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PATIENTS' BILL OF RIGHTS ACT OF 1999

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Mr. JEFFORDS, from the Committee on Health, Education, Labor, and Pensions, submitted the following

REPORT

together with

ADDITIONAL, MINORITY, AND SUPPLEMENTAL VIEWS

[To accompany S. 326]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 326) to improve the access and choice of patients to quality, affordable health care, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill do pass.

CONTENTS

		Page
I.	Purpose and summary of the legislation	1
II.	Background and need for the legislation	5
III.	Legislative history and votes in committee	16
IV.	Explanation of the legislation and committee views	28
V.	Cost estimate	57
VI.	Application of law to the legislative branch	62
VII.	Regulatory impact statement	62
VIII.	Section-by-section analysis	63
IX.	Additional views	96
X.	Minority views	100
XI.	Supplemental views	109
IX.	Changes in existing law	110

I. PURPOSE AND SUMMARY OF THE LEGISLATION

Purpose. The Employee Retirement Income Security Act (ERISA) of 1974 governs pension plans and employee welfare benefit plans, including group health plans. For group health plans, it contains

requirements pertaining to reporting and disclosure, fiduciary duties, administration and enforcement, portability, and plan design provisions pertaining to mental health, breast cancer, and maternity services. When ERISA was passed in 1974, health benefits were delivered almost exclusively on a fee-for-service basis. At that time, there were very few restrictions on an individual's ability to seek services and a provider's ability to get paid for services rendered. Today, pure fee-for-service is virtually nonexistent. According to the 1998 Mercer/Foster Higgins National Survey of Employer-sponsored Health Plans, some 87 percent of the 124 million Americans who have employer-sponsored health coverage governed by ERISA are enrolled in some type of managed care plan today. With the emergence of new forms of health care delivery systems that impose rules and restrictions on providers and patients, the public has called for new rights and protections to help them navigate these systems effectively.

Since its passage, a few substantive requirements have been added to ERISA. In 1996, Congress passed the Health Insurance Portability and Accountability Act (HIPAA), which makes health coverage more portable by limiting the use of preexisting condition exclusions and prohibiting discrimination in eligibility and premiums for group health plans. Congress also passed the Mental Health Parity Act, the Newborns' and Mothers' Health Protection Act and the Women's Health and Cancer Rights Act. These laws generally address plan design and benefit concerns. However, these laws do not address the full range of quality, access, and process concerns that have been raised by the evolution of new delivery systems.

In contrast, states have been actively pursuing reforms targeting access and delivery. A GAO report requested by the Chairman, indicates that, while approaches vary widely, States are actively pursuing the types of patient protections that are contained in Title I of this legislation. Many States have also passed reforms pertaining to utilization and grievance and appeals procedures, and states are beginning to pass legislation mandating an independent, external review of adverse coverage decisions.

Similar laws and regulations have already been adopted for Medicare, Medicaid, and the Federal Employees Health Benefits Program. Although independent, external review is widely- recognized as an important and necessary consumer protection, the Department of Labor lacks the authority to implement such a requirement through rulemaking. Only Congress can implement this important consumer right by passing legislation for the 124 million Americans covered under ERISA group health plans.

Summary. The primary goal of S. 326, The Patients' Bill of Rights Act, is to improve health care quality through better information; improved procedures and rights to help consumers and patients access benefits and services; reduced barriers to coverage because of genetic constitution; and federal investments in health quality research. An equally important goal is to provide these new protections without significantly increasing the cost of health coverage and causing more Americans to become uninsured.

The Patients' Bill of Rights Act will reduce many of the barriers that consumers with health coverage face in accessing health care

services. It will create new rights and provide consumers with information to help them make appropriate decisions and to exercise their rights in accessing covered benefits and services. In addition, the legislation will reduce barriers to obtaining health coverage that individuals face because of predictive genetic information. Finally, the legislation will enhance the overall quality of the nation's health care systems and increase the national investment in health care quality and research. The legislation, through a sense of the committee, expresses support for expanding coverage through tax incentives over which the Finance Committee has jurisdiction.

Recognizing that States have responded to consumer concerns associated with a rapidly evolving health care delivery system, the Patients' Bill of Rights Act seeks to create patient protections, similar to many State-enacted protections, for the 48 million Americans who receive their health coverage from plans that lie outside the regulatory jurisdiction of States. In addition, this legislation builds on the existing Federal regulatory framework under ERISA that includes information disclosure requirements and claims and appeals procedures for group health plans covering 124 million Americans. The legislation would enhance current information disclosure requirements and penalties and strengthen existing requirements for coverage determinations, grievances, and appeals, including the addition of a new requirement for independent, external review. The genetic non-discrimination provisions in the legislation would apply to all types of group health plans and individual insurance policies, helping as many as 140 million Americans. Finally, the quality provisions in the legislation will benefit every American who receives health care services.

The legislation achieves these goals through the following provisions. Provisions one through nine apply to plans that are not regulated by States. In these provisions, the bill amends ERISA to apply consumer protection provisions specifically to employer-sponsored group health plans that are not "fully insured." Provisions number ten (information disclosure) and eleven (coverage determinations and appeals) below apply to all group health plans, including fully insured and self insured plans. Provision number twelve (genetic information) applies to all group health plans and health insurance issuers in the group and individual markets.

1. *The legislation guarantees coverage for emergencies*.—The bill requires group health plans to cover emergency medical screening and stabilization using the "prudent layperson" standard. These services must be provided without requiring prior authorization and regardless of whether the services are provided by a network or non-network facility.

2. *The legislation enhances health plan choice*.—The bill requires group health plans that provide benefits through a single, closed network of health care professionals to offer participants the option to purchase point-of-service coverage. Plans offered by small employers (2–50 employees) and plans that offer coverage options with significantly different providers or networks are exempt from this provision.

3. *The legislation guarantees direct access to obstetric/gynecological care*.—The bill requires group health plans to provide female enrollees with direct access to an ob/gyn for routine care with-

out requiring authorization from the plan or a primary care physician.

4. *The legislation guarantees direct access to pediatric care*.—The bill requires plans to provide a child with direct access to a pediatrician for routine care without authorization from the plan or a primary care provider who is not a pediatrician.

5. *The legislation guarantees access to specialty care*.—The bill requires plans to ensure that participants have access to specialty care through network providers or through arrangements with non-network specialists. Plans may require authorization from a primary care provider so long as the authorization is for an adequate number of referrals under an approved treatment plan, if such a treatment plan is required by the plan.

6. *The legislation improves continuity in care*.—The bill requires plans to continue covering institutional care or care for terminal illness for up to 90 days when such care would otherwise be disrupted or terminated due to the termination of a relationship between the plan and the provider. Plans must also continue care through the postpartum period for pregnant women who are in their second trimester of pregnancy at the time of the termination.

7. *The legislation protects communications between providers and their patients*.—The bill bans plans from prohibiting or otherwise restricting a health care professional from advising a patient about health status and treatment options.

8. *The legislation improves access to medication*.—The bill requires plans to ensure that physicians and pharmacists participate in the development and review of prescription drug formularies and provide exceptions from the formulary when a non-formulary alternative is medically necessary and appropriate.

9. *The legislation protects a participant's right to self-pay for behavioral health services*.—The bill would prohibit plans that offer behavioral health services from barring or discouraging a participant from self-paying for behavioral health care services or terminating a provider who accepts self-payment, once the plan has denied coverage for such services.

10. *The legislation improves the efficiency of the health care market through enhanced information disclosure*.—The bill amends ERISA and the Internal Revenue Code to require all group health plans and issuers that provide coverage in connection with group health plans to disclose a wide variety of information, such as covered benefits, cost-sharing requirements, the plan's definition of medical necessity, and how to access specialists. Additional information must be provided upon request, including a summary description of the methods used for compensating providers and a list of medications included on the plan's formulary.

