/* Title V of the proposed Health Security Act follows. */

Title V QUALITY AND CONSUMER PROTECTION

Table of Contents

Part 2 Application of Fraud and Abuse Authorities Under the Social

Section

Section 5411 Exclusion from participation

Section 5412 Civil monetary penalties

Not later than 1 year after the date of the enactment of this Act, the National Health Board shall establish and oversee a

performance-based program of quality management and improvement designed to enhance the quality, appropriateness, and effectiveness of health care services and access to such services. The program shall be known as the National Quality Management Program and shall be administered by the National Quality Management Council established under section 5002.

Section 5002 NATIONAL QUALITY MANAGEMENT COUNCIL.

(a) Establishment. There is established a council to be known as the National Quality Management Council.

(b) Duties. The Council shall

(1) administer the National Quality Management Program;

(2) perform any other duty specified as a duty of the Council in this subtitle; and

(3) advise the National Health Board with respect its duties under this subtitle.

(c) Number and Appointment. The Council shall be composed of 15 members appointed by the President. The Council shall consist of members who are broadly representative of the population of the United States and shall include

(1) individuals representing the interests of governmental and corporate purchasers of health care;

(2) individuals representing the interests of health plans;

(3) individuals representing the interests of States;

(4) individuals representing the interests of health care providers and academic health centers (as defined in section 3101(c)); and

(5) individuals distinguished in the fields of public health, health care quality, and related fields of health services research.

(d) Terms.

(1) In general. Except as provided in paragraph (2),

members of the Council shall serve for a term of 3 years.

(2) Staggered rotation. Of the members first appointed to the Council under subsection (c), the President shall appoint 5 members to serve for a term of 3 years, 5 members to serve for a term of 2 years, and 5 members to serve for a term of 1 year.

(3) Service beyond term. A member of the Council may continue to serve after the expiration of the term of the member until a successor is appointed.

(e) Vacancies. If a member of the Council does not serve the full term applicable under subsection (d), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(f) Chair. The President shall designate an individual to serve as the chair of the Council.

(g) Meetings. The Council shall meet not less than once during each 4-month period and shall otherwise meet at the call of the President or the chair.

(h) Compensation and Reimbursement of Expenses. Members of the Council shall receive compensation for each day (including travel time) engaged in carrying out the duties of the Council. Such compensation may not be in an amount in excess of the maximum rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

(i) Staff. The National Health Board shall provide to the Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.

(j) Health Care Provider. For purposes of this subtitle, the term "health care provider" means an individual who, or entity that, provides an item or service to an individual that is covered under the health plan (as defined in section 1400) in which the individual is enrolled.

Section 5003 NATIONAL MEASURES OF QUALITY PERFORMANCE.

(a) In General. The National Quality Management Council shall develop a set of national measures of quality performance, which shall be used to assess the provision of health care services and

access to such services.

(b) Subject of Measures. National measures of quality performance shall be selected in a manner that provides information on the following subjects:

(1) Access to health care services by consumers.

(2) Appropriateness of health care services provided to consumers.

(3) Outcomes of health care services and procedures.

(4) Health promotion.

(5) Prevention of diseases, disorders, and other health conditions.

(6) Consumer satisfaction with care.

(c) Selection of Measures.

(1) Consultation. In developing and selecting the national measures of quality performance, the National Quality Management Council shall consult with appropriate interested parties, including

(A) States;

(B) health plans;

(C) employers and individuals purchasing health care through regional and corporate alliances;

(D) health care providers;

(E) the National Quality Consortium established under section 5009;

(F) individuals distinguished in the fields of law, medicine, economics, public health, and health services research;

(G) the Administrator for Health Care Policy and Research;

(H) the Director of the National Institutes of Health; and

(I) the Administrator of the Health Care Financing Administration.

(2) Criteria. The following criteria shall be used in developing and selecting national measures of quality performance:

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

(B) Range of services. The set of measures, taken as a whole, shall be representative of the range of services provided to consumers of health care.

(C) Reliability and validity. The measures shall be reliable and valid.

(D) Undue burden. The data needed to calculate the measures shall be obtained without undue burden on the entity or individual providing the data.

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

(F) Linkage to health outcome. When a measure is a rate of a process of care, the process shall be linked to a health outcome based upon the best available scientific evidence.

(G) Provider control and risk adjustment. When a measure is an outcome of the provision of care, the outcome shall be within the control of the provider and one with respect to which an adequate risk adjustment can be made.

(H) Public health. The measures may incorporate standards identified by the Secretary of Health and Human Services for meeting public health objectives.

(d) Updating. The National Quality Management Council shall review and update the set of national measures of quality performance annually to reflect changing goals for quality

improvement. The Council shall establish and maintain a priority list of performance measures that within a 5-year period it intends to consider for inclusion within the set through the updating process.

Section 5004 CONSUMER SURVEYS.

(a) In General. The National Quality Management Council shall conduct periodic surveys of health care consumers to gather information concerning access to care, use of health services, health outcomes, and patient satisfaction. The surveys shall monitor consumer reaction to the implementation of this Act and be designed to assess the impact of this Act on the general population of the United States and potentially vulnerable populations.

(b) Survey Administration. The National Quality Management Council shall develop and approve a standard design for the surveys, which shall be administered by the Administrator for Health Care Policy and Research on a plan-by-plan and State-by-State basis. A State may add survey questions on quality measures of local interest to surveys conducted in the State.

(c) Sampling Strategies. The National Quality Management Council shall develop sampling strategies that ensure that survey samples adequately measure populations that are considered to be at risk of receiving inadequate health care and may be difficult to reach through consumer-sampling methods, including individuals who

(1) fail to enroll in a health plan;

(2) resign from a plan; or

(3) are members of a vulnerable population.

Section 5005 EVALUATION AND REPORTING OF QUALITY PERFORMANCE.

(a) National Goals. In subject matter areas with respect to which the National Quality Management Council determines that sufficient information and consensus exist, the Council shall recommend to the Board that the Board establish goals for performance by health plans and health care providers on a subset of the set of national measures of quality performance.

(b) Impact of Reform. The National Quality Management Council shall evaluate the impact of the implementation of this Act on the quality of health care services in the United States and the access of consumers to such services.

(c) Performance Reports.

(1) Alliance and health plan reports. Each health alliance annually shall publish and make available to the public a performance report outlining in a standard format the performance of each health plan offered in the alliance on the set of national measures of quality performance. The report shall include the results of a smaller number of such measures for health care providers who are members of provider networks of such plans (as defined in section 1402(f)), if the available information is statistically meaningful. The report also shall include the results of consumer surveys described in section 5004 that were conducted in the alliance area during the year that is the subject of the report.

