3), if a health information network service violates a requirement imposed on such service under subtitle C, its certification under this section shall be terminated unless the Secretary determines that appropriate corrective action has been taken.

(2) DISCRETIONARY TERMINATION.—If a health information network service violates a requirement or standard imposed under this subtitle and a penalty has been imposed under section 5151, the Secretary shall review the certification of such service and may terminate such certification.

(3) CONDITIONAL CERTIFICATION.—The Secretary may establish a procedure under which a health information network service may remain certified on a conditional basis if the service is operating consistently with a plan intended to correct any violations described in paragraphs (1) or (2). Such procedure may provide for the appointment of a trustee to continue operation of the service until the requirements for full certification are met.

(d) CERTIFICATION BY PRIVATE ENTITIES.—The Secretary may designate private entities to conduct the certification procedures established by the Secretary under this section. A health information network service certified by such an entity in accordance with such designation shall be considered to be certified by the Secretary.

SEC. 5142. ENSURING AVAILABILITY OF INFORMATION.

The Secretary shall establish a procedure under which a health plan or health care provider which does not have the ability to transmit standard data elements directly or does not have access to a health information network service certified under section 5141 shall be able to make health information available for disclosure as authorized by this subtitle.

PART 6—PENALTIES

SEC. 5151. GENERAL PENALTY FOR FAILURE TO COMPLY WITH REQUIREMENTS AND STANDARDS.

(a) IN GENERAL.—Except as provided in subsection (b), the Secretary shall impose on any person that violates a requirement or standard imposed under this subtitle a penalty of not more than $1,000 for each violation. The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to the imposition of a civil money penalty under this subsection in the same manner as such provisions apply to the imposition of a penalty under section 1128A of the Social Security Act.

(b) LIMITATIONS.—

(1) NONCOMPLIANCE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—A penalty may not be imposed under subsection (a) if it is established to the satisfaction of the Secretary that the person liable for the penalty did not know, and by exercising reasonable diligence would not have known, that such person failed to comply with the requirement or standard described in subsection (a).

(2) FAILURES DUE TO REASONABLE CAUSE.—

(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), a penalty may not be imposed under subsection (a) if—

(i) the failure to comply was due to reasonable cause and not to willful neglect; and

(ii) the failure to comply is corrected during the 30-day period beginning on the 1st date the person liable for the penalty knew, or by exercising reasonable diligence would have known, that the failure to comply occurred.

(B) EXTENSION OF PERIOD.—

(i) NO PENALTY.—The period referred to in subparagraph (A)(ii) may be extended as determined appropriate by the Secretary based on the nature and extent of the failure to comply.

(ii) ASSISTANCE.—If the Secretary determines that a health plan or health care provider failed to comply because such person was unable to comply, the Secretary may provide technical assistance to such person. Such assistance shall be provided in any manner determined appropriate by the Secretary.

(3) REDUCTION.—In the case of a failure to comply which is due to reasonable cause and not to

willful neglect, any penalty under subsection (a) that is not entirely waived under paragraph (2) may be waived to the extent that the payment of such penalty would be excessive relative to the compliance failure involved.

PART 7—MISCELLANEOUS PROVISIONS

SEC. 5161. IMPOSITION OF ADDITIONAL REQUIREMENTS.

(a) DATA ELEMENT STANDARDS.—A person may not impose a standard on another person that is in addition to the standards adopted by the Secretary under section 5112 unless—

(1) such person voluntarily agrees to such standard; or

(2) a waiver is granted under subsection (c) to impose such standard.

(b) TRANSACTIONS AND ACCESS STANDARDS.—A person may not impose a standard on another person that is in addition to the standards adopted by the Secretary under section 5113 or 5131 unless such person voluntarily agrees to such standard.

(c) CONDITIONS FOR WAIVERS.—

(1) IN GENERAL.—A person may request a waiver from the Secretary in order to require another person to comply with a standard that is in

addition to the standards adopted by the Secretary under section 5112.

(2) CONSIDERATION OF WAIVER REQUESTS.—No waiver may be granted unless the Secretary determines that the value of the data to be exchanged for research or other purposes significantly outweighs the administrative cost of the additional standard taking into consideration the burden of the timing of the imposition of the additional standard.

(3) ANONYMOUS REPORTING.—If a person attempts to impose a standard in addition to the standards adopted by the Secretary under section 5112, the person on whom such additional standard is being imposed may contact the Secretary. The Secretary shall develop a procedure under which the contacting person shall remain anonymous. The Secretary shall notify the person imposing the additional standard that the additional standard may not be imposed unless the other person voluntarily agrees to such standard or a waiver is obtained under this subsection.

SEC. 5162. EFFECT ON STATE LAW.

(a) IN GENERAL.—Except as provided in subsection (b), a provision, requirement, or standard under this sub-

title shall supersede any contrary provision of State law, including—

(1) a provision of State law that requires medical or health plan records (including billing information) to be maintained or transmitted in written rather than electronic form, and

(2) a provision of State law which provides for requirements or standards that are more stringent than the requirements or standards under this subtitle;

except where the Secretary determines that the provision is necessary to prevent fraud and abuse, with respect to controlled substances, or for other purposes.

(b) PUBLIC HEALTH REPORTING.—Nothing in this subtitle 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. 5164. HEALTH INFORMATION CONTINUITY.

(a) INFORMATION HELD BY HEALTH PLANS AND PROVIDERS.—If a health plan or health care provider takes any action that would threaten the continued availability of the standard data elements of health information held by such plan or provider, such data elements shall

be transferred to a health plan or health care provider in accordance with procedures established by the Secretary.

(b) INFORMATION HELD BY HEALTH INFORMATION NETWORK SERVICES.—If a health information network service certified under section 5141 loses its certified status or takes any action that would threaten the continued availability of the standard data elements of health information held by such service, such data elements shall be transferred to another health information network service certified under section 5141, as designated by the Secretary.

SEC. 5165. PROTECTION OF COMMERCIAL INFORMATION.

In adopting standards under this subtitle, the Secretary shall not require disclosure of trade secrets and confidential commercial information by entities operating in the health information network except as required by law.

SEC. 5166. PAYMENT FOR HEALTH CARE SERVICES OR HEALTH PLAN PREMIUMS.

Nothing in this subtitle shall be construed to prohibit payments for health care services or health plan premiums from being made by debit, credit, or other payment cards or numbers or other electronic payment means.

SEC. 5167. HEALTH SECURITY CARDS.

(a) IN GENERAL.—The Secretary shall establish standards relating to the form of health security cards issued by health plans and the information to be encoded electronically on such cards.

(b) FORM DESCRIBED.—The standard form for a health security card shall be a card which—

(1) is made of plastic or a similar durable material with a useful life of at least 5 years;

(2) is resistant to counterfeiting;

(3) can store information that can be encoded and retrieved electronically; and

(4) can be produced in a cost-effective manner and used in all types of health care locations.

(c) INFORMATION DESCRIBED.—The information electronically encoded on a health security card shall include the identity of the individual to whom the card was issued, including such individual's personal health identifier specified under section 5112(c)(1), and may include any other information that the Secretary determines may be useful in order for the card to serve the purpose of easing access to and paying for health care services. A health plan shall make available to an individual cardholder, upon demand by such individual, a printed copy of all information electronically encoded on such individual's health security card.

SEC. 5168. MISUSE OF HEALTH SECURITY CARD OR PERSONAL HEALTH IDENTIFIER.

(a) HEALTH SECURITY CARD.—A person who—

(1) requires the display of, requires the use of, or uses a health security card for any purpose other than obtaining or paying for health care;

(2) falsely makes, forges, counterfeits or alters a health security card;

(3) without lawful authority prints, photographs, or makes any impression in the likeness of any health security card; or

(4) sells, transfers, or otherwise delivers a false, forged, counterfeited, or altered health security card knowing that the card is false, forged, counterfeited, or altered;

shall be fined not more than $25,000, imprisoned not more than 2 years, or both.

(b) PERSONAL HEALTH IDENTIFIER.—A person who requires the disclosure of, requires the use of, or uses an individual's personal health identifier for any purpose that is not authorized by the Secretary, shall be fined not more than $25,000, imprisoned not more than 2 years, or both.

SEC. 5169. DIRECT BILLING FOR CLINICAL LABORATORY SERVICES.

(a) IN GENERAL.—

(1) REQUIREMENT.—Except as provided in paragraph (2), in the case of a claim for payment for a clinical diagnostic laboratory test for which payment may otherwise be made, payment may be made only to the person who, or entity which, performed or supervised the test.

(2) EXCEPTION.—Payment for a clinical diagnostic laboratory test may be made—

(A) to a physician with whom the physician who performed the test shares a practice; or

(B) to a physician or physician group if clinical laboratory services are included in the services for which the physician or group is paid on a capitated basis.

(b) ADDITIONAL EXCEPTIONS.—The Secretary may, by regulation, establish exceptions to the requirement under subsection (a)(1) that are in addition to the exception under subsection (a)(2).

SEC. 5170. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated such sums as may be necessary to carry out the purposes of this subtitle.

PART 8—ASSISTANCE TO THE SECRETARY

SEC. 5171. GENERAL REQUIREMENT ON SECRETARY.

In complying with any requirements imposed under this subtitle, the Secretary shall rely on recommendations of the Health Information Advisory Committee established under section 5172 and shall consult with appropriate Federal agencies.

SEC. 5172. HEALTH INFORMATION ADVISORY COMMITTEE.

(a) ESTABLISHMENT.—There is established a committee to be known as the Health Information Advisory Committee.

(b) DUTY.—

(1) IN GENERAL.—The committee shall—

(A) provide assistance to the Secretary in complying with the requirements imposed on the Secretary under this subtitle and subtitle C;

(B) be generally responsible for advising the Secretary and the Congress on the status of the health information network; and

(C) make recommendations to correct any problems that may occur in the network's implementation and ongoing operations and to refine and improve the network.

(2) TECHNICAL ASSISTANCE.—In performing its duties under this subsection, the committee shall

receive technical assistance from appropriate Federal agencies.

(c) MEMBERSHIP.—

(1) IN GENERAL.—The committee shall consist of 15 members to be appointed by the President not later than 60 days after the date of the enactment of this subtitle. The President shall designate 1 member as the Chair.

(2) EXPERTISE.—The membership of the committee shall consist of individuals who are of recognized standing and distinction in the areas of information systems, consumer health, or privacy, and who possess the demonstrated capacity to discharge the duties imposed on the committee.

(3) TERMS.—Each member of the committee shall be appointed for a term of 5 years, except that the members first appointed shall serve staggered terms such that the terms of no more than 3 members expire at one time.

(4) VACANCIES.—

(A) IN GENERAL.—A vacancy on the committee shall be filled in the manner in which the original appointment was made and shall be subject to any conditions which applied with respect to the original appointment.

(B) FILLING UNEXPIRED TERM.—An individual chosen to fill a vacancy shall be appointed for the unexpired term of the member replaced.

(C) EXPIRATION OF TERMS.—The term of any member shall not expire before the date on which the member's successor takes office.

(5) CONFLICTS OF INTEREST.—Members of the committee shall disclose upon appointment to the committee or at any subsequent time that it may occur, conflicts of interest.

(d) MEETINGS.—

(1) IN GENERAL.—Except as provided in paragraph (2), the committee shall meet at the call of the Chair.

(2) INITIAL MEETING.—Not later than 30 days after the date on which all members of the committee have been appointed, the committee shall hold its first meeting.

(3) QUORUM.—A majority of the members of the committee shall constitute a quorum, but a lesser number of members may hold hearings.