11. *The legislation creates new standards for coverage determinations and internal and external appeal rights*.—The bill amends the claims and appeals requirements that apply to all group health plans under ERISA, modifying the time frames and standards for determinations and creating a new right to independent, external review. Expedited determinations must be made within 72 hours, if the routine time frame would jeopardize the individual's health. Adverse determinations on appeal must be made by a physician with appropriate expertise, if the denial is based on a lack of med-

ical necessity. Adverse internal appeal decisions involving a determination of medical necessity (that exceeds a significant financial threshold or jeopardizes the health of the individual), or a determination that an intervention is experimental or investigational, are appealable to an independent, external review entity. The plan selects an authorized external review entity, which then selects an independent reviewer who must have relevant experience and, when reasonably available, be of the same speciality. The reviewer then makes an independent decision based on the valid, relevant, scientific, and clinical evidence.

12. *The legislation guarantees that health coverage will not be discriminatory based on predictive genetic information*.—The bill amends ERISA, the Public Health Service Act, and the Internal Revenue Code and applies these protections to all group health plans and health insurance issuers in the group and individual markets. It prohibits these plans and issuers from requesting or requiring certain information and from denying coverage or adjusting premiums or rates based on predictive genetic information. The term predictive genetic information includes genetic tests of individuals, genetic tests of family members, and information about family medical history.

13. *The legislation fosters overall improvement in health care quality*.—The bill reauthorizes the Agency for Health Care Policy and Research, renames it, and focuses its activities on improving health care quality. The newly renamed Agency is to foster overall improvement in health care quality by advancing the development, evaluation, and dissemination of quality measures within the Agency, as well as by participating in public-private partnerships; facilitating innovation in patient care with streamlined assessment of new technologies; synthesizing and making the latest health care information accessible and widely available to all interested audiences; and reporting annually to Congress on the state of quality in the nation. In addition, through coordination of various Federal quality initiatives, the Agency is to become the hub and driving force of Federal efforts to improve quality of health care in all practice environments.

II. Background and Need for the Legislation

TITLE I—PATIENTS' BILL OF RIGHTS

A. EVOLUTION OF THE PRIVATE HEALTH INSURANCE MARKET

The marketplace has undergone substantial change in the past decade or so. Fee-for-service payment, enormous tax incentives, and increasing demand and supply of first dollar coverage for comprehensive medical benefits resulted in double-digit health care inflation for employer-sponsored health benefits in the 1980s and early 1990s. Employer purchasers of health care responded by requiring employees to pay a greater share of the cost and by demanding greater value for their health care dollars. In doing so, employers increasingly looked to various forms of managed care as a way to control utilization and costs and to promote health care quality. According to the 1998 Mercer/Foster Higgins National Survey of Employer-sponsored Health Plans, some 87 percent of Amer-

icans who have employer-sponsored health coverage are enrolled in some type of managed care plan today.

The private-sector shift to managed care has occurred fairly rapidly, with many employees having little say in the process. For individuals accustomed to fee-for-service benefits, the transition has not been an easy one. Limited choices, new restrictions and rules governing access and utilization, and administrative hassles have contributed to a public perception that managed care may sometimes restrict access to needed health care services.

Ongoing pressure by purchasers to curtail health care costs has motivated health care plans to closely guard utilization of services. Problems in health care quality are documented in both the overuse and underuse of services, and, with the exception of preventive services, managed care has tended to focus on the overuse problem. A focus on the overuse of services has led to requirements and restrictions on providers and patients in how they access services and too little focus on the underuse of services that can prevent illness and improve health care quality. In addition, with the rise in managed care enrollment, more people with serious and chronic conditions have been added to the managed care rolls. This has added new strains and challenges to delivery systems that are accustomed to healthier populations that require fewer services.

In the 1970s, when ERISA was passed, health benefits were delivered almost exclusively on a fee-for-service basis. At that time, there were very few restrictions on an individual's ability to seek services and a provider's ability to get paid for services rendered. Today, pure fee-for-service is virtually nonexistent, with many plans imposing utilization restrictions such as pre-certification for hospital admissions. With the emergence of new forms of health care delivery systems that impose rules and restrictions on providers and patients, the public has called for new rights and protections to help them navigate these systems effectively.

B. REGULATION OF HEALTH PLANS

Currently, responsibility for regulating health plans is divided between the Federal Government and the States. Under ERISA, the Federal Government regulates private health plans offered by employers and unions. The States are responsible for regulating health coverage sold by insurance carriers. According to data from the Robert Wood Johnson Foundation, approximately 13 percent of all employers in 1997 self-funded their plans, covering 33 percent of employees enrolled in employer-sponsored plans. However, the rise of managed care, and HMOs in particular, has contributed to a decline in the incidence of self-funding in recent years, according to Rand researchers.[1] Between 1993 and 1997, the number of self-insured employers fell from 19 percent to 13 percent in the seven states studied. As these trends evolve and the popularity of different types of delivery systems rise and fall, the trend in self-funding is also likely to change. Because ERISA prohibits States from regulating self-funded plans provided by employers and unions,

[1] M. Susan Marquis and Stephen H. Long, Recent Trends in Self-Insured Employer Health Plans, Health Affairs; May/June 1999; pg. 161.173.

States are not able to monitor the quality of the health care coverage offered to a significant portion of the employed population.

1. Self-funded plans

Currently, many employers self-fund their health plans by retaining the risk for paying the cost of claims directly out of company assets rather than purchasing commercial health insurance. In addition, multiemployer plans established pursuant to collective bargaining agreements (known as "Taft Hartley" plans) between workers' unions and workers' employers also may be self-funded.

Although the terms "self-funded" and "self-insured" are perceived as being synonymous with ERISA plans, these terms are not currently found in ERISA, nor is the ERISA-governed universe limited to just self-funded plans. Instead, they have been created and applied by the courts and, as a result, there is ambiguity and uncertainty among many employers and employees as to the status of certain employee benefit plans. Much of the current ambiguity is fostered by the financial arrangements and risk shifting inherent in managed care. It is not clear what level of risk sharing might cause an arrangement to become insured rather than self-insured and regulators and courts have not yet weighed in on this issue. Another factor leading to ambiguity about self-funded plans is the practice of purchasing stop-loss coverage by employers and unions who choose not to bear the entire risk of providing benefits to plan participants.

2. Preemption

Under current law, these "self-funded" and "self-insured" health plans are exempt from direct State regulation under ERISA. ERISA was crafted to leave the content and design of employer health plans to employers in negotiation with their work force, without requiring employers and multiemployer plans to comply with numerous, conflicting State laws. While ERISA does establish certain regulations for health benefit plans in the area of reporting and disclosure, fiduciary standards, claims review, and enforcement, these regulations do little to ensure the access to health care services and quality of care in the types of delivery systems that dominate the marketplace today. For example, Federal law currently does not include any requirements that help a participant gain access to a particular type of provider.

States have adopted regulations that pertain to access to services and health care quality. However, the changing nature of employer-sponsored arrangements coupled with evolving case law on preemption, has raised new questions about the application of some State regulations to all ERISA plans, not just self-funded ERISA plans. For instance, although the courts have established in *Pilot Life* v. *Dedeaux* that ERISA provides the exclusive remedy regarding the administration of plan benefits for all ERISA plan participants and preempts State remedies, it is not clear whether other State laws will be similarly preempted. Most State laws governing appeals, including the right to an external appeal, have only been recently adopted, and there have been very few court cases about preemption in this area. However, in a recent decision in Texas (*Corporate Health Insurance, Inc.* v. *The Texas Department of In-*

surance), the lower court held that ERISA does preempt the State's external review law.[2] How these preemption cases play out in the States cannot be fully predicted and depends on a variety of factors. Despite the ambiguity about plan types, regulatory jurisdiction, and emerging case law, there is no ambiguity that States cannot directly regulate self-funded ERISA plans.