(2) National quality reports. The National Quality Management Council annually shall provide to the Congress and to each health alliance a report that

(A) outlines in a standard format the performance of each regional alliance, corporate alliance, and health plan;

(B) discusses State-level and national trends relating to health care quality; and

(C) presents data for each health alliance from consumer surveys described in section 5004 that were conducted during the year that is the subject of the report.

(d) Public Availability of Information in National Practitioner Data Bank on Defendants, Awards, and Settlements.

(1) In general. Section 427(a) of the Health Care Quality Improvement Act (42 U.S.C. 11137(a)) is amended by adding at the end the following new sentence: "Not later than January 1, 1996, the Secretary shall promulgate regulations under which individuals seeking to enroll in health plans under the Health Security Act may obtain information reported under this part with respect to physicians and other licensed health practitioners participating in such plans for whom information has been reported under this part on repeated occasions.".

(2) Access to data bank for point-of-service contractors under medicare. Section 427(a) of such Act (42 U.S.C. 11137(a)) is amended

(A) by inserting "to sponsors of point-of-service networks under section 1890 of the Social Security Act," after "State licensing boards,", and

(B) in the heading, by inserting "Related" after "Care".

Section 5006 DEVELOPMENT AND DISSEMINATION OF PRACTICE GUIDELINES.

(a) Development of Guidelines.

(1) In general. The National Quality Management Council shall direct the Administrator for Health Care Policy and Research to develop and periodically review and update clinically relevant guidelines that may be used by health care providers to assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically.

(2) Certain Requirements. Guidelines under paragraph (1) shall

(A) be based on the best available research and professional judgment regarding the effectiveness and appropriateness of health care services and procedures;

(B) be presented in formats appropriate for use by health care providers, medical educators, medical review organizations, and consumers of health care;

(C) include treatment-specific or condition-specific practice guidelines for clinical treatments and conditions in forms appropriate for use in clinical practice, for use in educational programs, and for use in reviewing quality and appropriateness of medical care;

(D) include information on risks and benefits of alternative strategies for prevention, diagnosis, treatment, and management of a given disease, disorder, or other health

condition;

(E) include information on the costs of alternative strategies for the prevention, diagnosis, treatment, and management of a given disease, disorder, or other health condition, where cost information is available and reliable; and

(F) be developed in accordance with priorities that shall be established by the National Quality Management Council based on the research priorities that are established under section 5007(b) and the 5-year priority list of performance measures described in section 5003(d).

(3) Health service utilization protocols. The National Quality Management Council shall establish standards and procedures for evaluating the clinical appropriateness of protocols used to manage health service utilization.

(4) Use in medical malpractice liability pilot program. Guidelines developed under this subsection may be used by the Secretary of Health and Human Services in the pilot program applying practice guidelines to medical malpractice liability under section 5312.

(b) Evaluation and Certification of Other Guidelines.

(1) Methodology. The National Quality Management Council shall direct the Administrator for Health Care Policy and Research to develop and publish standards relating to methodologies for developing the types of guidelines described in subsection (a)(1).

(2) Evaluation and certification. The National Quality Management Council shall direct the Administrator for Health Care Policy and Research to establish a procedure by which individuals and entities may submit guidelines of the type described in subsection (a)(1) to the Council for evaluation and certification by the Council using the standards developed under paragraph (1).

(3) Use in medical malpractice liability pilot program. Guidelines certified under paragraph (2) may be used by the Secretary of Health and Human Services in the pilot program applying practice guidelines to medical malpractice liability under section 5312.

(c) Guideline Clearinghouse. The National Quality Management

Council shall direct the Administrator for Health Care Policy and Research to establish and oversee a clearinghouse and dissemination program for practice guidelines that are developed or certified under this section.

(d) Dissemination of Information on Ineffective Treatments. The National Quality Management Council shall collect and disseminate information documenting clinically ineffective treatments and procedures.

Section 5007 RESEARCH ON HEALTH CARE QUALITY.

(a) Research Support. The National Quality Management Council shall direct the Administrator for Health Care Policy and Research to support research directly related to the 5-year priority list of performance measures described in section 5003(d), including research with respect to

(1) outcomes of health care services and procedures;

(2) effective and efficient dissemination of information, standards, and guidelines;

(3) methods of measuring quality and shared decisionmaking; and

(4) design and organization of quality of care components of automated health information systems.

(b) Research Priorities. The National Quality Management Council shall establish priorities for research with respect to the quality, appropriateness, and effectiveness of health care and make recommendations concerning research projects. In establishing the priorities, the National Quality Management Council shall emphasize research involving diseases, disorders, and health conditions as to which

(1) there is the highest level of uncertainty concerning treatment;

(2) there is the widest variation in practice patterns;

(3) the costs associated with prevention, diagnosis, treatment, or clinical management are significant; and

(4) the rate of incidence or prevalence is high for the

population as a whole or for particular subpopulations.

Section 5008 REGIONAL PROFESSIONAL FOUNDATIONS.

(a) Establishment. The National Health Board shall establish and oversee regional professional foundations to perform the duties specified in subsection (c).

(b) Structure and Membership.

(1) In general. The National Quality Consortium established under section 5009 shall oversee the establishment of regional professional foundations, the membership requirements for each foundation, and any other requirement for the internal operation of each foundation.

(2) Entities eligible for membership. Each regional professional foundation shall include at least one academic health center (as defined in section 3101(c)). The following entities also shall be eligible to serve as members of the regional professional foundation for the region in which the entity is located:

(A) Schools of public health (as defined in section 799 of the Public Health Service Act).

(B) Other schools and programs defined in such section.

(C) Health plans.

(D) Regional alliances.

(E) Corporate alliances.

(F) Health care providers.

(c) Duties. A regional professional foundation shall carry out the following duties for the region in which the foundation is located (such region to be demarcated by the National Health Board with the advice of the National Quality Consortium established under section 5009):

(1) Developing programs in lifetime learning for health professionals (as defined in section 1112(c)(1)) to ensure the delivery of quality health care.

(2) Fostering collaboration among health plans and health care providers to improve the quality of primary and specialized health care.

(3) Disseminating information about successful quality improvement programs, practice guidelines, and research findings.

(4) Disseminating information on innovative uses of health professionals.

(5) Developing innovative patient education systems that enhance patient involvement in decisions relating their health care.

(6) Applying for and conducting research described in section 5007.

(d) Programs in Life time Learning.The programs described in subsection (c)(1) shall ensure that health professionals remain abreast of new knowledge, acquire new skills, and adopt new roles as technology and societal demands change.

Section 5009 NATIONAL QUALITY CONSORTIUM.

(a) Establishment. The National Health Board shall establish a consortium to be known as the National Quality Consortium.