(e) POWER TO HOLD HEARINGS.—The committee may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as

the committee considers advisable to carry out the purposes of this section.

(f) OTHER ADMINISTRATIVE PROVISIONS.—Subparagraphs (C), (D), and (H) of section 1886(e)(6) of the Social Security Act shall apply to the committee in the same manner as they apply to the Prospective Payment Assessment Commission.

(g) REPORTS.—

(1) IN GENERAL.—The committee shall annually prepare and submit to Congress and the Secretary a report including at least an analysis of—

(A) the status of the health information network established under this subtitle, including whether the network is fulfilling the purpose described in section 5101;

(B) the savings and costs of the network;

(C) the activities of health information network services certified under section 5141, health care providers, health plans, and other entities using the network to exchange health information;

(D) the extent to which entities described in subparagraph (C) are meeting the standards adopted under this subtitle and working to-

gether to form an integrated network that meets the needs of its users;

(E) the extent to which entities described in subparagraph (C) are meeting the privacy and security protections of subtitle C;

(F) the number and types of penalties assessed for noncompliance with the standards adopted under this subtitle;

(G) whether the Federal Government and State Governments are receiving information of sufficient quality to meet their responsibilities under the Health Reform Act;

(H) any problems with respect to implementation of the network;

(I) the extent to which timetables under this subtitle for the adoption and implementation of standards are being met; and

(J) any legislative recommendations related to the health information network.

(2) AVAILABILITY TO THE PUBLIC.—Any information in the report submitted to Congress under paragraph (1) shall be made available to the public unless such information may not be disclosed by law.

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

(i) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There are authorized to be appropriated such sums as may be necessary to carry out the purposes of this section.

(2) AVAILABILITY.—Any sums appropriated under the authorization contained in this subsection shall remain available, without fiscal year limitation, until expended.

SEC. 5181. GRANTS FOR DEMONSTRATION PROJECTS.

(a) IN GENERAL.—The Secretary may make grants for demonstration projects to promote the development and use of electronically integrated community-based clinical information systems and computerized patient medical records.

(b) APPLICATIONS.—

(1) SUBMISSION.—To apply for a grant under this part for any fiscal year, an applicant shall submit an application to the Secretary in accordance with the procedures established by the Secretary.

(2) CRITERIA FOR APPROVAL.—The Secretary may not approve an application submitted under paragraph (1) unless the application includes assur-

ances satisfactory to the Secretary regarding the following:

(A) USE OF EXISTING TECHNOLOGY.—Funds received under this part will be used to apply telecommunications and information systems technology that is in existence on the date the application is submitted in a manner that improves the quality of health care, reduces the costs of such care, and protects the privacy and confidentiality of information relating to the physical or mental condition of an individual.

(B) USE OF EXISTING INFORMATION SYSTEMS.—Funds received under this part will be used—

(i) to enhance telecommunications or information systems that are operating on the date the application is submitted;

(ii) to integrate telecommunications or information systems that are operating on the date the application is submitted; or

(iii) to connect additional users to telecommunications or information networks or systems that are operating on the date the application is submitted.

(C) MATCHING FUNDS.—The applicant shall make available funds for the demonstration project in an amount that equals at least 20 percent of the cost of the project.

(c) GEOGRAPHIC DIVERSITY.—In making any grants under this part, the Secretary shall, to the extent practicable, make grants to persons representing different geographic areas of the United States, including urban and rural areas.

(d) REVIEW AND SANCTIONS.—The Secretary shall review at least annually the compliance of a person receiving a grant under this part with the provisions of this part. The Secretary shall establish a procedure for determining whether such a person has failed to comply substantially within the provisions of this part and the sanctions to be imposed for any such noncompliance.

(e) ANNUAL REPORT.—The Secretary shall submit an annual report to the President for transmittal to Congress containing a description of the activities carried out under this part.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out the purposes of this section.

PART 9—MEDICARE AND MEDICAID COVERAGE DATA BANK

SEC. 5191. MEDICARE AND MEDICAID COVERAGE DATA BANK AND RELATED IDENTIFICATION PROCESSES.

(a) DELAY OF EMPLOYER REPORTING REQUIREMENT.—

(1) IN GENERAL.—Section 1144(c)(1)(A) of the Social Security Act (42 U.S.C. 1320–14(c)(1)(A)) is amended by striking "January 1, 1994" and inserting "January 1, 1996".

(2) EFFECTIVE DATE.—The amendment made by this paragraph shall be effective on the date of the enactment of this Act.

(b) REPEAL OF DATA BANK.—

(1) IN GENERAL.—Effective January 1, 1996, section 1144 of the Social Security Act (42 U.S.C. 1320b–14) and section 101(f) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1021(f)) are repealed.

(2) INTERNAL REVENUE CODE PROVISION.—Section 6103(*l*) of the Internal Revenue Code of 1986 is amended by striking paragraph (12).

(3) IDENTIFICATION OF MEDICARE SECONDARY PAYER SITUATIONS.—Section 1862(b) of the Social

Security Act (42 U.S.C. 1395y(b)) is amended by striking paragraph (5).

(4) CONFORMING AMENDMENTS.—(A) Section 1902(a)(25)(A)(i) of the Social Security Act (42 U.S.C. 1396a(a)(25)(A)(i)) is amended by striking "including the use of information collected by the Medicare and Medicaid Coverage Data Bank under section 1144 and any additional measures".

(B) Subsection (a)(8)(B) of section 552a of title 5, United States Code, is amended—

(i) in clause (v), by inserting "; or" at the end;

(ii) in clause (vi), by striking "or" at the end; and

(III) by striking clause (vii).

(5) EFFECTIVE DATE.—The amendments made by this paragraph shall be effective on and after January 1, 1996.

Subtitle C—Privacy of Health Information

PART 1—FINDINGS AND DEFINITIONS

SEC. 5201. FINDINGS AND PURPOSES.

(a) FINDINGS.—The Congress finds as follows:

(1) The improper disclosure of individually identifiable health care information may cause significant harm to an individual's interests in privacy, health care, and reputation and may unfairly affect the ability of an individual to obtain employment, education, insurance, and credit.

(2) The movement of people and health care related information across State lines, the availability of, access to, and exchange of health care related information with Federally funded health care systems, the medicare program under title XVIII of the Social Security Act, and the medicaid program under title XIX of such Act, through automated data banks and networks, and the emergence of other multistate health care providers and payors create a need for a uniform Federal law governing the disclosure of health care information.

(b) PURPOSE.—The purpose of this subtitle is to establish effective mechanisms to protect the privacy of individuals with respect to individually identifiable health care

mation can be used to identify an individual.

(2) DISCLOSE.—The term "disclose", when used with respect to protected health information, means to provide access to the information, but only if such access is provided to a person other than the individual who is the subject of the information.

(b) TERMS RELATING TO HEALTH CARE SYSTEM PARTICIPANTS.—In this subtitle:

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

(A) a health care provider, health plan, health oversight agency, certified health information network service, employer, life insurer, or school or university insofar as it creates, receives, maintains, uses, or transmits protected health information;

(B) any person who obtains protected health information under section 5213, 5217, 5218, 5221, 5222, 5226, or 5231; and

(C) any employee or agent of a person covered under subparagraphs (A) or (B).

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

(A) means—

(i) a preventative, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, counseling, service, or procedure—

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

(II) affecting the structure or function of the human body or any part of the human body; 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 examining, maintaining, or improving the health of an individual.

(3) HEALTH CARE PROVIDER.—The term "health care provider" means 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.

(4) HEALTH OVERSIGHT AGENCY.—The term "health oversight agency" means a person who—

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

(B)(i) performs or oversees the performance of an assessment, evaluation, determination, or investigation relating to the effectiveness of, compliance with, or applicability of legal, fiscal, medical, or scientific standards or aspects of performance related to the delivery of, or payment for, health care or relating to health care fraud or fraudulent claims for payment regarding health; 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 Federal or State law governing the assessment, evaluation, determination, or investigation described in clause (i).

(5) HEALTH PLAN.—The term "health plan" shall have the meaning given such term under section 5102.

(6) HEALTH RESEARCHER.—The term "health researcher" means a person who conducts a bio-

medical, public health, epidemiological, health services, or health statistics research project or a research project on social and behavioral factors relating to health.

(7) INSTITUTIONAL REVIEW BOARD.—The term "institutional review board" means—

(A) a board established in accordance with regulations of the Secretary under section 491(a) of the Public Health Service Act;

(B) a similar board established by the Secretary for the protection of human subjects in research conducted by the Secretary;

(C) a similar board established under regulations of a Federal Government authority other than the Secretary; or

(D) a board certified in accordance with regulations issued under section 5218(c).

(8) PUBLIC HEALTH AUTHORITY.—The term "public health authority" means an authority or instrumentality of the United States, a State, or a political subdivision of a State that is (A) responsible for public health matters; and (B) engaged in such activities as injury reporting, public health surveillance, and public health investigation or intervention.

(c) REFERENCES TO CERTIFIED ENTITIES.—In this subtitle:

(1) CERTIFIED HEALTH INFORMATION NETWORK SERVICE.—The term "certified health information network service" means a health information service (as defined under section 5102) that is certified under section 5141.

(2) CERTIFIED HEALTH INFORMATION PROTECTION ORGANIZATION.—The term "certified health information protection organization" means a health information protection organization (as defined in section 5102) that is certified under section 5141.

(d) OTHER TERMS.—In this subtitle:

(1) INDIVIDUAL REPRESENTATIVE.—The term "individual representative" means any individual legally empowered to make decisions concerning the provision of health care to an individual (where the individual lacks the legal capacity under State law to make such decisions) or the administrator or executor of the estate of a deceased individual.

(2) LAW ENFORCEMENT INQUIRY.—The term "law enforcement inquiry" means an investigation or official proceeding inquiring into whether there is 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.

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

PART 2—AUTHORIZED DISCLOSURES

Subpart A—General Provisions

SEC. 5206. GENERAL RULES REGARDING DISCLOSURE.

(a) GENERAL RULE.—A health information trustee may disclose protected health information only for a purpose that is authorized under this subtitle.

(b) DISCLOSURE WITHIN A TRUSTEE.—A health information trustee may disclose protected health information to an officer, employee, or agent of the trustee for a purpose that is compatible with and related to the purpose for which the information was collected or received by that trustee.

(c) SCOPE OF DISCLOSURE.—

(1) IN GENERAL.—Every disclosure of protected health information by a health information trustee shall be limited to the minimum amount of information necessary to accomplish the purpose for which the information is disclosed.

(2) REGULATIONS.—The Secretary, after notice and opportunity for public comment, may issue reg-

ulations under 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 disclosure.

(d) NO GENERAL REQUIREMENT TO DISCLOSE.—Nothing in this subtitle that permits a disclosure of health information shall be construed to require such disclosure.

(e) USE AND REDISCLOSURE OF INFORMATION.—The protected health information received under a disclosure permitted by the subtitle may not be used or disclosed unless the use or disclosure is necessary to fulfill the purpose for which the information was obtained and is not otherwise prohibited by law. Protected health information about an individual that is disclosed under this subtitle may not be used in, or disclosed to any person for use in, any administrative, civil, or criminal action or investigation directed against the individual unless specifically permitted by this subtitle.

(f) IDENTIFICATION OF DISCLOSED INFORMATION AS PROTECTED INFORMATION.—

(1) IN GENERAL.—Except with respect to protected health information that is disclosed under section 5213 and except as provided in paragraph (2), a health information trustee may not disclose protected health information unless such information is

clearly identified as protected health information that is subject to this subtitle.