C. STATE LAW AND FEDERAL REFORMS

Since the passage of ERISA in 1974, a few substantive requirements have been added to ERISA. In 1996, Congress passed the Health Insurance Portability and Accountability Act (HIPAA), which makes health coverage more portable by limiting the use of preexisting condition exclusions and prohibiting discrimination in eligibility and premiums for group health plans. Congress also passed the Mental Health Parity Act, the Newborns' and Mothers' Health Protection Act and the Women's Health and Cancer Rights Act. In addition to these ERISA provisions, Congress also passed the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985, which requires employers that sponsor plans to offer qualified beneficiaries the right to continue health care coverage as a result of a qualifying event. These laws primarily address plan design and benefit concerns. However, with the exception of the Newborns' and Mothers' Health Protection Act, these laws do not generally address the types of quality, access, and process concerns that have been raised by the evolution of new delivery systems.

In contrast, states have been actively pursuing reforms targeting access and delivery. A GAO report requested by the Chairman, indicates that, while approaches vary widely, states are actively pursuing the types of patient protections that are contained in Title I of this legislation. For instance, of the 15 States examined, most have passed legislation addressing access to certain specialists (including ob/gyns), protections pertaining to patient-provider communications, and emergency room coverage.

Many States have also passed reforms pertaining to utilization and grievance and appeals procedures, and approximately one-third of States have passed legislation mandating an independent, external review of adverse coverage decisions. In addition, the National Association of Insurance Commissioners (NAIC) is developing a model law on external review that States can consider for adoption.

In contrast, Federal law applicable to group health plans governed by ERISA has focused primarily on coverage and plan design issues and very little on access to benefits and services in new and evolving delivery system structures. Similar laws and regulations have already been adopted for Medicare, Medicaid, and the Federal Employees Health Benefits Program. Recognizing the need to update requirements and procedures for ERISA plans, the U.S. Department of Labor has recently proposed regulations that would improve standards and time frames for coverage determinations. However, the Department of Labor lacks the authority to imple-

[2] In another part of its decision, the court in this case ruled that ERISA does not preempt the state's Health Care Liability Act which allows patients to sue their managed care organizations (MCOs) for damages caused by the MCO's failure to exercise ordinary care in providing medical treatment. This case is currently pending on review to the higher court.

ment the scope of reforms that are needed. For instance, although independent, external review is widely-recognized as an important and necessary consumer protection, the Department of Labor lacks the authority to implement such a requirement through rulemaking. In order to guarantee that all 124 million Americans covered under ERISA group health plans have access to independent, external review, Congress must pass legislation.

D. QUALITY CONCERNS

Consumers and regulators have identified and documented a variety of problems in accessing needed health care services. A primary problem is the lack of information available to consumers to help them navigate the complexities of health delivery systems. Information is also necessary to access needed benefits and services that have been promised by the plan and to understand the limits of the plan. Many consumers also lack the necessary information to make appropriate choices and thus find themselves in situations where they are dissatisfied with the service and quality of care they receive. The committee believes that better information is necessary to improve the efficiency of the marketplace and to enhance consumer satisfaction.

Other quality problems stem from the ever-changing balance of power in the health care marketplace. As plans, payers, hospitals, physicians, and other stakeholders struggle to maintain or improve their market positions, consumers and patients are sometimes overlooked. Procedures and policies designed to curb spending and overuse of services by providers can create barriers to needed health care services. For instance, unreasonably restrictive payment policies for emergency room coverage may cause some consumers to forgo necessary and potentially life-saving care out of concern the plan will not provide coverage.

Consumers in ERISA group health plans currently have few rights and remedies to help them access covered benefits and services. The information disclosure and claims and appeals procedures under ERISA are seriously outdated for today's marketplace. Although ERISA plan participants have the right to appeal coverage denials, the time frames for making decisions are inadequate, particularly in an environment where many services must be approved before they can be provided. There is little to protect a consumer who needs care urgently or who faces repeated denials by a plan with insufficient explanation, other than paying out of pocket for the services. This is simply not feasible for most consumers. Moreover, it is unacceptable if the benefit is covered by the plan and is medically necessary and appropriate. The committee strongly believes that consumers should have access to better procedures and clearly articulated rights with respect to accessing covered benefits and services and that these basic rights will reduce barriers to needed care and improve the quality of health care.

TITLE II—GENETIC INFORMATION AND SERVICES

The legislation builds upon various State reforms (over 30 States have enacted laws related to the use of genetic information in health insurance) and the provisions in the Health Insurance Port-

ability and Accountability Act of 1996 (HIPAA), [P.L. 104–191]. There are two main provisions in HIPAA that deal with genetic information. First, the law prohibits discrimination in eligibility and premiums in group health plans and group health insurance based on health status, including "genetic information" (term is not defined in the statute). For example, an individual could not be singled out of a group and charged a higher premium contribution than others in the group. Second, the law states that genetic information is not considered to be a pre-existing condition "in the absence of a diagnosis" of the condition related to such information. For example, carrying a genetic mutation for breast cancer is not considered a pre-existing condition, but a positive diagnosis of breast cancer would be a pre-existing condition. These provisions apply to group health plans and health insurance issuers offering coverage in connection with a group health plan; the provisions do not apply to the individual insurance market in the same manner.

The committee's intent is to clarify and extend certain provisions in HIPAA with respect to genetic information, consistent with the original intent of the law. The committee agreed it was important to define genetic information and to extend certain provisions to protect healthy individuals from discrimination in certain health coverage and insurance practices based on predictive genetic information.

Scientists anticipate that the entire human genome will be decoded within the next few years. The advances in genetics research are providing the ability to predict what diseases individuals may be at risk for in the future. These developments have caused great concern that predictive genetic information may be used to discriminate against individuals and their families in certain health insurance practices. For example, genetic testing studies at the National Institutes of Health revealed that nearly 32 percent of women offered a test for breast cancer risk declined, citing concerns about health insurance discrimination. Without this necessary research data, scientists will be limited in finding better ways to diagnose and treat patients. The committee wants patients to benefit from the Federal investment in biomedical research and fully utilize medical advancements to improve their health. This will not be possible, unless individuals are willing to be tested.

Prohibition of genetic discrimination in insurance will remove the greatest barrier to testing and, thus, further accelerate our scientific progress. Therefore, the committee believed strongly that it was important to include the genetic nondiscrimination provisions in a health care bill designed to improve the quality of care that patients receive. Prohibiting genetic discrimination translates into a patient's right to quality care. Genuine quality of care means that patients and practitioners consider all the information available to them when they make health care decisions, including an individual's genetic profile. Patients should not be afraid to benefit from new genetic technologies that have the potential to improve care and save lives.

Genetic testing has not yet become standard practice in the medical community. At a hearing held by the committee on May 21, 1998, representatives of the health insurance industry testified that genetic testing is not currently utilized as part of medical un-

derwriting. The intent of the legislation is to prohibit the use of genetic testing in health insurance practice before these tests become more widely available in medical practice or part of the underwriting process.

TITLE III—HEALTH CARE RESEARCH AND QUALITY

Legislative History. Public Law 101–239, the Omnibus Budget Reconciliation Act of 1989, authorized the establishment of the Agency for Health Care Policy and Research (AHCPR) for 3 years in Title IX, the Public Health Service Act. In 1992, the Congress amended Title IX and reauthorized AHCPR through FY 1995 in P.L. 102–410. In P.L. 105–115, the Food and Drug Administration Modernization Act of 1997, the Congress amended Title IX to authorize the Agency to develop a demonstration program supporting Centers for Education and Research on Therapeutics (CERTs). In 1998, the Subcommittee on Public Health and Safety held three hearings on AHCPR, focusing on the Agency's overall research mission, its technology assessment function, and its role in improving quality. This title reauthorizes the Agency from FY 2000 to FY 2006, renames it, and refocuses its mission.

Summary. In developing this legislation, the Subcommittee on Public Health and Safety undertook a thorough review of the research and other activities of the Agency for Health Care Policy and Research (AHCPR) to determine whether these activities were an appropriate Federal responsibility, whether they warranted the continued existence of a separate Agency, and, if so, whether the Agency's mission needed to be refocused. The committee reached several conclusions. First, the Agency's research and other activities provide the science-based evidence that will improve the quality of patient care. Objective, reliable information, of the type developed by the Agency, is essential for the successful functioning of our competitive health care marketplace. Second, the continued existence of a separate Agency is justified because of its unique focus on the effectiveness of care in daily practice, its demonstrated ability to bridge the worlds of research and practice, and the dual focus of its research on the clinical aspects of care, as well as the economics, organization, and delivery of health care. Third, the committee believes that a renamed and strengthened Agency can play a critical role as the hub and driving force for the Federal Government's quality improvement efforts and in supporting private-sector quality efforts by advancing the young science of quality. Finally, the committee has concluded that a substantial investment in building our scientific knowledge regarding quality health care is an essential complement to the patient protections provided in the other titles of this legislation.