(b) Duties. The Consortium shall

(1) establish programs for continuing education for health professionals;

(2) advise the National Quality Management Council and the Administrator for Health Care Policy and Research on research priorities;

(3) oversee the development of the regional professional foundations established under section 5008;

(4) advise the National Quality Management Council with respect to the funding of proposals to establish such foundations;

(5) consult with the National Quality Management Council regarding the selection of national measures of quality

performance under section 5003(c); and

(6) advise the National Health Board and the National Quality Management Council with respect to any other duty of the Board or the Council under this subtitle.

(c) Membership. The Consortium shall be composed of 11 members appointed by the National Health Board. The members of the Consortium shall include

(1) 5 individuals representing the interests of academic health centers; and

(2) 6 other individuals representing the interests of one of the following persons:

(A) Schools of public health.

(B) Other schools and programs defined in section 799 of the Public Health Service Act (including medical schools, nursing schools, and allied health professional schools).

(d) Terms.

(1) In general. Except as provided in paragraph (2), members of the Consortium shall serve for a term of 3 years.

(2) Staggered rotation. Of the members first appointed to the Consortium under subsection (c), the National Health Board shall appoint 4 members to serve for a term of 3 years, 3 members to serve for a term of 2 years, and 4 members to serve for a term of 1 year.

(e) Chair. The National Health Board shall designate an individual to serve as the chair of the Consortium.

Section 5010 ELIMINATING CLIA REQUIREMENT FOR CERTIFICATE OF WAIVER FOR SIMPLE LABORATORY EXAMINATIONS AND PROCEDURES.

(a) In General. Section 353 of the Public Health Service Act (42 U.S.C. 263a) is amended

(1) in subsection (b), by inserting before the period at the end the following: "or unless the laboratory is exempt from the certificate requirement under subsection (d)(2)";

(2) by amending paragraph (2) of subsection (d) to read as follows:

"(2) Exemption from certificate requirement for laboratories performing only simple examinations and procedures. A laboratory which performs only laboratory examinations and procedures described in paragraph (3) is not required to have in effect a certificate under this section.";

(3) by striking paragraph (4) of subsection (d); and

(4) in subsection (m)(1), by striking ", except that the Secretary" and all that follows and inserting a period.

(b) Effective Date. The amendments made by this section shall take effect on the first day of the first month beginning after the date of the enactment of this Act.

Section 5011 UNIFORM STANDARDS FOR HEALTH CARE INSTITUTIONS.

(a) Development of Standards. Not later than 3 years after the date of the enactment of this Act, the National Health Board shall develop demonstration standards for the licensing of health care institutions that address essential performance requirements related to patient care. The standards shall be developed in a manner that permits them to be applied uniformly to all such institutions, except in the areas of fire safety, sanitation, and patient rights, and so as not to undermine ongoing nursing home reforms.

(b) Demonstration Projects. By January 1, 1996, the National Quality Management Council shall complete demonstration projects for the standards developed under subsection (a) and shall revise the standards according to the findings of such projects. The demonstration projects shall evaluate the impact of these standards in ensuring quality of care, reducing cost, and reducing burdens on health care providers.

(c) Preemptive Effect of Fully Implemented Standard. After a standard developed under this section is tested, evaluated, revised, and fully implemented, it shall replace existing standards, except in cases in which statutory changes are necessary to implement such standards. In such cases, the National Quality Management Council shall recommend to the

President and the Congress revisions in Federal statutes to conform the statutes to the standards.

(d) Consolidated Audit and Inspection. The National Quality Management Council shall undertake research efforts designed to develop a system for carrying out through grant or contract a single, consolidated annual audit and inspection of each health care institution and health care provider for the combined purposes of Federal, State, local, and private licensure, accreditation, and certification.

Section 5012 ROLE OF ALLIANCES IN QUALITY ASSURANCE.

Each regional alliance and each corporate alliance shall

(1) disseminate to consumers information related to quality and access to aid in their selection of plans in accordance with section 1325;

(2) disseminate information on the quality of health plans and health care providers contained in reports of the National Quality Management Council section 5005(c)(2);

(3) ensure through negotiations with health plans that performance and quality standards are continually improved; and

(4) conduct educational programs in cooperation with regional professional foundations to assist consumers in using quality and other information in choosing health plans.

Section 5013 ROLE OF HEALTH PLANS IN QUALITY MANAGEMENT.

Each health plan shall

(1) measure and disclose performance on quality measures used by

(A) participating States in which the plan does business;

(B) regional alliances and corporate alliances that offer the plan; and

(C) the National Quality Management Council;

(2) furnish information required under subtitle B of this title and provide such other reports and information on the quality of care delivered by health care providers who are members of a provider network of the plan (as defined in section 1402(f)) as may be required under this Act; and

(3) maintain quality management systems that

(A) use the national measures of quality performance developed by the National Quality Management Council under section 5003; and

(B) measure the quality of health care furnished to enrollees under the plan by all health care providers who are members ofa provider network of the plan.

Title V, Subtitle B

Subtitle B Information Systems, Privacy, and Administrative Simplification

Part 1 HEALTH INFORMATION SYSTEMS

Section 5101 ESTABLISHMENT OF HEALTH INFORMATION SYSTEM.

(a) In General. Not later than 2 years after the date of the enactment of this Act, the National Health Board shall develop and implement a health information system by which the Board shall collect, report, and regulate the collection and dissemination of the health care information described in subsection (e) pursuant to standards promulgated by the Board and (if applicable) consistent with policies established as part of the National Information Infrastructure Act of 1993.

(b) Privacy. The health information system shall be developed and implemented in a manner that is consistent with the privacy and security standards established under section 5120.

(c) Reduction in Administrative Costs. The health information system shall be developed and implemented in a manner that is consistent with the objectives of reducing wherever practicable and appropriate

(1) the costs of providing and paying for health care;

(2) the time, effort, and financial resources expended by persons to provide information to States, the Federal Government, health alliances, and health plans.

(d) Uses of Information. The health care information described in subsection (e) shall be collected and reported in a manner that facilitates its use for the following purposes:

(1) Health care planning, policy development, policy evaluation, and research by Federal, State, and local governments and regional and corporate alliances.

(2) Establishing and monitoring payments for health services by the Federal Government, States, regional alliances, and corporate alliances.

(3) Assessing and improving the quality of health care.

(4) Measuring and optimizing access to health care.

(5) Evaluating the cost of specific clinical or administrative functions.

(6) Supporting public health functions and objectives.

(7) Improving the ability of health plans, health care providers, and consumers to coordinate, improve, and make choices about health care.

(8) Managing and containing costs at the alliance and plan levels.