(2) ROUTINE DISCLOSURES SUBJECT TO WRITTEN AGREEMENT.—A health information trustee who routinely discloses protected health information to a person may satisfy the identification requirement in paragraph (1) through a written agreement between the trustee and the person with respect to the protected health information.

(g) CONSTRUCTION.—Nothing in this subtitle shall be construed to limit the ability of a health information trustee to charge a reasonable fee for the disclosure or reproduction of health information.

(h) INFORMATION IN WHICH PROVIDERS ARE IDENTIFIED.—The Secretary, after notice and opportunity for public comment, may issue regulations protecting information identifying providers in order to promote the availability of health care services.

SEC. 5207. AUTHORIZATIONS FOR DISCLOSURE OF PROTECTED HEALTH INFORMATION.

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

(1) WRITING.—The authorization is in writing, signed by the individual who is the subject of the information, 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 DISCLOSURES.—The authorization contains an acknowledgment that the individual who is the subject of the information has read a statement of the disclosures that the person to receive the protected health information intends to make, which statement shall be in writing, on a form that is distinct from the authorization for disclosure, and which statement must be received by the individual authorizing the disclosure on or before such authorization is executed.

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

(7) EXPIRATION DATE SPECIFIED.—The authorization specifies a date or event upon which the authorization expires, which shall not exceed 2 years from the date of the execution of the authorization.

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

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

(b) AUTHORIZATIONS REQUESTED IN CONNECTION WITH PROVISION OF HEALTH CARE.—

(1) IN GENERAL.—A health information trustee (other than a health facility) may not request that an individual provide to any other person an authorization described in subsection (a) on a day on which the trustee provides health care to the individual requested to provide the authorization.

(2) HEALTH FACILITY.—In the case of a health information trustee that is a health facility, the trustee may not request that an individual provide an authorization described in subsection (a) on a day on which the individual is admitted into the fa-

cility as a resident or inpatient in order to receive health care.

(3) EXCEPTION.—Paragraphs (1) and (2) shall not apply if a health information trustee requests that an individual provide an authorization described in subsection (a) for the purpose of assisting the individual in obtaining counseling or social services from a person other than the trustee.

(c) TIME LIMITATIONS ON AUTHORIZATIONS.—

(1) RECEIPT BY TRUSTEE.—For purposes of subsection (a)(8), an authorization is timely received if it is received by the trustee during—

(A) the 1-year period beginning on the date on which the authorization is signed under subsection (a)(1), if the authorization permits the disclosure of protected health information to a person who provides health counseling or social services to individuals;

(B) the 90-day period beginning on the date on which the authorization is signed under subsection (a)(1), if the authorization permits the disclosure of protected health information to a life insurer; or

(C) the 30-day period beginning on the date on which 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) or (B).

(2) DISCLOSURE BY TRUSTEE.—For purposes of subsection (a)(9), a disclosure is timely made if it occurs before the date or event specified in the authorization upon which the authorization expires.

(d) REVOCATION OR AMENDMENT OF AUTHORIZATION.—

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

(A) disclosure of protected health information has been authorized to permit validation of expenditures for health care; or

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

(2) NOTICE OF REVOCATION.—A health information trustee who discloses protected health information pursuant to 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 subtitle.

(e) DECEASED INDIVIDUAL.—The Secretary shall develop and establish through regulation a procedure for obtaining protected health information relating to a deceased individual when there is no individual representative for such individual.

(f) MODEL AUTHORIZATIONS.—The Secretary, after notice and opportunity for public comment, shall develop and disseminate model written authorizations of the type described in subsection (a) and model statements of intended disclosures of the type described in subsection (a)(5).

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

SEC. 5208. CERTIFIED HEALTH INFORMATION NETWORK SERVICES.

(a) IN GENERAL.—A health information trustee may disclose protected health information to a certified health information network service acting as an agent of the trustee for any purpose permitted by this subtitle. Such

a service, acting as an agent of a trustee, may disclose protected health information to another person as permitted under this subtitle to facilitate the completion of the purpose for which such information was disclosed to the service.

(b) CERTIFIED HEALTH INFORMATION PROTECTION ORGANIZATIONS.—A health information trustee may disclose protected health information to a certified health information protection organization for the purpose of creating non-identifiable health information (as defined in section 5102).

Subpart B—Specific Disclosures Relating to Patient

SEC. 5211. DISCLOSURES FOR TREATMENT AND FINANCIAL AND ADMINISTRATIVE TRANSACTIONS.

(a) HEALTH CARE TREATMENT.—A health care provider, health plan, employer, or person who receives protected health information under section 5213, may disclose protected health information to a health care provider for the purpose of providing health care to an individual if the individual who is the subject of the information has not previously objected in writing to the disclosure.

(b) DISCLOSURE TO HEALTH PLANS FOR FINANCIAL AND ADMINISTRATIVE PURPOSES.—A health care provider or employer may disclose protected health informa-

tion to a health plan for the purpose of providing for the payment for, or reviewing the payment of, health care furnished to an individual.

(c) DISCLOSURE BY HEALTH PLANS FOR FINANCIAL AND ADMINISTRATIVE PURPOSES.—A health plan may disclose protected health information to a health care provider or a health plan for the purpose of providing for the payment for, or reviewing the payment of, health care furnished to an individual.

SEC. 5212. NEXT OF KIN AND DIRECTORY INFORMATION.

(a) NEXT OF KIN.—A health care provider or person who receives protected health information under section 5213 may disclose protected health information to the next of kin, an individual representative of the individual who is the subject of the information, or an individual with whom that individual has a close personal relationship if—

(1) the individual who is the subject of the information—

(A) has been notified of the individual's right to object and has not objected to the disclosure;

(B) is not competent to be notified about the right to object; or

(C) exigent circumstances exist such that it would not be practicable to notify the individual of the right to object; and

(2) the information disclosed relates to health care currently being provided to that individual.

(b) DIRECTORY INFORMATION.—A health care provider and a person receiving protected health information under section 5213 may disclose protected health information to any person if—

(1) the information does not reveal specific information about the physical or mental condition of the individual who is the subject of the information or health care provided to that person;

(2) the individual who is the subject of the information—

(A) has been notified of the individual's right to object and has not objected to the disclosure;

(B) is not competent to be notified about the right to object; or

(C) exigent circumstances exist such that it would not be practicable to notify the individual of the right to object; and

(3) the information consists only of 1 or more of the following items:

(A) The name of the individual who is the subject of the information.

(B) If the individual who is the subject of the information is receiving health care from a health care provider on a premises controlled by the provider—

(i) the location of the individual on the premises; and

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

(d) IDENTIFICATION OF DECEASED INDIVIDUAL.—A health care provider, health plan, employer, or life insurer, may disclose protected health information if necessary to assist in the identification of a deceased individual.

SEC. 5213. EMERGENCY CIRCUMSTANCES.

(a) IN GENERAL.—A health care provider, health plan, employer, or person who receives protected health information under this section may disclose protected health information in emergency circumstances when necessary to protect the health or safety of an individual from imminent harm.

(b) SCOPE OF DISCLOSURE.—The disclosure of protected health information under this section shall be lim-

ited to persons who need the information to take action to protect the health or safety of the individual.

Subpart C—Disclosure for Oversight, Public Health, and Research Purposes

SEC. 5216. OVERSIGHT.

(a) IN GENERAL.—A health information trustee may disclose protected health information to a health oversight agency for an oversight function authorized by law.

(b) USE IN ACTION AGAINST INDIVIDUALS.—Notwithstanding section 5206(e), protected health information about an individual that is disclosed under this section may be used in, or disclosed to any person for use in, an administrative, civil, or criminal action or investigation directed against the individual who is the subject of the information if the action or investigation arises out of and is directly related to—

(1) receipt of health care or payment for health care;

(2) an action involving a fraudulent claim related to health; or

(3) an action involving a misrepresentation of the health of the individual who is the subject of the information.

SEC. 5217. PUBLIC HEALTH.

A health care provider, health plan, public health authority, employer, or person who receives protected health information under section 5213 may disclose protected health information to a public health authority or other person authorized by law for use in a legally authorized—

(1) disease or injury reporting;

(2) public health surveillance; or

(3) public health investigation or intervention.

SEC. 5218. HEALTH RESEARCH.

(a) IN GENERAL.—A health information trustee may disclose protected health information to a health researcher if an institutional review board determines that the research project engaged in by the health researcher—

(1) requires use of the protected health information for the effectiveness of the project; and

(2) is of sufficient importance to outweigh the intrusion into the privacy of the individual who is the subject of the information that would result from the disclosure.

(b) RESEARCH REQUIRING DIRECT CONTACT.—A health information trustee may disclose protected health information to a health researcher for a research project that includes direct contact with an individual who is the subject of protected health information if an institutional review board determines that—

(1) the research project meets the requirements of paragraphs (1) and (2) of subsection (a);

(2) direct contact is necessary to accomplish the research purpose; and

(3) the direct contact will be made in a manner that minimizes the risk of harm, embarrassment, or other adverse consequences to the individual.

(c) SPECIAL RULE FOR TRUSTEES OTHER THAN ACADEMIC CENTERS OR HEALTH CARE FACILITIES.—

(1) IN GENERAL.—If a health researcher described in subsection (a) or (b) is not an academic center or a health care facility, the determinations required by an institutional review board under such subsections shall be made by such a board that is certified under paragraph (2).

(2) CERTIFICATION.—

(A) REQUIREMENTS.—The Secretary, after notice and opportunity for public comment, shall issue regulations establishing certification requirements for institutional review boards that will review research projects undertaken by entities other than academic health centers or health care facilities. Such regulations shall—

(i) be based on regulations issued under section 491(a) of the Public Health Service Act, and

(ii) require that such an institutional review board be affiliated with an academic center or a health care facility.

(B) GRANT OF CERTIFICATION.—The Secretary shall certify an institutional review board that meets the requirements established by the Secretary under subparagraph (A).

(d) USE OF HEALTH INFORMATION NETWORK.—

(1) IN GENERAL.—A health information trustee may disclose protected health information to a health researcher using the health information network (as defined in section 5102) only if an institutional review board determines that the research project engaged in by the health researcher meets the requirements of this section and satisfies requirements established by the Secretary for protecting the confidentiality of information on research subjects in the health information network.

(e) OBLIGATIONS OF RECIPIENT.—A person who receives protected health information pursuant to subsection (a) or (b)—

(1) shall remove or destroy, at the earliest opportunity consistent with the purposes of the project, information that would enable an individual to be identified, unless—

(A) an institutional review board has determined that there is a health or research justification for retention of such identifiers; and

(B) there is an adequate plan to protect the identifiers from disclosure that is inconsistent with this section; and

(2) shall use protected health information solely for purposes of the health research project for which disclosure was authorized under this section.

Subpart D—Disclosure For Judicial, Administrative, and Law Enforcement Purposes

SEC. 5221. JUDICIAL AND ADMINISTRATIVE PURPOSES.

A health care provider, health plan, health oversight agency, employer, or life insurer 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 the individual who is the subject of the information—

(A) is a party and in which the individual has placed the individual's physical or mental condition in issue; or

(B) is deceased and in which the individual's physical or mental condition is in issue;

(2) to a court, and to others ordered by a court, if the protected health information is developed in response to a court-ordered physical or mental examination; or

(3) pursuant to a law requiring the reporting of specific medical information to law enforcement authorities.

SEC. 5222. LAW ENFORCEMENT.