Background. The health care system in America today is dramatically different from the system that existed a decade ago when the Congress established the Agency for Health Care Policy and Research (AHCPR). It is being transformed by the changing nature of our insurance system; the growing dominance of managed care plans; increased plan complexity; increasing concentration as a result of consolidations and mergers; demands of purchasers for accountability and value from health care providers; shifting financial incentives; and the growing tension between caregivers, patients,

and the policies of the systems through which care is delivered. At the same time, there has been an explosion in the number of medical journals and peer-reviewed articles published each year, reflecting in part the Congressional support for basic and biomedical research over the last few years. As a result, even the most conscientious clinicians face increasing difficulty in keeping abreast of the medical literature and putting into perspective the latest scientific findings. In fact, it has been estimated that if physicians were to read two peer-reviewed journal articles each night after a long day of practice, they would be 800 articles behind in their reading at the end of the year. The exponential growth in health-related web sites poses additional challenges for patients and caregivers alike in determining which information is based upon science and which information is less reliable.

While concern regarding variations in the rates at which medical procedures are conducted contributed to the decision to create AHCPR in 1989, public concern regarding the quality of patient care is growing and requires a more direct and coordinated public response. While millions of Americans receive high-quality care every day, peer-reviewed research has documented too many instances of underuse, overuse, and misuse of services. In addition, there is growing public concern regarding the number of medical errors that take place, in which patients suffer from adverse drug events, treatment or amputation of the wrong limb, or other oversights. The pioneering Harvard study in which Dr. Lucian Leape and his colleagues looked at the records of more than 30,000 hospital patients in New York found that nearly 4 percent suffered serious injuries that were related to the management of their illness rather than the illness itself. To their credit, health professionals have recognized the problem. To tackle these "system" issues successfully, there is a need for a sustained health services research initiative that is undertaken in partnership with the health professions and provider community.

Other challenges continue. As the debate on the Patients' Bill of Rights Act has demonstrated, issues such as those related to the cost and appropriate use of and access to health services, remain significant public policy concerns. Many of the issues addressed in other titles of this legislation have arisen because of the lack of reliable evidence about the risks and benefits of alternative approaches for containing health care costs, organizing health care delivery systems, and structuring the policies that govern systems of care. Similarly, the debate on the long-term stability of the Medicare program only serves to reinforce the critical need for this type of scientific evidence.

These developments have highlighted as never before the need for objective, science-based information at all levels of the health care system:

- at the clinical level, providing patients and those who deliver care the information they need to make informed decisions regarding treatment options;
- at the system level, getting good information to those who manage systems of care about alternative approaches to organizing and delivering care, and for individual consumers and those who make purchasing decisions for their employees or

members, information that will enable them to make more informed decisions in selecting health plans and providers and in comparing and assessing the value of the care that they are purchasing; and

• at the public policy level, providing scientific findings—about the impact on quality, cost, and access—concerning the ways we structure and deliver care, the incentives that are provided to clinicians, decisions regarding which services to offer, as well as information (not currently available) on national trends in quality.

The methods and tools of health services research are well suited for addressing these information needs. While AHCPR has served as the lead Federal Agency supporting health services research, it has not had the necessary budget or requisite coordinating authority to address these pressing information needs adequately. This legislation is intended to ensure that the newly renamed Agency for Healthcare Research and Quality (AHRQ) has the stature, resources, and authority to work in close collaboration with the private sector to meet the Federal responsibilities in these areas.

Appropriate Federal Role for the Agency. The rationale for a significant Federal commitment to the type of health services research supported by the AHRQ is strong.

First, the Federal Government has a compelling interest in ensuring that patients and society reap the full rewards of our growing investment in basic and biomedical research. This requires a corresponding investment in the kind of health services research that will support their effective use. Experience has repeatedly demonstrated that great opportunities for improving health, developed through biomedical research, are easily lost if physicians and patients are unable to make the best use of the knowledge in everyday care. The private sector often lacks the incentive to address these issues, because the cost of the research investment is far greater than the benefits to the individual health plan, which occurs when clinical conditions are common but not costly or when they are expensive but extremely rare. By contrast, the Federal Government has both an obligation to the American people and a responsibility to see that the goal of its investment in basic and biomedical research (higher quality patient care) is realized.

The Agency has demonstrated its ability to close this gap between the promise of biomedical research and improvements in daily practice. For example, National Institutes of Health (NIH)-supported research at the University of Wisconsin demonstrated the potential of warfarin (an anticoagulant) to prevent stroke in patients with atrial fibrillation, yet this lifesaving innovation was underused in daily practice. An Agency-supported research team at Duke University conducted a meta-analysis that established warfarin as the treatment of choice, undertook research that identified the reasons that physicians were often reluctant to use this effective intervention, and conducted a trial to develop effective approaches for administering warfarin that addressed the concerns of physicians. Findings from this research project led in part to development of guidelines from the American College of Physicians, the AHA, and the Joint Council of Vascular Surgeons. Medicare Peer Review Organizations (PROs) implemented 73 projects in 42 states

to increase anticoagulation. Rates from 28 projects in 20 States showed that patients discharged on anticoagulation therapy increased from 58 percent to 71 percent. Improved anticoagulation rates through the PRO projects is projected to have prevented 1285 strokes. As a result of the Agency's research, the promise of the Federal investment in the basic research that identified warfarin's potential is increasingly being realized. The final demonstration project, for which the private sector contributed $2.50 for every $1.00 of Agency funds, also demonstrated for the first time the Agency's ability to collaborate with and leverage private-sector funding.

In addition to supporting new research that identifies what works best in practice and how to make more effective use of existing innovations, the Federal Government can support the work of busy health care professionals by assessing and putting into perspective new scientific advances. The development of such syntheses requires methodologists to assess the research design of the studies and the scientific controls and statistics that were employed to determine the extent to which clinicians can use the studies to guide their daily practice. This is another area for which there appear to be few incentives in academia or the private sector to undertake such studies, and health professionals are seldom trained to undertake such methodological assessments. Yet the development and updating of such assessments are essential for clinicians and patients to benefit from our investments in basic and biomedical research. They provide essential information to clinicians which, when combined with a patient examination, medical history, and clinicians' own clinical experience, can ensure that their patients receive care that is informed by the best science available.

Second, as a purchaser and provider of health care services, the Federal Government has a compelling need for information that will help it to manage its programs more effectively and efficiently and provide information to beneficiaries of those programs. The subcommittee heard testimony from Dr. Stuart Butler of The Heritage Foundation that the Agency should play an even greater role in this area. Citing the potential conflicts of interest that Federal Agencies face in attempting both to run programs and to provide dispassionate and objective information, he argued for the importance of the Agency's independence "free from any interest in a particular way of providing care." The unique focus of the health services research supported by the Agency on the cost and appropriate use of and access to health care services is especially critical to the efforts of the Congress to ensure the long-term viability of the Medicare program.

Third, such research is an important public good in its own right. Scientific information on how to relieve suffering, maintain or restore health, and improve the effectiveness of the way we deliver health services needs to be in the public domain to the extent possible. Public funding ensures that the research methods are scrutinized, are publicly available, are peer reviewed, and are accessible.

Fourth, there was agreement among witnesses regarding the need for a Federal role in advancing the science of quality, developing and validating measures and tools for evaluating and improving quality, and making that information widely available. An

analogy was suggested during the subcommittee's hearings that the government's role in health care should be similar to the way it provides consumers with information that enables them to assess the safety of airlines or automobiles. In making those choices, consumers also have a variety of other standards or measures they can use in assessing which automobile to buy or which airline to fly. The committee concurs with this general framework and has provided the Agency with broad authority to develop and advance the science of quality but prohibits it from mandating a single approach or national standard toward assessing quality.