(e) Health Care Information. The health care information referred to in subsection (a) shall include data on

(1) enrollment and disenrollment in health plans;

(2) clinical encounters and other items and services provided by health care providers;

(3) administrative and financial transactions and activities of participating States, regional alliances, corporate alliances, health plans, health care providers, employers, and individuals that are necessary to determine compliance with this Act or an Act amended by this Act;

(4) the characteristics of regional alliances, including the number, and demographic characteristics of eligible individuals residing in each alliance area;

(5) the characteristics of corporate alliances, including the number, and demographic characteristics of individuals who are eligible to be enrolled in each corporate alliance health plan and individuals with respect to whom a large employer has exercised an option under section 1311 to make ineligible for such enrollment;

(6) terms of agreement between health plans and the health care providers who are members of provider networks of the plans (as defined in section 1402(f));

(7) payment of benefits in cases in which benefits may be payable under a health plan and any other insurance policy or health program;

(8) utilization management by health plans and health care providers;

(9) the information collected and reported by the Board or disseminated by other individuals or entities as part of the National Quality Management Program under subtitle A;

(10) grievances filed against regional alliances, corporate alliances, and health plans and the resolutions of such grievances; and

(11) any other fact that may be necessary to determine whether a health plan or a health care provider has complied with a Federal statute pertaining to fraud or misrepresentation in the provision or purchasing of health care or in the submission of a claim for benefits or payment under a health plan.

Section 5102 ADDITIONAL REQUIREMENTS FOR HEALTH INFORMATION SYSTEM.

(a) Consultation. The health information system shall be developed in consultation with

(1) Federal agencies that

(A) collect health care information;

(B) oversee the collection of information or records management by other Federal agencies;

(C) directly provide health care services;

(D) provide for payments for health care services; or

(E) enforce a provision of this Act or any Act amended by this Act;

(2) the National Quality Management Council established under section 5002;

(3) participating States;

(4) regional alliances and corporate alliances;

(5) health plans;

(6) representatives of health care providers;

(7) representatives of employers;

(8) representatives of consumers of health care;

(9) experts in public health and health care information and technology; and

(10) representatives of organizations furnishing health care supplies, services, and equipment.

(b) Collection and Transmission Requirements.In establishing standards under section 5101, the National Health Board shall specify the form and manner in which individuals and entities are required to collect or transmit health care information for or to the Board. The Board also shall specify the frequency with which individuals and entities are required to transmit such information to the Board. Such specifications shall include, to the extent practicable

(1) requirements for use of uniform paper forms containing standard data elements, definitions, and instructions for completion in cases where the collection or transmission of data in electronic form is not specified by the Board;

(2) requirements for use of uniform health data sets with

common definitions to standardize the collection and transmission of data in electronic form;

(3) uniform presentation requirements for data in electronic form; and

(4) electronic data interchange requirements for the exchange of data among automated health information systems.

(c) Preemption of State "Pen & Quill" Laws. A standard established by the National Health Board relating to the form in which medical or health plan records are required to be maintained shall supercede any contrary provision of State law, except where the Board determines that the provision is necessary to prevent fraud and abuse, with respect to controlled substances, or for other purposes.

Section 5103 ELECTRONIC DATA NETWORK.

(a) In General. As part of the health information system, the National Health Board shall oversee the establishment of an electronic data network consisting of regional centers that collect, compile, and transmit information.

(b) Consultation. The electronic data network shall be developed in consultation with

(1) Federal agencies that

(A) collect health care information;

(B) oversee the collection of information or records management by other Federal agencies;

(C) directly provide health care services;

(D) provide for payments for health care services; or

(E) enforce a provision of this Act or any Act amended by this Act;

(2) the National Quality Management Council established under section 5002;

(3) participating States;

(4) regional alliances and corporate alliances;

(5) health plans;

(6) representatives of health care providers;

(7) representatives of employers;

(8) representatives of consumers of health care;

(9) experts in public health and health care information and technology; and

(10) representatives of organizations furnishing health care supplies, services, and equipment.

(c) Demonstration Projects. The electronic data network shall be tested prior to full implementation through the establishment of demonstration projects.

(d) Disclosure of Individually Identifiable Information. The electronic data network may be used to disclose individually identifiable health information (as defined in section 5123(3)) to any individual or entity only in accordance with the health information system privacy standards promulgated by the National Health Board under section 5120.

Section 5104 UNIQUE IDENTIFIER NUMBERS.

(a) In General. As part of the health information system, the Board shall establish a system to provide for a unique identifier number for each

(1) eligible individual;

(2) employer;

(3) health plan; and

(4) health care provider.

(b) Impermissible Data Links. In establishing the system under subsection (a), the National Health Board shall ensure that a unique identifier number may not be used to connect individually identifiable health information (as defined in section 5123(3)) that is collected as part of the health

information system or that otherwise may be accessed through the number with individually identifiable information from any other source, except in cases where the National Health Board determines that such connection is necessary to carry out a duty imposed on any individual or entity under this Act.

(c) Permissible Uses of Identifier. The National Health Board shall by regulation establish the purposes for which a unique identifier number provided pursuant to this section may be used.

Section 5105 HEALTH SECURITY CARDS.

(a) Permissible Uses of Card. A health security card that is issued to an eligible individual under section 1001(b) may be used by an individual or entity, in accordance with regulations promulgated by the Board, only for the purpose of providing or assisting the eligible individual in obtaining an item or service that is covered under

(1) the applicable health plan in which the individual is enrolled (as defined in section 1902);

(2) a policy consisting of a supplemental health benefit policy (described in part 2 of subtitle E of title I), a cost sharing policy (described in such part), or both;

(3) a FEHBP supplemental plan (described in subtitle C of title VIII);

(4) a FEHBP medicare supplemental plan (described in such subtitle); or

(5) such other programs as the Board may specify.

(b) Form of Card and Encoded Information. The National Health Board shall establish standards respecting the form of health security cards and the information to be encoded in electronic form on the cards. Such information shall include

(1) the identity of the individual to whom the card is issued;

(2) the applicable health plan in which the individual is enrolled;

(3) any policy described in paragraph (2), (3), or (4) of

subsection (a) in which the individual is enrolled; and

(4) any other information that the National Health Board determines to be necessary in order for the card to serve the purpose described in subsection (a).

(c) Unique Identifier Numbers. The unique identifier number system developed by the National Health Board under section 5104 shall be used in encoding the information described in subsection (b).

(d) Registration of Card. The Board shall take appropriate steps to register the card, the name of the card, and other indicia relating to the card as a trademark or service mark (as appropriate) under the Trademark Act of 1946. For purposes of this subsection, the "Trademark Act of 1946" refers to the Act entitled "An Act to provide for the registration and protection of trademarks used in commerce, to carry out the provisions of international conventions, and for other purposes", approved July 5, 1946 (15 U.S.C. et seq.).

(e) Reference to Crime. For a provision relating to criminal penalties for misuse of a health security card or a unique identifier number, see section 5438.