(a) IN GENERAL.—A health care provider, health plan, health oversight agency, employer, life insurer or person who receives protected health information under section 5213 may disclose protected health information to a law enforcement agency (other than a health oversight agency governed by section 5216) if the information is requested for use—

(1) in an investigation or prosecution of a health information trustee;

(2) in the identification of a victim or witness in a law enforcement inquiry; or

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(3) in connection with the investigation of criminal activity committed against the trustee or on premises controlled by the trustee.

(b) CERTIFICATION.—When a law enforcement agency (other than a health oversight agency) requests that a health information trustee disclose protected health information under this section, the law enforcement agency shall provide the trustee with a written certification that—

(1) specifies the information requested;

(2) states that the information is needed for a lawful purpose under this section; and

(3) is signed by a supervisory official of a rank designated by the head of the agency.

(c) RESTRICTIONS ON ADDITIONAL DISCLOSURE.—Notwithstanding section 5206(e), protected health information about an individual that is disclosed to a law enforcement agency under this section may be used in, or disclosed for, an administrative, civil, or criminal action or investigation against the individual if the action or investigation arises out of and is directly related to the action or investigation for which the information was obtained.

Subpart E—Disclosure Pursuant to Government Subpoena or Warrant

SEC. 5226. GOVERNMENT SUBPOENAS AND WARRANTS.

(a) IN GENERAL.—A health care provider, health plan, health oversight agency, employer, life insurer or person who receives protected health information under section 5213 may disclose protected health information under this section if the disclosure is pursuant to—

(1) a subpoena issued under the authority of a grand jury, and the trustee is provided a written certification by the grand jury seeking the information that the grand jury has complied with the applicable access provisions of section 5227;

(2) an administrative subpoena or a judicial subpoena or 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 5227; or

(3) an administrative subpoena or a judicial subpoena or warrant, and the disclosure otherwise meets the conditions of section 5216, 5217, 5221, or 5222.

(b) RESTRICTIONS ON ADDITIONAL DISCLOSURE.—

(1) ACTIONS OR INVESTIGATIONS.—Notwithstanding section 5206(c), protected health information about an individual that is received under sub-

section (a) may be disclosed for, or used in, any administrative, civil, or criminal action or investigation against the individual if the action or investigation arises out of and is directly related to the inquiry for which the information was obtained.

(2) SPECIAL RULE.—Protected health information about an individual that is received under subsection (a)(3) may not be disclosed by the recipient unless the recipient complies with the conditions and restrictions on disclosure with which the recipient would have been required to comply if the disclosure had been made under section 5216, 5217, 5221, or 5222.

SEC. 5227. ACCESS PROCEDURES FOR LAW ENFORCEMENT SUBPOENAS AND WARRANTS.

(a) PROBABLE CAUSE REQUIREMENT.—A government authority may not obtain protected health information about an individual under paragraph (1) or (2) of section 5226(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.—A government authority that obtains protected health information about an individual under circumstances described in subsection (a) and pur-

suant to a warrant shall, not later than 30 days after the date the warrant was executed, serve the individual with, or mail to the last known address of the individual, a notice that protected health information about the individual was so obtained, together with a notice of the individual's right to challenge the warrant in accordance with section 5228.

(c) SUBPOENAS.—Except as provided in subsection (d), a government authority may not obtain protected health information about an individual under circumstances described in subsection (a) and pursuant to a subpoena unless a copy of the subpoena has been served on the individual on or before the date of return of the subpoena, together with a notice of the individual's right to challenge the subpoena in accordance with section 5228, and—

(1) 30 days have passed since the date of service on the individual and within that time period the individual has not initiated a challenge in accordance with section 5228; or

(2) disclosure is ordered by a court after challenge under section 5228.

(d) APPLICATION FOR DELAY.—

(1) IN GENERAL.—A government authority may apply ex parte and under seal to an appropriate

court to delay (for an initial period of not longer than 90 days) serving a notice or copy of a subpoena required under subsection (b) or (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 notice, an order prohibiting the disclosure of the request for, or disclosure of, the protected health information, and an order requiring the disclosure of the protected health information 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;

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

(D) there is reasonable ground to believe that receipt of 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.

SEC. 5228. CHALLENGE PROCEDURES FOR LAW ENFORCEMENT WARRANTS AND SUBPOENAS.

(a) MOTION TO QUASH.—Within 30 days after the date of service of a notice of execution or a copy of a subpoena of a government authority seeking protected health information about an individual under paragraph (1) or (2) of section 5226(a), the individual may file a motion to quash—

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

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

(3) in the case of any other warrant or subpoena issued under the authority of a Federal court or the United States, in the United States district court for the district in which the individual resides or in which the warrant or subpoena was issued.

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

(c) PROCEEDINGS.—The government authority may file with the court such papers, including affidavits and other sworn documents, as sustain the validity of the warrant or subpoena. The individual may file with the court reply papers in response to the government authority's filing. The court, upon the request of the individual or the government authority or both, may proceed in camera. The court may conduct such proceedings as it deems appropriate to rule on the motion, but shall endeavor to expedite its determination.

(d) STANDARD FOR DECISION.—A court may deny a motion under subsection (a) if it finds there is probable cause to believe the protected health information is relevant to a legitimate law enforcement inquiry being conducted by the government authority, unless the court finds 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 by the government authority for the information.

(e) SPECIFIC CONSIDERATIONS WITH RESPECT TO PRIVACY INTEREST.—In reaching its determination, the court shall consider—

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

(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.

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

(g) NO INTERLOCUTORY APPEAL.—A ruling denying a motion to quash under this section shall not be deemed to be 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 protected health information disclosed.

Subpart F—Disclosure Pursuant to Private Party Subpoena

SEC. 5231. PRIVATE PARTY SUBPOENAS.

A health care provider, health plan, employer, life insurer, or person who receives protected health information under section 5213 may disclose protected health information under this section if the disclosure is pursuant to a subpoena issued on behalf of a private party who has complied with the access provisions of section 5232.

SEC. 5232. ACCESS PROCEDURES FOR PRIVATE PARTY SUBPOENAS.

A private party may not obtain protected health information about an individual pursuant to a subpoena unless a copy of the subpoena together with a notice of the individual's right to challenge the subpoena in accordance with section 5233 has been served upon the individual on or before the date of return of the subpoena, and—

(1) 30 days have passed since the date of service on the individual, and within that time period the individual has not initiated a challenge in accordance with section 5233; or

(2) disclosure is ordered by a court under section 5233.

SEC. 5233. CHALLENGE PROCEDURES FOR PRIVATE PARTY SUBPOENAS.

(a) MOTION TO QUASH SUBPOENA.—Within 30 days after service of a copy of the subpoena seeking protected health information under section 5231, the individual who is the subject of the protected health information may file in any court of competent jurisdiction a motion to quash the subpoena and serve a copy of the motion on the person seeking the information.

(b) STANDARD FOR DECISION.—The court shall grant a motion under subsection (a) unless the respondent demonstrates that—

(1) there is reasonable ground to believe the information is relevant to a lawsuit or other judicial or administrative proceeding; and

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

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

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

(2) the degree to which disclosure of the information would 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 relevant factor.

(d) ATTORNEY'S FEES.—In the case of a motion brought under subsection (a) in which the individual has substantially prevailed, the court may assess against the respondent a reasonable attorney's fee and other litigation

costs and expenses (including expert's fees) reasonably incurred.

PART 3—PROCEDURES FOR ENSURING SECURITY OF PROTECTED HEALTH INFORMATION

Subpart A—Establishment of Safeguards

SEC. 5236. ESTABLISHMENT OF SAFEGUARDS.

(a) IN GENERAL.—A health information trustee shall establish and maintain appropriate administrative, technical, and physical safeguards—

(1) to ensure the integrity and confidentiality of protected health information created or received by the trustee; and

(2) to protect against any anticipated threats or hazards to the security or integrity of such information.

(b) REGULATIONS.—The Secretary shall promulgate regulations regarding security measures for protected health information.

SEC. 5237. ACCOUNTING FOR DISCLOSURES.

(a) IN GENERAL.—

(1) REQUIREMENT TO CREATE OR MAINTAIN RECORD.—A health information trustee shall create and maintain, with respect to any protected health information disclosed in exceptional circumstances (as described in paragraph (2)), a record of—

(A) the date and purpose of the disclosure;

(B) the name of the person to whom or to which the disclosure was made;

(C) the address of the person to whom or to which the disclosure was made or the location to which the disclosure was made; and

(D) the information disclosed, if the recording of the information disclosed is practicable, taking into account the technical capabilities of the system used to maintain the record and the costs of such maintenance.

(2) EXCEPTIONAL CIRCUMSTANCES DESCRIBED.—For purposes of paragraph (1) protected health information is disclosed in exceptional circumstances if the disclosure—

(A) is not a routine part of doing business, as determined in accordance with guidelines promulgated by the Secretary; or

(B) is permitted under sections 5213 and 5217.

(b) DISCLOSURE RECORD PART OF INFORMATION.—A record created and maintained under paragraph (a) shall be maintained as part of the protected health information to which the record pertains.

Subpart B—Review of Protected Health Information By Subjects of the Information

SEC. 5241. INSPECTION OF PROTECTED HEALTH INFORMATION.

(a) IN GENERAL.—Except as provided in subsection (c), a health care provider or health plan—

(1) shall permit an individual who is the subject of protected health information to inspect any such information that the provider or plan maintains;

(2) shall permit the individual to have a copy of the information;

(3) shall permit a person who has been designated in writing by the individual who is the subject of the information to inspect, or to have a copy of, 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) ADDITIONAL REQUESTS.—Except as provided in subsection (c), a health plan or health care provider shall, upon written request of an individual—

(1) determine the identity of previous providers to the individual; and

(2) obtain protected health information regarding the individual.

(c) EXCEPTIONS.—A health care provider or health plan is not required by this section to permit inspection or copying of protected health information if any of the following conditions apply:

(1) MENTAL HEALTH TREATMENT NOTES.—The information consists of psychiatric, psychological, or mental health treatment notes, and the provider or plan determines, based on reasonable medical judgment, that inspection or copying of the notes would cause sufficient harm to the individual who is the subject of the notes so as to outweigh the desirability of permitting access, and the provider or plan has not disclosed 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 individual seeking to inspect or have a copy of the information and the provider or plan determines, based on reasonable medical judgment, that inspection or copying of the information would cause sufficient harm to 1 or both of the individuals so as to outweigh the desirability of permitting access.

(3) ENDANGERMENT TO LIFE OR SAFETY.—The provider or plan determines that disclosure of the information could reasonably be expected to endanger the life or physical safety of any individual.

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

(5) ADMINISTRATIVE PURPOSES.—The information—

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

(B) has not been disclosed by the provider or plan to any other person.

(d) INSPECTION AND COPYING OF SEGREGABLE PORTION.—A health care provider or health plan 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 (c).

(e) CONDITIONS.—A health care provider or health plan may require a written request for the inspection and

copying of protected health information under this subsection. The health care provider or health plan may require a cost reimbursement for such inspection and copying.

(f) STATEMENT OF REASONS FOR DENIAL.—If a health care provider or health plan denies a request for inspection or copying under this section, the provider or plan shall provide the individual who made the request (or the individual's designated representative) with a written statement of the reasons for the denial.

(g) DEADLINE.—A health care provider or health plan 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 on which the provider or plan receives the request.

SEC. 5242. AMENDMENT OF PROTECTED HEALTH INFORMATION.

(a) IN GENERAL.—A health care provider or health plan shall, within the 45-day period beginning on the date on which the provider or plan receives from an individual a written request that the provider or plan correct or amend the information—

(1) make the correction or amendment requested;

(2) inform the individual of the correction or amendment that has been made; and

(3) inform any person who is identified by the individual, who is not an officer, employee or agent of the provider or plan, and to whom the uncorrected or unamended portion of the information was previously disclosed, of the correction or amendment that has been made.