Finally, the committee concludes that the Agency should be reauthorized, renamed, and strengthened to carry out these legitimate Federal functions. As the Food and Drug Administration Modernization Act of 1997 conference report noted on the decision to assign responsibility for CERTs to the Agency:

> The conferees designated AHCPR as the lead agency because of its expertise in the evaluation of the effectiveness of clinical care, its non-regulatory role, and its close working relationship with the health care community in the improvement of the quality of care.

The committee reaffirms that position in this report. The Agency has demonstrated an ability to maintain its role as an independent, objective, scientific research agency while developing close working relationships with disparate portions of the health care community. Its three-way partnership with the American Medical Association and the managed care trade association, the American Association of Health Plans, in the National Guideline Clearinghouse is an excellent example of its ability to bridge the worlds of research and practice in a way that supports private-sector efforts without Federal dictates or intrusive policy. The Agency's development of the Consumer Assessment of Health Plans Survey (CAHPS) kit, which has now been voluntarily adopted by private- and public-sector plans, employers, and accreditors, is another example of the Agency's responsiveness in providing the tools that the private-sector needs to improve the quality of patient care. In light of the increasing user-direction of its work and the growing number and success of these public-private sector partnerships, it is the committee's view that shifting these activities to another agency would be shortsighted and destructive. The committee's bill takes the opposite approach by recognizing the Agency's success in re-orienting its activities, and strengthening its mandate and its resources. The committee especially values the Agency's demonstrated ability to serve as a convener of groups with different philosophies, ideologies, and economic agendas.

The committee recognizes that other agencies conduct and support health services research and quality measurement and improvement activities. To eliminate unnecessary duplication of effort and to streamline existing functions, the committee has included two important provisions in the bill. The first is to provide the Director of the Agency with authority to coordinate these activities across other agencies and departments. The second provision directs the Institute of Medicine to review existing quality activities across departments, with special emphasis on programs under Ti-

tles XVIII, XIX, and XXI of the Social Security Act that are administered by the Department of Health and Human Services, and develop recommendations for consolidation and coordination.

Responding to These Needs. The committee's proposal strengthens the newly renamed Agency and more specifically outlines the Agency's mission but also recognizes the concerns expressed during the subcommittee's hearings on the need for limitations on the overall Federal role in quality. Therefore, the committee proposal strengthens the Agency's primary mission as a scientific research agency, which subjects its research proposals to peer review; publicly discloses the methods and approaches it uses to assess scientific evidence and to conduct technology assessments; and cites the scientific evidence and the strength of that evidence in publishing clinical recommendations.

The committee has also structured the Agency to serve as a "science partner" in its work with the private and public sectors. The committee has explicitly included directions for the Agency to work in collaboration and partnership with the public- and private-sector users of its research in a number of sections of the bill. The committee deleted the word "Policy" from the Agency's name to eliminate any potential confusion regarding the Agency's role in policy making. The committee clearly intends that the Agency's research and other activities inform policy, not make policy. The committee includes a disclaimer stating that the role of the Agency is not to mandate national standards of clinical practice. In response to testimony at its hearings, the committee included a rule of construction stating that the Agency is not to mandate a national standard of specific approach to quality measurement and reporting. This bill is based on the premise that definitions and measurement of quality is an evolving science.

III. Legislative History and Votes in Committee

The Patients' Bill of Rights Act, S. 326, was introduced on January 28, 1999, by Senators Jeffords, Frist, DeWine, Enzi, Hutchinson, Collins, Brownback, Hagel, Sessions, and Burns. The bill was referred to the Senate Committee on Health, Education, Labor, and Pensions. Shortly before the introduction of S. 326, the Patients' Bill of Rights Act Plus, S. 300, was introduced in the Senate with 51 cosponsors. The Patients' Bill of Rights Act Plus, S. 300, was referred to the Senate Committee on Finance. As it was introduced, S. 326 was virtually identical to S. 300, except that S. 300 contains a number of tax provisions that are within the jurisdiction of the Finance Committee.

Both bills, S. 326 and S. 300, build on the efforts of the 105th Congress' Republican Health Care Task Force, chaired by Senator Nickles. The Task Force developed health care consumer protection legislation which resulted in the introduction of S. 2330, sponsored by Senator Nickles and 48 cosponsors. In preparation for the markup of S. 326, a number of changes were made in the nature of a Chairman's substitute. These changes are described in detail throughout Section IV of this report.

Title I of S. 326 contains key protections for health care consumers. After S. 326 was referred to the committee, Title I was amended and incorporated into the Chairman's substitute which

was considered by the committee. Title II of S. 326 (as adopted) relates to health coverage discrimination based on genetic information. It was introduced as S. 543, the Genetic Information Nondiscrimination in Health Insurance Act of 1999, on March 4, 1999, by Senators Snowe, Frist, Jeffords, Hagel, Collins, and Enzi. Senate bill 543 was referred to the Committee on Health, Education, Labor, and Pensions and incorporated as part of S. 326 in the Chairman's substitute. Title III of S. 326 (as adopted) was introduced as S. 580, the Healthcare Research and Quality Act of 1999, on March 10, 1999, by Senators Frist, Jeffords, Kennedy, Nickles, Collins, Breaux, Inouye, Mack, Hagel, Santorum, Mikulski, and Bingaman. Senate bill 580 was referred to the Committee on Health, Education, Labor, and Pensions and incorporated as part of S. 326 in the Chairman's substitute.

Throughout the 105th and 106th Congresses, the committee explored thoroughly issues related to health care quality, consumer protections, and genetics. The committee held a total of 12 hearings (see below) relating to these issues. The Patients' Bill of Rights Act adopted by the committee reflects the knowledge obtained from these hearings.

Committee Hearings on Health Care Quality, Consumer Protections, and Genetics

March 6, 1997, "Health Care Quality and Consumer Protection" (S. Hrg. 105–15)

May 20, 1997, "Health Care Quality" (S. Hrg. 105–87)

February 11, 1998, "Agency for Health Care Policy and Research Role in Health Care Quality Improvement" (S. Hrg. 105–423)

March 12, 1998, "Assessment of New Health Care Technologies: The Role of the Agency for Health Care Policy and Research" (S. Hrg. 105–503)

March 24, 1998, "Federal Legislation Relating to Health Care Quality" (S. Hrg. 105–510)

April 20, 1998, "Health Care Quality Education, Security, and Trust Act" (S. Hrg. 105–513)

April 30, 1998, "Public Expectations of Health Care Quality: Role of the Agency for Health Care Policy and Research" (S. Hrg. 105–548)

May 19, 1998, "Health Care Quality: Grievance Procedures" (S. Hrg. 105–560)

May 21, 1998, "Genetic Information and Health Care" (S. Hrg. 105–580)

January 20, 1999, "Group Health Plan Comparative Information and Coverage Determination Standards" (S. Hrg. 106–2)

March 2, 1999, "Medical Necessity" (S. Hrg. 106–9)

March 11, 1999, "Key Patients' Protections: Lessons from the Field" (S. Hrg. 106–10)

On March 17 and 18, 1999, the committee held executive sessions to consider S. 326. Senator Jeffords offered a technical corrections amendment that was accepted without objection. Twenty-seven additional amendments were considered in the executive sessions. Senate bill 326, as amended, was approved along party lines by a rollcall vote of 10 yeas to 8 nays.

A. AMENDMENTS AND MOTIONS ADOPTED BY VOICE VOTE DURING EXECUTIVE SESSIONS

Two amendments were adopted in the executive sessions by voice vote:

1. Senator Harkin offered an amendment clarifying that collection of data by the Agency for Healthcare Quality and Research would include rural areas. The amendment was adopted on a voice vote.