Section 5106 TECHNICAL ASSISTANCE IN THE ESTABLISHMENT OF HEALTH INFORMATION SYSTEMS.

The National Health Board shall provide information and technical assistance to participating States, regional alliances, corporate alliances, health plans, and health care providers with respect to the establishment and operation of automated health information systems. Such assistance shall focus on (1) the promotion of community-based health information systems; and

(2) the promotion of patient care information systems that collect data at the point of care or as a by-product of the delivery of care.

Part 2 PRIVACY OF INFORMATION

Section 5120 HEALTH INFORMATION SYSTEM PRIVACY STANDARDS.

(a) Health Information System Standards. Not later than 2 years after the date of the enactment of this Act, the National

Health Board shall promulgate standards respecting the privacy of individually identifiable health information that is in the health information system described in part 1 of this subtitle. Such standards shall include standards concerning safeguards for the security of such information. The Board shall develop and periodically revise the standards in consultation with

(1) Federal agencies that

(A) collect health care information;

(B) oversee the collection of information or records management by other Federal agencies;

(C) directly provide health care services;

(D) provide for payments for health care services; or

(E) enforce a provision of this Act or any Act amended by this Act;

(2) the National Quality Management Council established under section 5002;

(3) participating States;

(4) regional alliances and corporate alliances;

(5) health plans; and

(6) representatives of consumers of health care.

(b) Information Covered. The standards established under subsection (a) shall apply to individually identifiable health information collected for or by, reported to or by, or the dissemination of which is regulated by, the National Health Board under section 5101.

(c) Principles. The standards established under subsection (a) shall incorporate the following principles:

(1) Unauthorized disclosure. All disclosures of individually identifiable health information by an individual or entity shall be unauthorized unless

(A) the disclosure is by the enrollee identified in

the information or whose identity can be associated with the information;

(B) the disclosure is authorized by such enrollee in writing in a manner prescribed by the Board;

(C) the disclosure is to Federal, State, or local law enforcement agencies for the purpose of enforcing this Act or an Act amended by this Act; or

(D) the disclosure otherwise is consistent with this Act and specific criteria governing disclosure established by the Board.

(2) Minimal disclosure.All disclosures of individually identifiable health information shall be restricted to the minimum amount of information necessary to accomplish the purpose for which the information is being disclosed.

(3) Risk adjustment. No individually identifiable health information may be provided by a health plan to a regional alliance or a corporate alliance for the purpose of setting premiums based on risk adjustment factors.

/* A very important change in previous attitudes towards health care. The principal of universiality is clear. In addition, the Health Security Act as clear in insuring that the information is not even available for the individual underwriting of insurance. */

(4) Required safeguards. Any individual or entity who maintains, uses, or disseminates individually identifiable health information shall implement administrative, technical, and physical safeguards for the security of such information.

(5) Right to know. An enrollee (or an enrollee representative of the enrollee) has the right to know

(A) whether any individual or entity uses or maintains individually identifiable health information concerning the enrollee; and

(B) for what purposes the information may be used or maintained.

(6) Right to access. Subject to appropriate procedures,

an enrollee (or an enrollee representative of the enrollee) has the right, with respect to individually identifiable health information concerning the enrollee that is recorded in any form or medium

(A) to see such information;

(B) to copy such information; and

(C) to have a notation made with or in such information of any amendment or correction of such information requested by the enrollee or enrollee representative.

(7) Right to notice. An enrollee and an enrollee representative have the right to receive a written statement concerning

(A) the purposes for which individually identifiable health information provided to a health care provider, a health plan, a regional alliance, a corporate alliance, or the National Health Board may be used or disclosed by, or disclosed to, any individual or entity; and

(B) the right of access described in paragraph (6).

(8) Use of Unique Identifier. When individually identifiable health information concerning an enrollee is required to accomplish the purpose for which information is being transmitted between or among the National Health Board, regional and corporate alliances, health plans, and health care providers, the transmissions shall use the unique identifier number provided to the enrollee pursuant to section 5104 in lieu of the name of the enrollee.

(9) Use for Employment Decisions. Individually identifiable health care information may not be used in making employment decisions.

Section 5121 OTHER DUTIES WITH RESPECT TO PRIVACY.

(a) Research and Technical Support. The National Health Board may sponsor

(1) research relating to the privacy and security of individually identifiable health information;

(2) the development of consent forms governing disclosure of such information; and

(3) the development of technology to implement standards regarding such information.

(c) Education. The National Health Board shall establish education and awareness programs

(1) to foster adequate security practices by States, regional alliances, corporate alliances, health plans, and health care providers;

(2) to train personnel of public and private entities who have access to individually identifiable health information respecting the duties of such personnel with respect to such information; and

(3) to inform individuals and employers who purchase health care respecting their rights with respect to such information.

Section 5122 COMPREHENSIVE HEALTH INFORMATION PRIVACY PROTECTION ACT.

(a) In General. Not later than 3 years after the date of the enactment of this Act, the National Health Board shall submit to the President and the Congress a detailed proposal for legislation to provide a comprehensive scheme of Federal privacy protection for individually identifiable health information.

(b) Code of Fair Information Practices. The proposal shall include a Code of Fair Information Practices to be used to advise enrollees to whom individually identifiable health information pertains of their rights with respect to such information in an easily understood and useful form.

(c) Enforcement. The proposal shall include provisions to enforce effectively the rights and duties that would be created by the legislation.

Section 5123 DEFINITIONS.

For purposes of this part:

(1) Enrollee. The term "enrollee" means an individual who

enrolls or has enrolled under a health plan. The term includes a deceased individual who was enrolled under a health plan.

(2) Enrollee representative. The term "enrollee representative" means any individual legally empowered to make decisions concerning the provision of health care to an enrollee or the administrator or executor of the estate of a deceased enrollee.

(3) Individually identifiable health information. The term "individually identifiable health information" means any information, whether oral or recorded in any form or medium, that--

(A) identifies or can readily be associated with the identity of an enrollee; and

(B) relates to

(i) the past, present, or future physical or mental health of the enrollee;

(ii) the provision of health care to the enrollee; or

(iii) payment for the provision of health care to the enrollee.

Part 3 INTERIM REQUIREMENTS FOR ADMINISTRATIVE SIMPLIFICATION

Section 5130 STANDARD BENEFIT FORMS.

(a) Development. Not later than 1 year after the date of the enactment of this Act, the National Health Board shall develop, promulgate, and publish in the Federal Register the following standard health care benefit forms:

(1) An enrollment and disenrollment form to be used to record enrollment and disenrollment in a health benefit plan.

(2) A clinical encounter record to be used by health benefit plans and health service providers.

(3) A claim form to be used in the submission of claims for benefits or payment under a health benefit plan.