(b) REFUSAL TO CORRECT.—If the provider or plan refuses to make the corrections, the provider or plan shall inform the individual of—

(1) the reasons for the refusal of the provider or plan to make the correction or amendment;

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

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

(c) BASES FOR REQUEST TO CORRECT OR AMEND.—An individual may request correction or amendment of protected health information about the individual under paragraph (a) if the information is not timely, accurate, relevant to the system of records, or complete.

(d) STATEMENT OF DISAGREEMENT.—After an individual has filed a statement of disagreement under paragraph (b)(3), the provider or plan, in any subsequent disclosure of the disputed portion of the information—

(1) shall include a copy of the individual's statement; and

(2) may include a concise statement of the reasons of the provider or plan for not making the requested correction or amendment.

(e) RULE OF CONSTRUCTION.—This section shall not be construed to require a health care provider or health plan to conduct a formal, informal, or other hearing or proceeding concerning a request for a correction or amendment to protected health information the provider or plan maintains.

(f) CORRECTION.—For purposes of paragraph (a), a correction is deemed to have been made to protected health information when information that is not timely, accurate, relevant to the system of records, or complete is clearly marked as incorrect or when supplementary correct information is made part of the information.

SEC. 5243. NOTICE OF INFORMATION PRACTICES.

(a) PREPARATION OF WRITTEN NOTICE.—A health care provider or health plan shall prepare a written notice of information practices describing the following:

(1) PERSONAL RIGHTS OF AN INDIVIDUAL.—The rights under this subpart of an 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) PROCEDURES OF PROVIDER OR PLAN.—The procedures established by the provider or plan for the exercise of the rights of individuals about whom protected health information is maintained.

(3) AUTHORIZED DISCLOSURES.—The disclosures of protected health information that are authorized.

(b) DISSEMINATION OF NOTICE.—A health care provider or health plan—

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

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

(c) MODEL NOTICE.—The Secretary, after notice and opportunity for public comment, shall develop and dissemi-

nate a model notice of information practices for use by health care providers and health plans under this section.

Subpart C—Standards for Electronic Disclosures

SEC. 5246. STANDARDS FOR ELECTRONIC DISCLOSURES.

The Secretary shall promulgate standards for disclosing protected health information in accordance with this subtitle in electronic form. Such standards shall include standards relating to the creation, transmission, receipt, and maintenance, of any written document required or authorized under this subtitle.

PART 4—SANCTIONS

Subpart A—No Sanctions for Permissible Actions

SEC. 5251. NO LIABILITY FOR PERMISSIBLE DISCLOSURES.

A health information trustee who makes a disclosure of protected health information about an individual that is permitted by this subtitle shall not be liable to the individual for the disclosure under common law.

SEC. 5252. NO LIABILITY FOR INSTITUTIONAL REVIEW BOARD DETERMINATIONS.

If the members of an institutional review board make a determination in good faith that—

(1) a health research project is of sufficient importance to outweigh the intrusion into the privacy of an individual; and

(2) the effectiveness of the project requires use of protected health information,

the members, the board, and the parent institution of the board shall not be liable to the individual as a result of the determination.

SEC. 5253. RELIANCE ON CERTIFIED ENTITY.

If a health information trustee contracts with a certified health information network service to make a disclosure of any protected health information on behalf of such trustee in accordance with this subtitle and such service makes a disclosure of such information that is in violation of this subtitle, the trustee shall not be liable to the individual who is the subject of the information for such unlawful disclosure.

Subpart B—Civil Sanctions

SEC. 5256. CIVIL PENALTY.

(a) VIOLATION.—Any health information trustee who the Secretary determines has substantially failed to comply with this subtitle shall be subject, in addition to any other penalties that may be prescribed by law, to a civil penalty of not more than $10,000 for each such violation.

(b) PROCEDURES FOR IMPOSITION OF PENALTIES.—Section 1128A of the Social Security Act, other than subsections (a) and (b) and the second sentence of subsection (f) of that section, 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. 5257. CIVIL ACTION.

(a) IN GENERAL.—An individual who is aggrieved by conduct in violation of this subtitle may bring a civil action to recover—

(1) the greater of actual damages or liquidated damages of $5,000;

(2) punitive damages;

(3) a reasonable attorney's fee and expenses of litigation;

(4) costs of litigation; and

(5) such preliminary and equitable relief as the court determines to be appropriate.

(b) LIMITATION.—No action may be commenced under this section more than 3 years after the date on which the violation was or should reasonably have been discovered.

(c) TRANSFER OF PUNITIVE DAMAGES.—Of the total amount awarded for punitive damages in any civil action under this section, 95 percent shall be transferred to the Secretary to fund activities designed to ensure that the privacy of individuals is protected with respect to health information.

Subpart C—Criminal Sanctions

SEC. 5261. WRONGFUL DISCLOSURE OF PROTECTED HEALTH INFORMATION.

(a) OFFENSE.—A person who knowingly—

(1) obtains protected health information relating to an individual in violation of this subtitle; or

(2) discloses protected health information to another person in violation of this subtitle,

shall be punished as provided in subsection (b).

(b) PENALTIES.—A person described in subsection (a) shall—

(1) be fined not more than $50,000, imprisoned not more than 1 year, or both;

(2) if the offense is committed under false pretenses, be fined not more than $100,000, imprisoned not more than 5 years, or both; and

(3) if the offense is committed with intent to sell, transfer, or use protected health information for commercial advantage, personal gain, or malicious harm, fined not more than $250,000, imprisoned not more than 10 years, or both.

PART 5—ADMINISTRATIVE PROVISIONS

SEC. 5266. RELATIONSHIP TO OTHER LAWS.

(a) STATE LAW.—Except as provided in subsections (b), (c), and (d), this subtitle preempts State law.

(b) LAWS RELATING TO PUBLIC OR MENTAL HEALTH.—Nothing in this subtitle shall be construed to preempt or operate to the exclusion of any State law relating to public health or mental health that prevents or regulates disclosure of protected health information otherwise allowed under this subtitle.

(c) PRIVILEGES.—Nothing in this subtitle is intended to preempt or modify State common or statutory law to the extent such law concerns a privilege of a witness or person in a court of the State. This subtitle does not supersede or modify Federal common or statutory law to the extent such law concerns a privilege of a witness or person in a court of the United States. Authorizations pursuant to section 5207 shall not be construed as a waiver of any such privilege.

(d) CERTAIN DUTIES UNDER STATE OR FEDERAL LAW.—This subtitle shall not be construed to preempt, supersede, or modify the operation of—

(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); or

(4) any Federal law or regulation governing confidentiality of alcohol and drug patient records.

SEC. 5267. RIGHTS OF INCOMPETENTS.

(a) EFFECT OF DECLARATION OF INCOMPETENCE.—Except as provided in section 5268, if an individual has been declared to be incompetent by a court of competent jurisdiction, the rights of the individual under this subtitle shall be exercised and discharged in the best interests of the individual through the individual's representative.

(b) NO COURT DECLARATION.—Except as provided in section 5268, if a health care provider determines that an individual, who has not been declared to be incompetent by a court of competent jurisdiction, 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 may be exercised and discharged in the best interest of the individual by the individual's representative.

SEC. 5268. EXERCISE OF RIGHTS.

(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; or

(2) who, acting alone, has the legal right, as determined by State law, to apply for and obtain a type of medical examination, care, or treatment and who has sought such examination, care, or treatment, the individual shall exercise all rights of an individual under this subtitle with respect to protected health information relating to such examination, care, or treatment.

(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 rights of inspection and amendment, and the right to authorize disclosure of protected health information of the individual may be exercised either by the individual or by the parent or legal guardian of the individual.

Subtitle D—Review of Benefit Determinations for Enrolled Individuals

SEC. 5301. DEFINITIONS.

For purposes of this subtitle—

(1) CLAIM.—The term "claim" means—

(A) a request for payment for or provision of a health care intervention under a health plan;

(B) a request for preauthorization of a health care intervention which is submitted to a health plan prior to receipt of such intervention;

(C) a request for a utilization review of a health care intervention which is submitted to a health plan prior to or concurrent with receipt of such intervention;

(D) a request for a determination on enrollment or disenrollment of an individual in a health plan; or

(E) a request for a determination on whether an individual is eligible for coverage under a health plan.

(2) CLAIMANT.—The term "claimant" with respect to a claim means—

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(A) any individual who submits the claim, or on whose behalf a claim is submitted, to a health plan in connection with the individual's enrollment under the plan; or

(B) a provider with a valid assignment who submits a claim to the plan.

(3) HEALTH CARE INTERVENTION.—The term "health care intervention" has the meaning given such term by section 1101(4).

SEC. 5302. CLAIMS PROCEDURES FOR HEALTH PLANS.

(a) GENERAL RULES GOVERNING TREATMENT OF CLAIMS.—

(1) ADEQUATE NOTICE OF DISPOSITION OF CLAIM.—

(A) CLAIM IN COMPLETE FORM.—In any case in which a claim is submitted in complete form to a health plan, the plan shall provide to the claimant with respect to the claim a written notice of—

(i) the plan's approval of the claim within 25 days after the date of the submission of the claim; or

(ii) the plan's denial of the claim within the earlier of—

(I) 25 days after such date of submission, or

(II) 5 days after the date of the determination to deny the claim.

The notice of denial shall set forth the reasons for the denial, clearly explain the right to request an explanation under paragraph (2) of the specific reasons and facts underlying the decision to reduce or fail to provide the health care intervention or to pay the claim, the right to appeal the denial pursuant to this subtitle, and a description of the process for appealing such decision sufficient to allow the claimant to initiate appeals and submit evidence to the decision maker in support of the position of the claimant.

(B) CLAIM IN INCOMPLETE FORM.—In any case in which a claim that is submitted is not complete, the health plan shall within 15 days after the date on which the claim is submitted notify the claimant of any required matter remaining to be filed in order to complete the claim and to respond to questions the claimant may have about completing the claim.

(C) FAILURE TO COMPLY WITH TIME LIMITS TREATED AS APPROVAL.—The failure by any health plan to comply with any time limits of this paragraph with respect to any claim submitted to the plan shall be treated as approval by the plan of the claim.

(D) FORM OF NOTICE.—Any notice to the claimant under this paragraph shall be written in language easily calculated to be understood by an average individual enrolled in the plan.

(2) ADDITIONAL NOTICE AND DISCLOSURE REQUIREMENTS FOR HEALTH PLANS.—In the case of a denial of a claim, upon written request of the claimant, the plan shall provide, within 10 working days of the request, a response which includes, together with the reasons provided to the claimant under paragraph (1)(A)—

(A) if the denial is based in whole or in part on a determination that the claim is for a health care intervention which is not covered by the applicable benefits package, the factual basis for the determination;

(B) if the denial is based in whole or in part on exclusion of coverage with respect to a health care intervention because the interven-

tion is not a qualified investigational treatment (as defined in section 1101(7)), the basis for the determination and a description of the process used in making the determination; and

(C) if the denial is based in whole or in part on a determination that the health care intervention is not medically necessary or appropriate, the basis for the determination, and a description of the process used in making the determination.

(3) PLAN'S DUTY TO REVIEW DENIALS UPON TIMELY REQUEST.—The health plan shall review its denial of a claim if the claimant submits to the plan a written request for reconsideration of the claim after receipt of written notice from the plan of the denial. The plan shall allow any such claimant not less than 60 days after receipt of written notice from the plan of the denial or, if no such notice was received, from the date claimant discovers, or reasonably should have discovered, the denial, to submit the claimant's request for reconsideration of the claim.