2. Senator Frist offered an amendment regarding access to specialists that requires a health plan to ensure that patients have access to specialty care and clarifies that such access may be provided through contractual arrangements with specialized providers outside of the plan's network. The plan may require that specialty care be provided as part of a treatment plan, and a plan may require the specialist to share necessary medical information and provide updates on care to the primary care provider. The plan may require authorizations by the primary care provider if such authorizations provide for an "adequate number of referrals." The amendment was adopted on a voice vote.

Three amendments were filed but not offered during the executive session:

1. Senator Kennedy's amendment preventing Congress from including Medical Savings Accounts in the Patients' Bill of Rights Act.

2. Senator Kennedy's amendment requiring disclosure of comparative data about plans and establishing a public-private health care quality board.

3. Senator Kennedy's amendment establishing participation rules for health professionals in all plans and giving health professionals notice of adverse participation decisions and a process for appeal.

B. ROLLCALL VOTES TAKEN DURING THE EXECUTIVE SESSIONS

Twenty-five rollcall votes on amendments were taken during the executive session:

1. Senator Kennedy offered an amendment to strike the text of S. 326 and insert new language as a complete substitute. The complete substitute was introduced as S. 6 by Senators Daschle and Kennedy. Senate bill S. 6 contains protections that would apply to all patients in private insurance. It includes many of the same concerns as S. 326 and also includes additional protections, including access to clinical trials, a prohibition on plans arbitrarily overriding physician decisions, a definition of medical necessity, and the removal of ERISA preemption with respect to claims for damages brought in state court when a health plan injures or kills a patient. The amendment was defeated on a rollcall vote of 10 nays to 8 yeas.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Gregg
Harkin	Frist
Mikulski	DeWine
Bingaman	Enzi
Wellstone	Hutchinson

Murray	Collins
Reed	Brownback
	Hagel
	Sessions

2. Senator Collins offered an amendment requiring plans to ensure the participation of physicians and pharmacists in developing and reviewing drug formularies, for those plans that cover prescription drugs limited by a formulary. It requires plans to provide for exceptions from the formulary limitation when a nonformulary alternative is medically necessary and appropriate, in accordance with the applicable quality assurance and utilization review standards. The amendment was adopted on a rollcall vote of 18 yeas.

YEAS	NAYS
Jeffords	
Gregg	
Frist	
DeWine	
Enzi	
Hutchinson	
Collins	
Brownback	
Hagel	
Sessions	
Kennedy	
Dodd	
Harkin	
Mikulski	
Bingaman	
Wellstone	
Murray	
Reed	

3. Senator Mikulski offered an amendment that requires 90 days of transitional coverage for all patients who are undergoing a course of treatment when a plan drops the provider from its network or the employer changes plans. Certain exceptions apply: patients who are terminally ill are covered until death; women in their second trimester of pregnancy are covered through postpartum care; and patients who are in a facility are covered until discharge. For such extended transitional care, no additional cost-sharing requirements may be imposed on the patient, and the provider must agree to continue abiding by the plan's procedures for prior authorization and quality assurance standards. The amendment was defeated on a rollcall vote of 10 nays to 8 yeas.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Gregg
Harkin	Frist
Mikulski	DeWine
Bingaman	Enzi
Wellstone	Hutchinson
Murray	Collins
Reed	Brownback

Hagel
Sessions

4. Senator Wellstone offered an amendment that would establish a State grant program to create State-level consumer assistance programs. The amendment was defeated on a rollcall vote of 10 nays to 8 yeas.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Gregg
Harkin	Frist
Mikulski	DeWine
Bingaman	Enzi
Wellstone	Hutchinson
Murray	Collins
Reed	Brownback
	Hagel
	Sessions

5. Senator Dodd offered an amendment that limits disclosure of predictive genetic information, establishes enforcement for the genetics provisions, and prohibits employers from discriminating against employees or potential employees on the basis of their genetic information. The amendment was defeated on a rollcall vote of 10 nays to 8 yeas.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Gregg
Harkin	Frist
Mikulski	DeWine
Bingaman	Enzi
Wellstone	Hutchinson
Murray	Collins
Reed	Brownback
	Hagel
	Sessions

6. Senator Mikulski offered an amendment that prohibits managed care organizations from denying payment for covered services provided by a continuing care senior community, skilled nursing facility, or other "qualified" facility regardless of whether the managed care organization has a contract with that facility. The amendment failed on a rollcall vote of 9 nays to 9 yeas.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Gregg
Harkin	Frist
Mikulski	Enzi
Bingaman	Hutchinson
Wellstone	Collins
Murray	Brownback
Reed	Hagel
DeWine	Sessions

7. Senator Harkin offered an amendment that requires group and individual health plans to have a sufficient number, distribution, and variety of qualified participating health care providers and offer out-of-network coverage (at network prices) when specific types of participating providers are located more than 30 miles or 30 minutes' driving time from the enrollee. It also requires plans to allow enrollees to use any qualified participating primary care provider as their primary care provider. The amendment was defeated on a rollcall vote of 10 nays to 8 yeas.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Gregg
Harkin	Frist
Mikulski	DeWine
Bingaman	Enzi
Wellstone	Hutchinson
Murray	Collins
Reed	Brownback
	Hagel
	Sessions

8. Senator Kennedy offered an amendment that expands the scope of patient protections in the bill to apply to all 161 million individuals with private health plans. The amendment was defeated on a rollcall vote of 10 nays to 8 yeas.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Gregg
Harkin	Frist
Mikulski	DeWine
Bingaman	Enzi
Wellstone	Hutchinson
Murray	Collins
Reed	Brownback
	Hagel
	Sessions

9. Senator Bingaman offered an amendment that would prohibit plans from discriminating against providers based on a provider's license or based on race, color, religion, sex, national origin, age, sexual orientation, or disability. The amendment was defeated on a rollcall vote of 10 nays to 8 yeas.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Gregg
Harkin	Frist
Mikulski	DeWine
Bingaman	Enzi
Wellstone	Hutchinson
Murray	Collins
Reed	Brownback
	Hagel
	Sessions

10. Senator Dodd offered an amendment requiring plans to cover routine patient care costs for certain patients participating in clinical trials approved and funded by the National Institutes of Health, the Department of Veterans Affairs, or the Department of Defense. Under the Dodd amendment, group health plan under ERISA may not deny an individual participation in a clinical trial, may not deny the coverage of routine patient costs for items and services associated with participation in the trial, and may not discriminate against the individual on the basis of the enrollee's participation in such trial. The amendment was defeated on a rollcall vote of 10 nays to 8 yeas.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Gregg
Harkin	Frist
Mikulski	DeWine
Bingaman	Enzi
Wellstone	Hutchinson
Murray	Collins
Reed	Brownback
	Hagel
	Sessions

11. Senator Frist offered an amendment to order the Institute of Medicine (IOM) to conduct a comprehensive study to assess patient access to clinical trials and the coverage of routine patient care by private health plans and insurers. The IOM would report its findings and recommendations to the committee in 12 months. The amendment was adopted on a rollcall vote of 10 yeas to 8 nays.

YEAS	NAYS
Jeffords	Kennedy
Gregg	Dodd
Frist	Harkin
DeWine	Mikulski
Enzi	Bingaman
Hutchinson	Wellstone
Collins	Murray
Brownback	Reed
Hagel	
Sessions	

12. Senator Frist offered an amendment that requires an external reviewer to make an independent determination based on the valid, relevant, scientific, and clinical evidence. It mandates consideration of appropriate and available information, including evidence offered by the patient and the patient's physician, expert consensus, peer-reviewed literature, as well as the plan's clinical practice guidelines by the external reviewer. It also requires that the independent external reviewer have expertise of the same specialty in the issue under determination. Senator Frist eliminated the provision of rebuttable presumption originally included in the amendment. The amendment was adopted on a rollcall vote of 11 yeas to 7 nays.