(b) Instructions, Definitions, and Codes. Each standard form developed under subsection (a) shall include instructions for completing the form that

(1) specifically define, to the extent practicable, the data elements contained in the form; and

(2) standardize any codes or data sets to be used in completing the form.

(c) Requirements for Adoption of Forms.

(1) Health service providers. On or after the date that is 270 days after the publication of the standard forms developed under subsection (a), a health service provider that furnishes items or services in the United States for which payment may be made under a health benefit plan may not

(A) maintain records of clinical encounters involving such items or services that are required to be maintained by the National Health Board in a paper form that is not the clinical encounter record promulgated by the Board; or

(B) submit any claim for benefits or payment for such services to such plan in a paper form that is not the claim form promulgated by the National Health Board.

(2) Health benefit plans. On or after the date that is 270 days after the publication of the standard forms developed under subsection (a), a health benefit plan may not

(A) record enrollment and disenrollment in a paper form that is not the enrollment and disenrollment form promulgated by the National Health Board;

(B) maintain records of clinical encounters that are required to be maintained by the National Health Board in a paper form that is not the clinical encounter record promulgated by the Board; or

(C) reject a claim for benefits or payment under the plan on the basis of the form or medium in which the claim is submitted if

(i) the claim is submitted on the claim form promulgated by the National Health Board; and

(ii) the plan accepts claims submitted in paper form.

(d) Definitions.For purposes of this subtitle:

(1) Health benefit plan.

(A) In general. The term "health benefit plan" means, except as provided in subparagraphs (B) through (D), any public or private entity or program that provides for payments for health care services, including

(i) a group health plan (as defined in section 5000(b)(1) of the Internal Revenue Code of 1986); and

(ii) any other health insurance arrangement, including any arrangement consisting of a hospital or medical expense incurred policy or certificate, hospital or medical service plan contract, or health maintenance organization subscriber contract.

(B) Plans excluded. Such term does not include

(i) accident-only, credit, or disability income insurance;

(ii) coverage issued as a supplement to liability insurance;

(iii) an individual making payment on the individual's own behalf (or on behalf of a relative or other individual) for deductibles, coinsurance, or services not covered under a health benefit plan; and

(iv) such other plans as the National Health Board may determine, because of the limitation of benefits to a single type or kind of health care, such as dental services or hospital indemnity plans, or other reasons should not be subject to the requirements of this section.

(C) Plans included. Such term includes

(i) workers compensation or similar insurance insofar as it relates to workers compensation medical benefits (as defined in section 10000(3)) provided by or through health plans; and

(ii) automobile medical insurance insofar as it relates to automobile insurance medical benefits (as defined in section 10100(2)) provided by or through health plans.

(D) Treatment of direct provision of services.Such term does not include a Federal or State program that provides directly for the provision of health services to beneficiaries.

(2) Health service provider. The term "health service provider" includes a provider of services (as defined in section 1861(u) of the Social Security Act), physician, supplier, and other person furnishing health care services. Such term includes a Federal or State program that provides directly for the provision of health services to beneficiaries.

(e) Interim Nature of Requirements. The National Health Board may modify, update, or supercede any standard form or requirement developed, promulgated, or imposed under this section through the establishment of a standard under section 5101.

Part 4 GENERAL PROVISIONS

Section 5140 NATIONAL PRIVACY AND HEALTH DATA ADVISORY COUNCIL.

(a) Establishment. There is established an advisory council to be known as the National Privacy and Health Data Advisory Council.

(b) Duties. The Council shall advise the National Health Board with respect its duties under this subtitle.

(c) Number and Appointment. The Council shall be composed of 15 members appointed by the National Health Board. The members of the Council shall include

(1) individuals representing the interests of consumers, employers, and other purchasers of health care;

(2) individuals representing the interests of health plans, health care providers, corporate alliances, regional alliances, public health agencies, and participating States; and

(3) individuals distinguished in the fields of data collection, data protection and privacy, law, ethics, medical and health services research, public health, and civil liberties and patient advocacy.

(d) Terms.

(1) In general. Except as provided in paragraph (2), members of the Council shall serve for a term of 3 years.

(2) Staggered rotation. Of the members first appointed to the Council under subsection (c), the National Health Board shall appoint 5 members to serve for a term of 3 years, 5 members to serve for a term of 2 years, and 5 members to serve for a term of 1 year.

(3) Service beyond term. A member of the Council may continue to serve after the expiration of the term of the member until a successor is appointed.

(e) Vacancies. If a member of the Council does not serve the full term applicable under subsection (d), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(f) Chair. The National Health Board shall designate an individual to serve as the chair of the Council.

(g) Meetings. The Council shall meet not less than once during each 4-month period and shall otherwise meet at the call of the National Health Board or the chair.

(h) Compensation and Reimbursement of Expenses. Members of the Council shall receive compensation for each day (including travel time) engaged in carrying out the duties of the Council. Such compensation may not be in an amount in excess of the maximum rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

(i) Staff. The National Health Board shall provide to the Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.

(j) Duration. Notwithstanding section 14(a) of the Federal Advisory Committee Act, the Council shall continue in existence until otherwise provided by law.

Section 5141 CIVIL MONEY PENALTIES.

(a) Violation of Health Information System Standards. Any person who the Secretary of Health and Human Services determines

(1) is required, but has substantially failed, to comply with a standard established by the National Health Board under section 5101 or 5120;

(2) has required the display of, has required the use of, or has used a health security card for any purpose other than a purpose described in section 5105(a); or

(3) has required the disclosure of, has required the use of, or has used a unique identifier number provided pursuant to section 5104 for any purpose that is not authorized by the National Health Board pursuant to such section shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $10,000 for each such violation.

(b) Standard Benefit Forms. Any health service provider or health benefit plan that the Secretary of Health and Human Services determines is required, but has substantially failed, to comply with section 5130(c) shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $10,000 for each such violation.

(c) Process. The process for the imposition of a civil money penalty under the All-Payer Health Care Fraud and Abuse Control Program under part 1 of subtitle E of this title shall apply to a civil money penalty under this section in the same manner as such process applies to a penalty or proceeding under such program.

Section 5142 RELATIONSHIP TO OTHER LAWS.

(a) Court Orders. Nothing in this title shall be construed to invalidate or limit the power or authority of any court of competent jurisdiction with respect to health care information.

(b) Public Health Reporting. Nothing in this title shall be construed to invalidate or limit the authorities, powers, or procedures established under any law that provides for the reporting of disease, child abuse, birth, or death.

Title V, Subtitle C

Subtitle C Remedies and Enforcement

Part 1 REVIEW OF BENEFIT DETERMINATIONS FOR ENROLLED INDIVIDUALS

Subpart A General Rules

Section 5201 HEALTH PLAN CLAIMS PROCEDURE.