(4) TIME LIMIT FOR REVIEW.—The health plan shall complete any review required under paragraph (3), and shall provide the claimant written notice of

the plan's decision on the claim after reconsideration pursuant to the review, within 30 days after the date of the receipt of the request for reconsideration.

(5) DE NOVO REVIEWS.—

(A) IN GENERAL.—Any review required under paragraph (3)—

(i) shall be de novo;

(ii) shall be conducted by an individual who did not make the initial decision denying the claim and who is authorized to approve the claim; and

(iii) shall include review by—

(I) a qualified physician with similar expertise to the treating physician if the resolution of any issues involved requires medical expertise, or

(II) a certified medical reviewer.

(B) CERTIFIED MEDICAL REVIEWERS.—The Secretary of Labor, in consultation with the Secretary, shall by regulation—

(i) establish qualifications and standards for certified medical reviewers; and

(ii) establish procedures for the certification or decertification of such reviewers.

Certified medical reviewers shall be recognized experts in their medical fields and shall not be employees of health plans.

(c) TREATMENT OF URGENT REQUESTS TO PLANS FOR PREAUTHORIZATION AND UTILIZATION REVIEW.—

(1) IN GENERAL.—This subsection applies in the case of any claim submitted by the claimant consisting of a request for preauthorization of or a utilization review determination with respect to a health care intervention (other than an emergency health care intervention which may not be subject to preauthorization or utilization review) which is accompanied by an attestation by the treating physician that—

(A) failure to immediately or within 10 days provide the health care intervention could reasonably be expected to result in—

(i) placing the health of the claimant (or, with respect to a claimant who is a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, or

(ii) serious impairment to bodily functions which may lead to death; or

(B) immediate provision of the health care intervention is necessary because the claimant

has made or is at serious risk of making an attempt to harm such claimant or another individual.

A request for preauthorization or a utilization review determination with respect to a health care intervention may be filed under this subsection at any time prior to completion by the plan of any review conducted pursuant to subsection (b)(3).

(2) SHORTENED TIME LIMIT FOR CONSIDERATION OF URGENT REQUESTS.—Notwithstanding subsection (a)(1), a health plan shall approve or deny any claim in complete form described in paragraph (1) within 3 days after submission of the claim to the plan, except that a hearing officer may, pursuant to section 5304(e), order a plan to render a decision in less than 3 days. Failure by the plan to comply with the time limits of this paragraph with respect to the claim shall be treated as approval by the plan of the claim.

(3) EXPEDITED EXHAUSTION OF PLAN REMEDIES.—Any claim described in paragraph (1) or any claim for an emergency health care intervention which is denied by the health plan shall be treated as a claim with respect to which all remedies under the plan provided pursuant to this section are ex-

hausted, irrespective of any review provided under subsection (b)(3).

(4) DENIAL OF PREVIOUSLY AUTHORIZED CLAIMS NOT PERMITTED.—In any case in which a health plan approves a claim described in paragraph (1)—

(A) the plan may not subsequently deny payment or provision of benefits pursuant to the claim, unless the claimant, or another individual, misrepresented or failed to disclose a material fact;

(B) in the case of a violation of subparagraph (A) in connection with the claim, all remedies under the plan provided pursuant to this section with respect to the claim shall be treated as exhausted; and

(C) notwithstanding subparagraph (A), subsequent to the preauthorization of or utilization review determination with respect to the health care intervention which is the subject of the claim, the plan may deny payment in the case of a change in the claimant's eligibility under the plan.

(d) DETERMINATION OF INCOMPLETENESS OF CLAIM.—A claim shall be considered submitted in com-

plete form when the health plan is in receipt of all information reasonably required by the plan to make a decision on the claim.

(e) WAIVER OF RIGHTS PROHIBITED.—A health plan may not require any party to waive any right under the plan or this Act as a condition for approval of any claim under the plan, except to the extent otherwise specified in a formal settlement agreement.

SEC. 5303. REVIEW IN AREA CLAIMS DISPUTE OFFICES OF GRIEVANCES BASED ON ACTS OR PRACTICES BY HEALTH PLANS.

(a) CLAIMS DISPUTE OFFICES.—The Secretary of Labor shall establish and maintain claims dispute offices which shall have exclusive jurisdiction over complaints described in subsection (c).

(b) APPOINTMENT AND QUALIFICATIONS OF HEARING OFFICERS.—The Secretary of Labor may retain or employ hearing officers for the claims dispute offices. No individual may serve as a hearing officer unless the individual meets standards which shall be prescribed by the Secretary of Labor. Such standards shall include, but not be limited to, experience in the health benefits area, training, ability to communicate with the claimant, affiliations, diligence, absence of actual or potential, conflicts of inter-

est, and other qualifications deemed relevant by the Secretary of Labor.

(c) FILINGS OF COMPLAINTS.—

(1) IN GENERAL.—A claimant may file a complaint regarding a claim with the appropriate claims dispute office if such claimant is aggrieved by an act or practice engaged in by a health plan which consists of, or results in, a denial or delay of payment or provision of benefits under the plan, if such denial or delay consists of a failure to comply with the terms of the plan (including the provision of benefits in full when due in accordance with the terms of the plan) or consists of a failure to comply with the applicable requirements of this Act.

(2) EXCEPTION.—Paragraph (1) shall not apply in the case of a claim for payment for a health care intervention which has already been rendered to the claimant if such claim is for less than $500.

(d) EXHAUSTION OF PLAN REMEDIES.—No complaint may be filed until the claimant has exhausted all remedies (as defined by this subtitle) provided under the plan with respect to the claim in accordance with section 5302.

(e) PROCEDURES.—The Secretary of Labor shall promulgate rules governing the filing, service, and disposition

of complaints filed pursuant to this section, including procedures for the amendment of complaints, answers or responses to complaints, and for the submission and disposition of any related motions.

(f) TIME LIMITATION.—Complaints shall be filed not later than 60 days after receipt by the claimant of the written notice of the plan's decision upon review.

(g) EXCLUSIVE PROCEDURE.—Except as provided in section 5305 and the amendments made by section 5308, and notwithstanding any other provision of this Act or any other law, the filing of a complaint with the claims dispute office shall be the sole and exclusive means of seeking redress with respect to any act or practice described in subsection (c).

SEC. 5304. PROCEEDINGS BEFORE HEARING OFFICERS IN CLAIMS DISPUTE OFFICES.

(a) ASSIGNMENT OF COMPLAINTS TO HEARING OFFICERS.—Upon filing, a complaint shall be assigned to a hearing officer. At no time shall a hearing officer have any official, financial, or personal conflict of interest with respect to issues in controversy before the hearing officer.

(b) MEDIATION.—

(1) IN GENERAL.—Within 30 days of the filing of the complaint, and prior to rendering a final decision, the hearing officer shall attempt to mediate the

dispute and shall convene at least one mediation conference. Such conference may be conducted in person or through electronic communication.

(2) INAPPLICABILITY OF FORMAL RULES.—Formal rules of evidence shall not apply to mediation conferences.

(3) CONFIDENTIALITY.—

(A) IN GENERAL.—Under regulations of the Secretary of Labor, rules similar to the rules under section 574 of title 5, United States Code (relating to confidentiality in dispute resolution proceedings), shall apply to the mediation conference.

(B) CIVIL REMEDIES.—The Secretary of Labor may assess a civil penalty against any individual who discloses information in violation of the regulations prescribed pursuant to subparagraph (A) in the amount of 3 times the amount of the claim involved. The Secretary of Labor may bring a civil action to enforce such civil penalty in the United States district court for the district in which is located the claims dispute office within which the complaint was filed under section 5303.

(4) PROCESS NON-BINDING.—Any findings and conclusions made in the mediation conference shall be treated as advisory in nature and non-binding. Statements made in the course of the conference shall not be admissible in any other proceedings.

(5) ENFORCEMENT.—Any party to a settlement agreement entered into pursuant to a mediation conference under this subtitle may, in the case of an alleged violation of such agreement, petition the United States district court for the district in which is located the claims dispute office within which the complaint was filed under section 5303 for the enforcement of the agreement. In any such action, a prevailing claimant shall be entitled to reasonable costs and expenses (including a reasonable attorney's fee and reasonable expert witness fees) on the charges on which the claimant prevails.

(c) ADJUDICATIONS.—

(1) IN GENERAL.—If the matters in the complaint are not resolved through mediation, the hearing officer shall determine whether the claimant is entitled to relief but only on the basis of submissions in writing.

(2) STANDARD OF REVIEW.—

(A) PAYMENT DISPUTES.—In the case of a complaint based upon claim for payment for a health care intervention which has already been rendered to the claimant, the hearing officer shall review the decision of the health plan to determine—

(i) whether the plan's decision is justified by substantial evidence based on the record considered as a whole;

(ii) whether the plan's decision is in excess of statutory jurisdiction, authority, or limitations, in violation of a statutory right, or otherwise not in accordance with the law; or

(iii) whether the determination is without observance of procedure required by law, taking due account of the rule of prejudicial error.

(B) OTHER DISPUTES.—With respect to a complaint other than one described in subparagraph (A), the hearing officer shall determine all issues de novo. The claimant shall have the burden of proving each element of the complaint by a preponderance of the evidence. A determination by a certified medical reviewer

that a health care intervention is not medically necessary or appropriate shall be rebuttably presumed to be correct if such determination meets the requirements of section 1106(c)(1).

(3) TESTIMONY.—The testimony taken by the hearing officer shall be in the form of affidavits or declarations submitted under oath.

(4) AUTHORITY OF HEARING OFFICERS.—The hearing officer may compel by subpoena the production of evidence in written form. In case of contumacy or refusal to obey a subpoena lawfully issued under this paragraph and upon application of the hearing officer, the United States district court for the district in which the claims dispute office is located may issue an order requiring compliance with the subpoena.

(d) DECISION OF HEARING OFFICER.—

(1) IN GENERAL.—Not later than 120 days after the date on which a complaint is filed, the hearing officer shall issue a written decision. Each such written decision—

(A) shall include the hearing officer's findings of fact; and

(B) shall constitute the hearing officer's final disposition of the proceedings.

(2) DECISIONS FINDING IN FAVOR OF CLAIMANT.—If the hearing officer's decision includes a determination that any party named in the complaint has engaged in or is engaged in an act or practice described in section 5303(c), the hearing officer shall issue and cause to be served on such party an order which requires such party—

(A) to provide the benefits due under the terms of the plan and to otherwise comply with the terms of the plan and the applicable requirements of this Act;

(B) to pay to the claimant prejudgment interest on the actual costs incurred in obtaining the health care intervention at issue in the complaint; and

(C) to pay to the prevailing claimant costs, including a reasonable attorney's fee, reasonable expert witness fees, and other reasonable costs relating to the hearing on the charges on which the claimant prevails.

(3) DECISIONS NOT IN FAVOR OF CLAIMANT.—If the hearing officer's decision includes a determination that the party named in the complaint has not engaged in or is not engaged in an act or practice referred to in section 5303(c) with respect to

any charge in the complaint on which the claimant does not prevail, the hearing officer—

(A) shall include in the decision a dismissal with prejudice of the charge; and

(B) upon a finding that such charge is frivolous, shall issue and cause to be served on the claimant an order which requires the claimant to pay to such party a reasonable attorney's fee, reasonable expert witness fees, and other reasonable costs relating to the proceedings on such charge.

In determining whether a charge is frivolous, the court shall consider whether the claimant was appearing pro se or with the assistance of counsel.