YEAS	NAYS
Jeffords	Kennedy
Gregg	Dodd
Frist	Harkin
DeWine	Mikulski
Enzi	Wellstone
Hutchinson	Murray
Collins	Reed
Brownback	
Hagel	
Sessions	
Bingaman	

13. Senator Kennedy offered an amendment that requires all group health plans to have a process for making coverage decisions and internal appeal decisions. It also establishes a system of independent, external review. It requires plans to have a grievance process. The amendment was defeated on a rollcall vote of 10 nays to 8 yeas.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Gregg
Harkin	Frist
Mikulski	DeWine
Bingaman	Enzi
Wellstone	Hutchinson
Murray	Collins
Reed	Brownback
	Hagel
	Sessions

14. Senator Kennedy offered an amendment that prohibits a health plan from arbitrarily interfering with or altering the decision of the treating physician regarding the manner or setting (defined as location of treatment—inpatient/outpatient, and duration of treatment—number of days) in which particular services are delivered, if the services are medically necessary or appropriate (defined as consistent with generally accepted principles of professional medical practice) for treatment or diagnosis to the extent that such treatment or diagnosis is otherwise a covered benefit. The amendment was defeated on a rollcall vote of 10 nays to 8 yeas.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Gregg
Harkin	Frist
Mikulski	DeWine
Bingaman	Enzi
Wellstone	Hutchinson
Murray	Collins
Reed	Brownback
	Hagel
	Sessions

15. Senator Wellstone offered an amendment to allow participants to self-pay for the services of a mental health provider, if the self-funded group health plan does not approve coverage or in cases where the participant has exhausted the number of visits available under the plan. The amendment was adopted on a rollcall vote of 17 yeas to 1 nay.

YEAS	NAYS
Jeffords	Sessions
Gregg	
Frist	
DeWine	
Enzi	
Hutchinson	
Collins	
Brownback	
Hagel	
Kennedy	
Dodd	
Harkin	
Mikulski	
Bingaman	
Wellstone	
Murray	
Reed	

16. Senator Dodd offered an amendment that requires health care plans that cover prescription drugs through a formulary to include participating physicians and pharmacists in developing the formulary; to disclose the nature of the formularies; and, consistent with the utilization review program, to provide for exceptions from the formulary limitation when a nonformulary alternative is medically indicated. In addition, it prohibits health care plans that offer coverage of prescription drugs or medical devices from denying coverage on the basis that the use is investigational, if it is prescribed in the manner approved by the FDA. The amendment was defeated on a rollcall vote of 10 nays to 8 yeas; however, many of the provisions in this amendment were included in the Collins amendment (No. 2), which was adopted unanimously.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Gregg
Harkin	Frist
Mikulski	DeWine
Bingaman	Enzi
Wellstone	Hutchinson
Murray	Collins
Reed	Brownback
	Hagel
	Sessions

17. Senator Harkin offered an amendment that requires health plans that cover specialty care to ensure that patients who need specialty care have access to appropriate specialists, including pediatric specialists for children. If the plan refers an individual to a

nonparticipating specialist because the plan does not have an appropriate or available specialist in its network, the care is required to be covered at no additional cost beyond what the individual would pay for a participating provider. For individuals with ongoing special conditions, health plans would be required to allow direct access to certain specialists or to choose an appropriate specialist as their primary care physician. The amendment was defeated on a rollcall vote of 10 nays to 8 yeas.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Gregg
Harkin	Frist
Mikulski	DeWine
Bingaman	Enzi
Wellstone	Hutchinson
Murray	Collins
Reed	Brownback
	Hagel
	Sessions

18. Senator Wellstone offered an amendment that prohibits self-funded group health plans from involuntarily disenrolling a participant for disruptive, unruly, or uncooperative behavior that seriously impedes the plan's ability to furnish services, if the participant has diminished mental capacity, severe and persistent mental illness, or a serious childhood mental and emotional disorder. The amendment was defeated on a rollcall vote of 10 nays to 8 yeas.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Gregg
Harkin	Frist
Mikulski	DeWine
Bingaman	Enzi
Wellstone	Hutchinson
Murray	Collins
Reed	Brownback
	Hagel
	Sessions

19. Senator Wellstone offered an amendment to protect certain health care providers from retaliation by the managed care organization for reporting quality of care problems to a supervisor, oversight agency, or accrediting organization, or for engaging in patient advocacy. The amendment was defeated on a rollcall vote of 10 nays to 8 yeas.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Gregg
Harkin	Frist
Mikulski	DeWine
Bingaman	Enzi
Wellstone	Hutchinson
Murray	Collins

Reed	Brownback
	Hagel
	Sessions

20. Senator Hutchinson offered an amendment that prohibits health care plans from denying coverage with respect to emergency services when an individual reasonably believes he or she is experiencing an emergency, under the prudent layperson definition of emergency. It also requires that the patient shall incur no more liability than he or she would have incurred if he or she went to a participating provider. This amendment prevents insurance companies from charging patients for the emergency care they receive from non-network hospitals. The amendment was adopted on a rollcall vote of 12 yeas to 6 nays.

YEAS	NAYS
Jeffords	Kennedy
Gregg	Dodd
Frist	Harkin
DeWine	Mikulski
Enzi	Murray
Hutchinson	Reed
Collins	
Brownback	
Hagel	
Sessions	
Bingaman	
Wellstone	

21. Senator Murray offered an amendment prohibiting plans from denying coverage with respect to emergency services when an individual reasonably believes that he or she is experiencing an emergency, under the prudent layperson definition of emergency. Coverage cannot be denied if a patient, in such an emergency, does not obtain prior authorization or goes to a nonparticipating provider. If a patient goes to a nonparticipating provider, the amendment provides that the patient will incur no more liability than he or she would have had he or she gone to a participating provider. Coverage includes "post-stabilization and maintenance" care, similar to coverage under Medicare. The amendment was defeated on a rollcall vote of 10 nays to 8 yeas.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Gregg
Harkin	Frist
Mikulski	DeWine
Bingaman	Enzi
Wellstone	Hutchinson
Murray	Collins
Reed	Brownback
	Hagel
	Sessions

22. Senator Murray offered an amendment that requires group health plans to cover inpatient care following a mastectomy, lumpectomy, or lymph node dissection for the treatment of breast

cancer. The length of stay would be determined by the physician, in consultation with the patient. The amendment was defeated on a rollcall vote of 9 nays to 8 yeas.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Frist
Harkin	DeWine
Mikulski	Enzi
Bingaman	Hutchinson
Wellstone	Collins
Murray	Brownback I43Reed
	Hagel
	Sessions

23. Senator Wellstone offered an amendment that requires all group health plans to offer a point-of-service product option if only closed-panel network plans would otherwise be available. The amendment was defeated on a rollcall vote of 10 nays to 8 yeas.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Gregg
Harkin	Frist
Mikulski	DeWine
Bingaman	Enzi
Wellstone	Hutchinson
Murray	Collins
Reed	Brownback
	Hagel
	Sessions

24. Senator Reed offered an amendment requiring health care plans to provide referrals to a pediatric specialist for a child with a mental or physical condition, disability, or disease of sufficient seriousness and complexity to require diagnosis, evaluation, or treatment by a specialist. If the plan refers the child to a nonparticipating specialist, the plan is required to cover the services at no additional cost beyond those paid-for services received from a participating specialist. The amendment was defeated on a rollcall vote of 10 nays to 8 yeas.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Gregg
Harkin	Frist
Mikulski	DeWine
Bingaman	Enzi
Wellstone	Hutchinson
Murray	Collins
Reed	Brownback
	Hagel
	Sessions

25. Senator Kennedy offered an amendment that permits individuals covered under ERISA plans to hold such plans accountable for

actions that result in injury or death. The amendment was defeated by a rollcall vote of 10 nays to 8 yeas.

YEAS	NAYS
Kennedy	Jeffords
Dodd	Gregg
Harkin	Frist
Mikulski	DeWine
Bingaman	Enzi
Wellstone	Hutchinson
Murray	Collins
Reed	Brownback
	Hagel
	Sessions

IV. Explanation of the Legislation and Committee Views

A. Overview of Provisions Amended in Chairman's Substitute of S. 326

Title II, Individual Rights with Respect to Personal Medical Information, was struck from the Chairman's mark, which was adopted without objection in executive session. The Chairman struck this title in order to consider separately more comprehensive legislation on this issue. In striking this title, Title III, Genetic Information and Services, becomes Title II; and Title IV, Health Care Research and Quality, becomes Title III. Additional changes were made to existing provisions in the Chairman's substitute and are described in detail in the corresponding section under paragraph B.