(a) Definitions.For purposes of this section

(1) Claim.The term "claim" means a claim for payment or provision of benefits under a health plan or a request for preauthorization of items or services which is submitted to a health plan prior to receipt of the items or services.

(2) Individual claimant. The term "individual claimant" with respect to a claim means any individual who submits the claim to a health plan in connection with the individual's enrollment under the plan, or on whose behalf the claim is submitted to the plan by a provider.

(3) Provider claimant. The term "provider claimant" with respect to a claim means any provider who submits the claim to a health plan with respect to items or services provided to an individual enrolled under the plan.

(b) General Rules Governing Treatment of Claims.

(1) Adequate notice of disposition of claim. In any case in which a claim is submitted in complete form to a health plan, the plan shall provide to the individual claimant and any provider claimant with respect to the claim a written notice of the plan's approval or denial of the claim within 30 days after the date of the submission of the claim. The notice to the individual claimant shall be written in language calculated to be understood by the typical individual enrolled under the plan and in a form which takes into account accessibility to the information by individuals whose primary language is not English. In the case of a denial of the claim, the notice shall be provided within 5 days after the date of the determination to deny the claim, and shall set forth the specific reasons for the denial. The notice of a denial shall include notice of the right to appeal the denial under paragraph (2). Failure by any plan to comply with the requirements of this paragraph with respect to any claim submitted to the plan shall be treated as approval by the plan of the claim.

(2) Plan's duty to review denials upon timely request. The plan shall review its denial of the claim if an individual

claimant or provider claimant with respect to the claim 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, to submit the claimant's request for reconsideration of the claim.

(3) Time limit for review. The plan shall complete any review required under paragraph (2), and shall provide the individual claimant and any provider claimant with respect to the claim 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.

(4) De novo reviews. Any review required under paragraph (2)

(A) shall be de novo,

(B) 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

(C) shall include review by a qualified physician if the resolution of any issues involved requires medical expertise.

(c) Treatment of Urgent Requests to Plans for Preauthorization.

(1) In general. This subsection applies in the case of any claim submitted by an individual claimant or a provider claimant consisting of a request for preauthorization of items or services (other than emergency services which under section 1406(b) may not be subject to preauthorization) which is accompanied by an attestation that

(A) failure to immediately provide the items or services could reasonably be expected to result in

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

(ii) serious impairment to bodily functions, or

(iii) serious dysfunction of any bodily organ or part, or

(B) immediate provision of the items or services is necessary because the individual claimant has made or is at serious risk of making an attempt to harm such individual claimant or another individual.

(2) Shortened time limit for consideration of requests for preauthorization.Notwithstanding subsection (b)(1), a health plan shall approve or deny any claim described in paragraph (1) within 24 hours after submission of the claim to the plan. Failure by the plan to comply with the requirements 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) which is denied by the plan shall be treated as a claim with respect to which all remedies under the plan provided pursuant to this section are exhausted, irrespective of any review provided under subsection (b)(2).

(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 plan makes a showing of an intentional misrepresentation of a material fact by the individual claimant, and

(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.

(d) Time Limit for Determination of Incompleteness of Claim. For purposes of this section

(1) any claim submitted by an individual claimant and accepted by a provider serving under contract with a health plan and any claim described in subsection (b)(1) shall be treated with respect to the individual claimant as submitted in complete form, and

(2) any other claim for benefits under the plan shall be treated as filed in complete form as of 10 days after the date of the submission of the claim, unless the plan provides to the

individual claimant and any provider claimant, within such period, a written notice of any required matter remaining to be filed in order to complete the claim. Any filing by the individual claimant or the provider claimant of additional matter requested by the plan pursuant to paragraph (2) shall be treated for purposes of this section as an initial filing of the claim.

(e) Additional Notice and Disclosure Requirements for Health Plans. In the case of a denial of a claim for benefits under a health plan, the plan shall include, together with the specific reasons provided to the individual claimant and any provider claimant under subsection (b)(1)

(1) if the denial is based in whole or in part on a determination that the claim is for an item or service which is not covered by the comprehensive benefit package or exceeds payment rates under the applicable alliance or State fee schedule, the factual basis for the determination,

(2) if the denial is based in whole or in part on exclusion of coverage with respect to services because the services are determined to comprise an experimental treatment or investigatory procedure, the medical basis for the determination and a description of the process used in making the determination, and

/* An important potential right for those with AIDS seeking treatments which may not have had time for acceptance under the tradional means of proving health treatments. */

(3) if the denial is based in whole or in part on a determination that the treatment is not medically necessary or appropriate or is inconsistent with the plan's practice guidelines, the medical basis for the determination, the guidelines used in making the determination, and a description of the process used in making the determination.

(f) 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.

Section 5202 REVIEW IN REGIONAL ALLIANCE COMPLAINT REVIEW OFFICES OF GRIEVANCES BASED ON ACTS OR PRACTICES BY HEALTH PLANS.

(a) Complaint Review Offices.

(1) In general. In accordance with rules which shall be prescribed by the Secretary of Labor, each State shall establish and maintain a complaint review office for each regional alliance established by such State. According to designations which shall be made by each State under regulations of the Secretary of Labor, the complaint review office for a regional alliance established by such State shall also serve as the complaint review office for corporate alliances operating in the State with respect to individuals who are enrolled under plans described in subsection (b) maintained by such corporate alliances and who reside within the area of the regional alliance.

(2) Regional alliances not established by States.In the case of any regional alliance established in any State by the Secretary of Health and Human Services, the Secretary of Health and Human Services shall assume all duties and obligations of such State under this part in accordance with the applicable regulations of the Secretary of Labor under this part.

(b) Filings of Complaints by Aggrieved Persons. In the case of any person who is aggrieved by

(1) any act or practice engaged in by any health plan which consists of or results in denial of payment or provision of benefits under the plan or delay in the payment or provision of benefits, or

(2) any act or practice engaged in by any other plan maintained by a regional alliance or a corporate alliance which consists of or results in denial of payment or provision of benefits under a supplemental benefit policy described in section 1421(b)(1) or a cost sharing policy described in section 1421(b)(2) or delay in the payment or provision of the benefits, if the 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 with the applicable requirements of this Act, such person may file a complaint with the appropriate complaint review office.

(c) Exhaustion of Plan Remedies. Any complaint including a claim to which section 5201 applies may not be filed until the complainant has exhausted all remedies provided under the plan with respect to the claim in accordance with such section.

(d) Exclusive Means of Review for Plans Maintained by Corporate Alliances. Notwithstanding part 2, proceedings under sections 5203 and 5204 pursuant to complaints filed under subsection (b), and review under section 5205 of determinations made under section 5204, shall be the exclusive means of review of acts or practices described in subsection (b) which are engaged in by a corporate alliance health plan or by any plan maintained by a corporate alliance with respect to benefits under a supplemental benefit policy described in section 1421(b)(1) or a cost sharing policy described in section 1421(b)(2).