(e) TREATMENT OF URGENT REQUESTS FOR PREAUTHORIZATION AND UTILIZATION REVIEW.—

(1) IN GENERAL.—In the case of an urgent request for preauthorization of or a utilization review determination made to a plan under section 5302(c), a complaint may be filed with a complaint dispute office at any time after a request has been submitted to the plan under section 5302(c), regardless of whether the plan has rendered a decision on such a request. Any complaint filed pursuant to this para-

graph shall be accompanied by a request for expedited consideration.

(2) REQUEST FOR EXPEDITED CONSIDERATION.—A claimant may, at any time prior to issuance of a final decision by a hearing officer, request expedited consideration with respect to any complaint filed by the claimant. Any request for expedited consideration shall be accompanied by the attestation by the treating physician described in section 5302(c)(1).

(3) REQUEST FOR IMMEDIATE PLAN DECISION.—Upon receipt of a request for expedited consideration, if the plan has not already rendered a decision with respect to the request, the hearing officer may order the plan to render such decision within such time as the officer believes is necessary to prevent harm to the claimant or another individual.

(4) HEARING AND DECISION.—Upon receipt of a request for expedited consideration, the hearing officer shall set a time and date for a hearing on both the complaint and request for expedited consideration. Such hearing shall occur within 3 days of the time set by the hearing officer for a decision by the plan. Such hearing may be conducted electronically

or in person, and the hearing officer shall issue a written decision immediately.

(5) TEMPORARY EMERGENCY ORDER.—Subject to the requirements of Rule 65 of the Federal Rules of Civil Procedure (as applied to temporary restraining orders), a hearing officer may grant a temporary emergency order if the claimant demonstrates—

(A) a substantial likelihood of success on the merits;

(B) that irreparable injury will result in the absence of the requested relief;

(C) that no other parties will be harmed if temporary relief is granted; and

(D) that the public interest favors entry of a temporary emergency order.

In any instance in which a temporary emergency order is issued, the hearing officer shall as soon as possible thereafter conduct a hearing pursuant to paragraph (4).

(f) REVIEW.—

(1) IN GENERAL.—Unless an appeal is taken as provided in this subsection, the decision of the hearing officer shall be final and binding upon all parties. Any party may, within 60 days after service of the decision by the claims dispute office, file an ap-

peal of the decision with the United States court of appeals for the circuit in which the claims dispute office is located.

(2) SCOPE OF REVIEW.—The court of appeals shall review the decision of the hearing officer from which the appeal is made, except that the review shall be only for the purposes of determining—

(A) whether the determination is supported by substantial evidence on the record considered as a whole;

(B) whether the determination is in excess of statutory jurisdiction, authority, or limitations, in violation of a statutory right, or otherwise not in accordance with the law; or

(C) whether the determination is without observance of procedure required by law, taking due account of the rule of prejudicial error.

(3) FURTHER REVIEW.—Upon the filing of the record with the court, the jurisdiction of the court shall be exclusive and its judgment shall be final, subject only to review as provided in section 1254 of title 28 of the United States Code.

(4) AWARDING OF ATTORNEYS' FEES AND OTHER COSTS AND EXPENSES.—

(A) IN GENERAL.—In any judicial proceeding under this subsection, the court may, in its discretion, award to a prevailing claimant reasonable costs and expenses (including a reasonable attorney's fee) on the causes on which the claimant prevails.

(B) DENIAL OF COMPLAINT.—Upon a finding that a complaint is frivolous, the court may, in its discretion, award to the party named in the complaint reasonable costs and expenses (including a reasonable attorney's fee).

(g) COURT ENFORCEMENT OF ORDERS.—

(1) IN GENERAL.—If a final decision of a hearing officer is not appealed under subsection (f), any party may petition the United States district court for the district in which the claims dispute office is located for enforcement of the order. In any such proceeding, the order of the hearing officer shall not be subject to review.

(2) AWARDING OF COSTS.—In any action by a claimant for court enforcement under this subsection, a prevailing claimant shall be entitled to costs, including a reasonable attorney's fee, reasonable expert witness fees, and other reasonable costs relating to such action.

(h) REPRESENTATION.—Parties may participate pro se or be represented by attorneys in all proceedings with respect to a complaint filed pursuant to this section.

SEC. 5305. SMALL CLAIMS DISPUTES.

(a) CIVIL ACTION.—Any claimant aggrieved, with respect to a health care intervention already rendered to the claimant, by a failure to pay for such intervention under the plan, may, if the amount of such payment is less than $500, commence a civil action to recover the amount of the claim in any court of competent jurisdiction.

(b) EXHAUSTION OF PLAN REMEDIES.—No complaint may be filed until the claimant has exhausted all remedies (as defined by this subtitle) provided under the plan with respect to the claim in accordance with section 5302.

(c) STANDARD OF REVIEW AND BURDEN OF PROOF.—In any action filed pursuant to subsection (a), the court shall review the decision of the health plan in accordance with the standards set forth in section 5304(c)(2)(A).

(d) REMEDIES.—The sole remedy available to the prevailing claimant shall be the amount of the payment for benefits under the plan and costs, including a reasonable attorney's fee.

(e) FEDERAL COURT JURISDICTION.—The district courts of the United States shall not have jurisdiction based on section 1331 or 1337 of title 28, United States Code, over any civil action brought pursuant to this section. An action brought in a State court pursuant to this section shall not be subject to removal to Federal court without regard to the citizenship or residence of the parties.

SEC. 5306. ALTERNATIVE BINDING ARBITRATION.

(a) IN GENERAL.—A health plan may establish an alternative claims dispute arbitration procedure, and may require claimants to use such procedure in lieu of review by a claims dispute office pursuant to sections 5303 and 5304, but only as provided in this section.

(b) CONSUMER PROTECTION STANDARDS.—The Secretary of Labor shall by regulation develop and promulgate minimum consumer protection standards for any alternative claims dispute arbitration procedure adopted by a plan pursuant to this section. Such minimum consumer protections should include provisions governing—

(1) the time frame for decisions, including urgent decisions, by the alternative claims dispute resolution process;

(2) the selection and compensation of a neutral third party arbitrator;

(3) publication of decisions of any third party arbitrator, and filing of such decisions with the Department of Labor;

(4) expertise and qualifications of any third party arbitrators;

(5) compliance with the provisions of this Act;

(6) enforceability of an arbitrator's award, including provisions to have a judgment of a United States district court entered upon the award, pursuant to section 8 of title 9, United States Code;

(7) the provision of adequate and prominent notice to claimants that such alternative claims dispute arbitration is the sole and exclusive means of claims dispute resolution under the plan;

(8) procedures for consideration of urgent review requests that provide protection to claimants functionally equivalent to the protections provided under section 5304(e).

(c) STANDARDS OF REVIEW AND PROOF.—

(1) IN GENERAL.—In any arbitration conducted pursuant to this section, the arbitrator shall hear complaints and motions under the standard of review prescribed in section 5304(c)(2).

(2) BURDEN OF PROOF.—The claimant shall have to meet the burden of proof on the contents of

the claimant's complaint by a preponderance of the evidence.

(d) REMEDIES.—The remedies available to the arbitrator shall be the same as those provided in paragraphs (2) and (3) of section 5304(d).

(e) CERTIFICATION OF ARBITRATION PROCESSES.—Before claimants can be required to agree to arbitration as a condition of receiving benefits under the plan, the plan must be certified by the Secretary of Labor as complying with the consumer protection standards issued by the Secretary pursuant to subsection (b).

(f) WITHDRAWAL OF CERTIFICATION.—With respect to any plan that has received certification from the Secretary of Labor pursuant to subsection (e), the Secretary may, either upon petition or upon the Secretary's own motion, withdraw such certification after notice to the plan and opportunity for a hearing, if the Secretary concludes that the plan is not in compliance with the consumer protection standards issued pursuant to subsection (b). The Secretary may provisionally withdraw such certification without notice and a hearing if the Secretary determines that the plan's violations of consumer protection standards pose a significant and imminent danger to the health of claimants. In the event of such a provisional withdrawal, the Secretary shall, within 5 working days, afford the plan

the opportunity for a hearing to determine whether such withdrawal shall become permanent.

(g) APPLICABILITY OF ARBITRATION ACT.—The provisions of title 9, United States Code, shall apply to all arbitrations conducted pursuant to this section.

SEC. 5307. CIVIL MONEY PENALTIES.

(a) BAD FAITH PLANS.—The Secretary of Labor may assess a civil penalty against any health plan in an amount not to exceed $750,000, upon a finding by clear and convincing evidence of a pattern or practice of denial or delay in the payment or provision of benefits thereunder without any reasonable basis and carried out in bad faith.

(b) DEFINITIONS.—For purposes of this section—

(1) a health plan shall be treated as engaging in a pattern or practice if, with respect to violations, the health plan or those who act on its behalf have knowingly engaged in such violations with such frequency and regularity as to indicate a general practice to engage in that type of conduct; and

(2) the term "bad faith" means the willful or reckless—

(A) failure to pay a claim within 20 business days after the plan has determined that the claimant has established eligibility for receipt of the benefit and there is no reasonable

basis for questioning the claimant's eligibility for receipt of the benefit,

(B) requirement of a claimant to file a complaint to recover a claim when there is no reasonable basis for questioning the claimant's eligibility for receipt of the benefit, or

(C) refusal to pay a claim following a failure to conduct an investigation of the claim requested by a claimant.

(c) MISREPRESENTATION.—Upon petition by a plan, the Secretary of Labor may assess a civil monetary penalty in an amount not to exceed the greater of $2,000 or 2 times the amount of the claim—

(1) against a claimant, upon a finding that claimant, or another individual whose misrepresentation or failure to disclose is known to the claimant, knowingly and willfully misrepresented or failed to disclose a material fact with respect to a claim submitted for urgent review pursuant to section 5302(c); or

(2) against an individual other than the claimant, upon a finding that such individual knowingly and willfully misrepresented or failed to disclose a material fact with respect to a claim submitted for urgent review pursuant to section 5302(c).

(d) CIVIL ACTION TO ENFORCE CIVIL PENALTY.—The Secretary of Labor may commence a civil action in the United States district court for the district in which the defendant resides to enforce a civil penalty assessed under subsections (a) or (c).

SEC. 5308. TECHNICAL AMENDMENTS.

(a) Section 502(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(a)) is amended—

(1) in paragraph (1)(A), by inserting "except for an action relating to a health plan (as defined in section 3(a) of the Health Reform Act)," before "to recover"; and

(2) in paragraph (3), by inserting "except for an action relating to a health plan (as so defined)," before "by a participant".

(b) Section 503 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1133) is amended by inserting ", other than a health plan (as defined in section 3(a) of the Health Reform Act)," after "every employee benefit plan".

SEC. 5309. REASONABLE CARE IN CONDUCTING PREAUTHORIZATION AND UTILIZATION REVIEW.

(a) IN GENERAL.—Any individual or entity who both—

(1) conducts a preauthorization or utilization review with respect to a health care intervention requested under a health plan, prior to receipt by the claimant of such intervention; and

(2) in the course of conducting such preauthorization or utilization review determines whether a health care intervention is medically necessary or appropriate,

shall exercise reasonable care with respect to all medical judgments made in the course of such review.

(b) STANDARD OF CARE.—The standard of care of an individual or entity described in subsection (a) shall be that of a similarly situated, reasonably prudent individual or entity conducting a preauthorization or utilization review who is determining whether a health care intervention is medically necessary or appropriate.

(c) PRIVATE RIGHT OF ACTION.—

(1) IN GENERAL.—Except as provided in paragraph (2), any claimant (other than a provider), or the estate or successor of such claimant, aggrieved by a violation of subsection (a), may bring an action

against the individual or entity who conducted such review in a court of competent jurisdiction where the claimant resides, where the health care intervention was rendered or was to be rendered, or where the preauthorization or utilization review is conducted.

(2) NO ACTION AGAINST CERTIFIED MEDICAL REVIEWER.—No action may be brought under this section against a certified medical reviewer.

(d) ELEMENTS OF AN ACTION.—In any action brought pursuant to subsection (c), such a claimant shall demonstrate, by a preponderance of the evidence, that—

(1) the defendant failed to use reasonable care in exercising medical judgment with respect to determining whether a health care intervention requested by the claimant, or on behalf of such claimant, was medically necessary or appropriate with respect to a preauthorization or utilization review under the claimant's plan;

(2) such failure to exercise reasonable care was the actual and proximate cause of a material delay in the provision, or denial, of the health care intervention actually covered by the plan;

(3) such delay or denial of the health care intervention covered by the plan actually and proxi-

mately resulted in actual and demonstrable physical injury to the claimant; and

(4) the claimant, or the agent of such claimant, exhausted all remedies available pursuant to sections 5303 through 5306, including, where appropriate, remedies for urgent review.

(e) DEFENSES.—

(1) IN GENERAL.—It shall be a complete defense to any action brought pursuant to subsection (c) that a hearing officer, acting pursuant to sections 5303 and 5304, or, where appropriate, an arbitrator conducting an alternative claims dispute arbitration pursuant to section 5306, affirmed or concurred in the preauthorization or utilization review determination.

(2) MITIGATION.—Any claimant who brings an action pursuant to this section shall have a duty to take all reasonable actions to mitigate harm or otherwise, where affordable, to obtain the health care intervention. In the event the court determines that the claimant failed to take all reasonable actions to mitigate harm, the court shall determine the proportion of claimant's injury attributable to such failure to take reasonable actions to mitigate harm, and

shall diminish proportionately any amount awarded as damages.

(f) PRESUMPTIONS.—An individual or entity that conducts a preauthorization or utilization review with respect to a health care intervention and that, in the course of such review, relies in good faith on—

(1) a coverage recommendation issued by the National Health Benefits and Coverage Commission pursuant to section 1104(b);

(2) a practice guideline described in section 1104(a); or

(3) a decision by a certified medical reviewer that the requested health care intervention was not medically necessary or appropriate,

shall be rebuttably presumed to have used reasonable care with respect to medical judgments incorporated in such recommendation, guideline, or decision. The failure of such individual or entity to follow such recommendation or guideline or to request such a decision shall not give rise to a presumption that such individual failed to exercise reasonable care.

(g) REMEDIES.—In any action brought pursuant to subsection (c), a court may award with respect to a violation of subsection (a)—

(1) compensatory economic damages; and

(2) compensatory non-economic damages, the total amount of which shall not exceed the greater of $100,000 (indexed annually based on the Consumer Price Index), or 2 times the amount of the benefits claim, the decision with respect to which forms the basis of the action, regardless of the number of actions brought with respect to such violation.

A court may not award punitive damages.

(h) SEVERAL LIABILITY.—With respect to any action brought pursuant to this section, the liability of each defendant joined in such action for non-economic damages shall be several only, and shall not be joint. Each defendant shall be liable only for the amount of non-economic damages allocated to such defendant in direct proportion to such defendant's percentage of responsibility. The court shall determine the proportion of responsibility of each party for claimant's harm.

(i) LIMITATION ON ATTORNEY'S CONTINGENCY FEES.—With respect to an attorney or attorneys who represent, on a contingency fee basis, a claimant or claimants in an action brought pursuant to this section, the total amount of such fees that may be charged, received, or collected for services rendered in connection with such action shall not exceed—

(1) 33 1/3 percent of the first $150,000 of the total amount recovered by judgment or settlement in such action (based on after tax recovery); plus

(2) 25 percent of any amount recovered in excess of the amount described in paragraph (1).

(j) ALTERNATIVE DISPUTE RESOLUTION PRESERVED.—Nothing in this section shall be construed as prohibiting parties from agreeing to resolve disputes under this section pursuant to private contractual arrangements.

(k) DEFINITIONS.—For the purposes of this section—

(1) the term "compensatory economic damages" means any damages awarded medical expense loss, work loss, replacement services loss, loss due to death, and burial costs, but excluding amounts paid or to be paid by the health plan;

(2) the term "compensatory non-economic damages" means any damages (other than punitive damages) awarded for subjective, non-monetary loss resulting from a violation of subsection (a), including, but not limited to, pain, suffering, emotional distress, loss of society and companionship, loss of consortium, but excluding pecuniary loss or loss for mere inconvenience or frustration resulting from delay; and

(3) the term "contingency fee" means all compensation for professional legal services which is payable only if a recovery is effected on behalf of one or more claimants.

SEC. 5310. EXCLUSIVE REMEDIES.

Notwithstanding any other provision of State law and any other provision of this Act, the provisions of this subtitle shall constitute the exclusive remedies with respect to a claim, or the manner of conducting a preauthorization or utilization review with respect to health care interventions requested under a health plan.

Subtitle E—Enhanced Penalties for Health Care Fraud

PART 1—ALL-PAYER FRAUD AND ABUSE CONTROL PROGRAM

SEC. 5401. ALL-PAYER FRAUD AND ABUSE CONTROL PROGRAM.

(a) ESTABLISHMENT OF PROGRAM.—

(1) IN GENERAL.—Not later than January 1, 1995, the Secretary of Health and Human Services (in this subtitle referred to as the "Secretary"), acting through the Office of the Inspector General of the Department of Health and Human Services, and the Attorney General shall establish a program—

(A) to coordinate Federal, State, and local law enforcement programs to control fraud and abuse with respect to the delivery of and payment for health care in the United States,

(B) to conduct investigations, audits, evaluations, and inspections relating to the delivery of and payment for health care in the United States,

(C) to facilitate the enforcement of the provisions of sections 1128, 1128A, and 1128B of the Social Security Act and other statutes applicable to health care fraud and abuse, and

(D) to provide for the modification and establishment of safe harbors and to issue interpretative rulings and special fraud alerts pursuant to section 5403.

(2) COORDINATION WITH HEALTH PLANS.—In carrying out the program established under paragraph (1), the Secretary and the Attorney General shall consult with, and arrange for the sharing of data with representatives of health plans.

(3) REGULATIONS.—

(A) IN GENERAL.—The Secretary and the Attorney General shall by regulation establish standards to carry out the program under paragraph (1).

(B) INFORMATION STANDARDS.—

(i) IN GENERAL.—Such standards shall include standards relating to the furnishing of information by health plans, providers, and others to enable the Secretary and the Attorney General to carry out the program (including coordination with health plans under paragraph (2)).

(ii) CONFIDENTIALITY.—Such standards shall include procedures to assure that such information is provided and uti-

lized in a manner that appropriately protects the confidentiality of the information and the privacy of individuals receiving health care services and items.

(iii) QUALIFIED IMMUNITY FOR PROVIDING INFORMATION.—The provisions of section 1157(a) of the Social Security Act (relating to limitation on liability) shall apply to a person providing information to the Secretary or the Attorney General in conjunction with their performance of duties under this section, in the same manner as such section applies to information provided to organizations with a contract under subtitle B of title V of this Act, with respect to the performance of such a contract.

(C) DISCLOSURE OF OWNERSHIP INFORMATION.—

(i) IN GENERAL.—Such standards shall include standards relating to the disclosure of ownership information described in clause (ii) by any entity providing health care services and items.

(ii) OWNERSHIP INFORMATION DESCRIBED.—The ownership information described in this clause includes—

(I) a description of such items and services provided by such entity;

(II) the names and unique physician identification numbers of all physicians with a financial relationship (as defined in section 1877(a)(2) of the Social Security Act) with such entity;

(III) the names of all other individuals with such an ownership or investment interest in such entity; and

(IV) any other ownership and related information required to be disclosed by such entity under section 1124 or section 1124A of the Social Security Act, except that the Secretary shall establish procedures under which the information required to be submitted under this subclause will be reduced with respect to health care provider entities that the Secretary determines will be unduly bur-

dened if such entities are required to comply fully with this subclause.

(4) AUTHORIZATION OF APPROPRIATIONS FOR INVESTIGATORS AND OTHER PERSONNEL.—In addition to any other amounts authorized to be appropriated to the Secretary and the Attorney General for health care anti-fraud and abuse activities for a fiscal year, there are authorized to be appropriated additional amounts as may be necessary to enable the Secretary and the Attorney General to conduct investigations and audits of allegations of health care fraud and abuse and otherwise carry out the program established under paragraph (1) in a fiscal year.

(5) ENSURING ACCESS TO DOCUMENTATION.—The Inspector General of the Department of Health and Human Services is authorized to exercise the authority described in paragraphs (4) and (5) of section 6 of the Inspector General Act of 1978 (relating to subpoenas and administration of oaths) with respect to the activities under the all-payer fraud and abuse control program established under this subsection to the same extent as such Inspector General may exercise such authorities to perform the functions assigned by such Act.

(6) AUTHORITY OF INSPECTOR GENERAL.—Nothing in this Act shall be construed to diminish the authority of any Inspector General, including such authority as provided in the Inspector General Act of 1978.

(7) HEALTH PLAN DEFINED.—For the purposes of this subsection, the term "health plan" shall have the meaning given such term in section 3(a)(1) of this Act.

(b) HEALTH CARE FRAUD AND ABUSE CONTROL ACCOUNT.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—There is hereby established an account to be known as the "Health Care Fraud and Abuse Control Account" (in this section referred to as the "Anti-Fraud Account"). The Anti-Fraud Account shall consist of—

(i) such gifts and bequests as may be made as provided in subparagraph (B);

(ii) such amounts as may be deposited in the Anti-Fraud Account as provided in subsection (a)(4), sections 5441(b) and 5442(b), and title XI of the Social Security Act; and

(iii) such amounts as are transferred to the Anti-Fraud Account under subparagraph (C).

(B) AUTHORIZATION TO ACCEPT GIFTS.—The Anti-Fraud Account is authorized to accept on behalf of the United States money gifts and bequests made unconditionally to the Anti-Fraud Account, for the benefit of the Anti-Fraud Account or any activity financed through the Anti-Fraud Account.

(C) TRANSFER OF AMOUNTS.—

(i) IN GENERAL.—The Secretary of the Treasury shall transfer to the Anti-Fraud Account an amount equal to the sum of the following:

(I) Criminal fines imposed in cases involving a Federal health care offense (as defined in section 982(a)(6)(B) of title 18, United States Code).

(ii) Administrative penalties and assessments imposed under titles XI, XVIII, and XIX of the Social Security Act (except as otherwise provided by law).

(iii) Amounts resulting from the forfeiture of property by reason of a Federal health care offense.

(iv) Penalties and damages imposed under the False Claims Act (31 U.S.C. 3729 et seq.), in cases involving claims related to the provision of health care items and services (other than funds awarded to a relator or for restitution).

(2) USE OF FUNDS.—

(A) IN GENERAL.—Amounts in the Anti-Fraud Account shall be available without appropriation and until expended as determined jointly by the Secretary and the Attorney General of the United States in carrying out the health care fraud and abuse control program established under subsection (a) (including the administration of the program), and may be used to cover costs incurred in operating the program, including costs (including equipment, salaries and benefits, and travel and training) of—

(i) prosecuting health care matters (through criminal, civil, and administrative proceedings);