(e) Form of Complaint. The complaint shall be in writing under oath or affirmation, shall set forth the complaint in a manner calculated to give notice of the nature of the complaint, and shall contain such information as may be prescribed in regulations of the Secretary of Labor.

(f) Notice of Filing. The complaint review office shall serve by certified mail a notice of the complaint (including the date, place, and circumstances of the alleged violation) on the person or persons alleged in the complaint to have committed the violation within 10 days after the filing of the complaint.

(g) Time Limitation. Complaints may not be brought under this section with respect to any violation later than one year after the date on which the violation occurs. This subsection shall not prevent the subsequent amending of a complaint.

Section 5203 INITIAL PROCEEDINGS IN COMPLAINT REVIEW OFFICES.

(a) Elections. Whenever a complaint is brought to the complaint review office under section 5202(b), the complaint review office shall provide the complainant with an opportunity, in such form and manner as shall be prescribed in regulations of the Secretary of Labor, to elect one of the following:

(1) to forego further proceedings in the complaint review office and rely on remedies available in a court of competent jurisdiction, with respect to any matter in the complaint with respect to which proceedings under this section and section 5204, and review under section 5205, are not under section 5202(d) the exclusive means of review,

(2) to submit the complaint as a dispute under the Early

Resolution Program established under subpart B and thereby suspend further review proceedings under this section pending termination of proceedings under the Program, or

(3) in any case in which an election under paragraph (2) is not made, or such an election was made but resolution of all matters in the complaint was not obtained upon termination of proceedings pursuant to the election by settlement agreement or otherwise, to proceed with the complaint to a hearing in the complaint review office under section 5204 regarding the unresolved matters.

(b) Effect of Participation in Early Resolution Program. Any matter in a complaint brought to the complaint review office which is included in a dispute which is timely submitted to the Early Resolution Program established under subpart B shall not be assigned to a hearing under section 5204 unless the proceedings under the Program with respect to the dispute are terminated without settlement or resolution of the dispute with respect to such matter. Upon termination of any proceedings regarding a dispute submitted to the Program, the applicability of this section to any matter in a complaint which was included in the dispute shall not be affected by participation in the proceedings, except to the extent otherwise required under the terms of any settlement agreement or other formal resolution obtained in the proceedings.

Section 5204 HEARINGS BEFORE HEARING OFFICERS IN COMPLAINT REVIEW OFFICES.

(a) Hearing Process.

(1) Assignment of complaints to hearing officers and notice to parties.

(A) In general. In the case of an election under section 5203(a)(3)

(i) the complaint review office shall assign the complaint, and each motion in connection with the complaint, to a hearing officer employed by the State in the office; and

(ii) the hearing officer shall have the power to issue and cause to be served upon the plan named in the complaint a copy of the complaint and a notice of hearing before the hearing officer at a place fixed in the notice, not less than 5 days after the

serving of the complaint.

(B) Qualifications for hearing officers. No individual may serve in a complaint review office as a hearing officer unless the individual meets standards which shall be prescribed by the Secretary of Labor. Such standards shall include experience, training, affiliations, diligence, actual or potential conflicts of interest, and other qualifications deemed relevant by the Secretary of Labor. 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.

(2) Amendment of complaints. Any such complaint may be amended by the hearing officer conducting the hearing, upon the motion of the complainant, in the hearing officer's discretion at any time prior to the issuance of an order based thereon.

(3) Answers. The party against whom the complaint is filed shall have the right to file an answer to the original or amended complaint and to appear in person or otherwise and give testimony at the place and time fixed in the complaint.

(b) Additional Parties. In the discretion of the hearing officer conducting the hearing, any other person may be allowed to intervene in the proceeding and to present testimony.

(c) Hearings.

(1) De novo hearing. Each hearing officer shall hear complaints and motions de novo.

(2) Testimony.The testimony taken by the hearing officer shall be reduced to writing. Thereafter, the hearing officer, in his or her discretion, upon notice may provide for the taking of further testimony or hear argument.

(3) Authority of hearing officers. The hearing officer may compel by subpoena the attendance of witnesses and the production of evidence at any designated place or hearing. In case of contumacy or refusal to obey a subpoena lawfully issued under this paragraph and upon application of the hearing officer, an appropriate district court of the United States may issue an order requiring compliance with the subpoena and any failure to obey the order may be punished by the court as a contempt thereof. The hearing officer may also seek enforcement of the

subpoena in a State court of competent jurisdiction.

(4) Expedited hearings. Notwithstanding section 5203 and the preceding provisions of this section, upon receipt of a complaint containing a claim described in section 5201(c)(1), the complaint review office shall promptly provide the complainant with the opportunity to make an election under section 5203(a)(3) and assignment to a hearing on the complaint before a hearing officer. The complaint review office shall ensure that such a hearing commences not later than 24 hours after receipt of the complaint by the complaint hearing office.

(d) Decision of Hearing Officer.

(1) In general. The hearing officer shall decide upon the preponderance of the evidence whether to decide in favor of the complainant with respect to each alleged act or practice. Each such 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 complainant.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 5202(b), the hearing officer shall issue and cause to be served on such party an order which requires such party

(A) to cease and desist from such act or practice,

(B) 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,

(C) to pay to the complainant prejudgment interest on the actual costs incurred in obtaining the items and services at issue in the complaint, and

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

(3) Decisions not in favor of complainant. 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 5202(b), the hearing officer

(A) shall include in the decision a dismissal of the charge in the complaint relating to the act or practice, and

(B) upon a finding that such charge is frivolous, shall issue and cause to be served on the complainant an order which requires the complainant 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.

(4) Submission and service of decisions. The hearing officer shall submit each decision to the complaint review office at the conclusion of the proceedings and the office shall cause a copy of the decision to be served on the parties to the proceedings.

(e) Review.

(1) In general. The decision of the hearing officer shall be final and binding upon all parties. Except as provided in paragraph (2), any party to the complaint may, within 30 days after service of the decision by the complaint review office, file an appeal of the decision with the Federal Health Plan Review Board under section 5205 in such form and manner as may be prescribed by such Board.

(2) Exception. The decision in the case of an expedited hearing under subsection (c)(4) shall not be subject to review.

(f) Court Enforcement of Orders.

(1) In general. If a decision of the hearing officer in favor of the complainant is not appealed under section 5205, the complainant may petition any court of competent jurisdiction 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 for court enforcement under this subsection, a prevailing complainant shall be entitled to a reasonable attorney's fee, reasonable expert witness fees, and other reasonable costs relating to such action.