B. Detailed Explanation of Key Provisions of the Legislation Adopted by the Committee

TITLE I—PATIENTS' BILL OF RIGHTS

Subtitle A—Right to Advice and Care

Sec. 101. Patient right to medical advice and care

The purpose of Subtitle A is to improve access to needed health care services across all types of health care delivery systems.

Sec. 721. Patient access to emergency medical care

Section 721 requires a group health plan, other than a fully insured group health plan, that provides coverage for emergency services to pay for appropriate emergency medical screening exams using a prudent layperson standard and any additional emergency care necessary to stabilize an emergency condition after a screening exam. The legislation incorporates the definition of "stabilize" that is used in the Emergency Medical Treatment and Labor Act (EMTALA) (Sec. 1867(e)(3) of the Social Security Act) which defines "stabilize" as medical treatment for an emergency medical condition "necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility, or, with respect to" a pregnant woman, to deliver (including the placenta). The committee intends for the phrase "provide coverage

for" to include reimbursement. This coverage must be provided without requiring prior authorization and regardless of whether the emergency facility is within the plan's network.

Plans may impose cost-sharing so long as it is uniformly applied to similarly situated individuals and to all benefits consisting of emergency medical care. The committee believes that it would be acceptable to have a differential cost-sharing for in-network emergency coverage and out-of-network emergency coverage, so long as such cost-sharing is applied consistently across a category (i.e., in-network, out-of-network) and uniformly to similarly situated individuals and communicated in advance to participants and beneficiaries (in accordance with section 714 (b)(1) and (b)(2) as added by section 111).

Under the prudent layperson standard, a person who possesses an average knowledge of health and medicine would identify emergency care to be necessary for an emergency medical condition for which there are acute symptoms of significant severity (including severe pain). The prudent layperson would expect the absence of immediate medical attention to result in serious jeopardy to the individual's health, serious impairment to bodily function, or serious dysfunction of any bodily organ or part.

The purpose of this provision is to address the committee's concern that emergency service denials may cause some patients to forgo necessary care out of concern they will have to pay for these services out of their own pocket. The committee is also concerned that some plans may refuse to cover care that is necessary and appropriately provided in the emergency room, even though these plans hold themselves out as providing coverage of emergency room services.

Some plans and managed care organizations have also required prior authorization for emergency department services and/or have denied payment retroactively for emergency room services if it turns out the patient's situation does not meet the plan's or managed care organization's definition of an emergency. In such cases presently, if a plan participant seeks care in an emergency room and the MCO later determines that emergency care was not medically necessary, the participant may be liable for the entire bill.

It is the committee's belief that the typical health care consumer who has not undergone medical training may not always be capable of distinguishing an emergency medical situation from a non-emergency medical condition with similar symptoms. For instance, severe chest pain could be a symptom of indigestion or a heart attack. In addition, there are some situations when obtaining advance approval is simply not feasible, such as if a patient is unconscious or does not have his or her membership card available.

The committee adopted an amendment offered by Senator Hutchinson, adding a new paragraph (2) to Section 721(b), clarifying that plans may not hold a participant or beneficiary liable for any additional charges from a non-participating provider who has provided emergency services for the participant or beneficiary. In many communities, plans and MCOs typically contract with specific providers and hospitals. However, an individual acting as a prudent layperson may seek services at the nearest facility, depending on the severity of the symptoms. It is the committee's intent to ensure

that individuals acting under the prudent layperson standards are not held liable financially for exercising this right when they seek care at a non-network facility.

The committee recognizes that this provision will require plans and providers (including treating facilities) that do not have contractual relationships to negotiate acceptable payment for these services. The committee is also interested in encouraging a fair payment arrangement that provides reasonable compensation for emergency services under the prudent layperson standard and that is equitable to the provider and the plan paying for the treatment.

The committee recognizes the reimbursement structure for hospitals and providers under Medicare's traditional fee-for-service program as an example of a fair payment arrangement. Moreover, the committee believes that such an arrangement can be implemented with ease, since the prudent layperson standard under the Medicare+Choice program uses this payment model and since most facilities and managed care organizations that administer health benefits on behalf of group health plans also participate in traditional Medicare. To the extent the Secretary of Labor promulgates guidance addressing payment issues, the committee expects that such guidance would treat payment arrangements consistent with the Medicare reimbursement model as acceptable.

Sec. 722. Offering choice of coverage options

Section 722 of the legislation requires a group health plan, other than a fully insured group health plan, that provides coverage only through a single closed-panel network of providers to offer participants the option to enroll in point-of-service coverage at the time of enrollment and such other times when the plan offers a choice of coverage options. Alternatively, the requirements of this section would be satisfied if there is a choice of two or more closed-panel coverage options with significantly different provider networks. It is the committee's intent that the requirements of this section would also be satisfied if there is an option to enroll in a fee-for-service coverage option, a preferred provider organization (PPO) coverage option, or any other coverage option that does not limit coverage or reimbursement to network providers only. The legislation provides an exemption for small employers (2–50 employees) that sponsor group health plans.

In order to satisfy the requirements of this section by offering two or more closed-panel options, the networks must differ significantly in their selection of participating health care professionals or networks. The committee intends that the requirements of this section would be satisfied, regardless of whether these options are provided under a single employer plan with two coverage options, or under two separate plans (regardless of whether the plans have similar or identical plan designs), so long as the options differ significantly in their provider network composition.

The committee recognizes that there may be administrative costs associated with the offering of a point-of-service option. However, the legislation does not require employers to pay any additional costs associated with this section or make equal contributions to different health coverage options. In addition, the employer or plan may impose higher premiums for participants who select the point-

of-service option. The committee recognizes that point-of-service plans typically require greater out-of-pocket cost-sharing for the use of non-network providers and believes that such practices are consistent with the requirements of this section. This provision does not require a plan to cover the services of a particular type of health care professional or to cover services provided by health care professionals that the plan has excluded for reasons of fraud, poor quality, or other similar reasons.

Subparagraph (A) of subsection (a)(2) was struck from the Chairman's substitute. This subparagraph would have extended an exemption to situations where there is a choice of coverage through more than one insurance issuer. The provision was deleted because it did not fit within the scope of this subtitle, which does not apply to fully insured group health plans.

Sec. 723. Access to obstetric and gynecological care

Section 723 of the legislation requires a group health plan, other than a fully insured group health plan, to provide female enrollees with direct access to routine obstetric and gynecological (ob/gyn) care without requiring authorization by a gatekeeper, such as a referral from a primary care physician or approval by the plan's utilization reviewer. The committee intends for plans that allow for the designation of an ob/gyn as a female participant's primary care provider to be considered in compliance with this requirement. However, the committee does not intend for this section to be interpreted to require plans to allow for the designation of an ob/gyn as a primary care provider. Moreover, the committee does not intend for a plan's rules regarding payment or cost-sharing for in-network and out-of-network coverage to be changed by the requirements of this section.

Many plans allow female enrollees direct access to an ob/gyn for an annual visit and "well woman exam." However, some plans require an authorization before a female participant can see an ob/gyn for this type of routine care. The purpose of this section is to provide women with access to routine ob/gyn care by removing any barriers that could deter women from seeking this type of preventive care.

The committee intends for the term "routine care" to mean preventive and primary ob/gyn care provided in an outpatient setting. Primary follow-up care, including minor procedures which are performed in the physician's office setting, is also intended by the committee to be considered routine follow-up care. The committee does not intend for this provision to require direct access to an ob/gyn subspecialist or to secondary or tertiary ob/gyn services, such as inpatient care or inpatient or outpatient surgery, if a plan requires an authorization for such services. Nor is the committee's intent for this provision to allow the ob/gyn specialist to authorize such care or services, if the plan does not allow designation of an ob/gyn as a primary care provider. Section 723 does not prevent a plan from requiring the ob/gyn specialist to notify the designated primary care provider of any treatment decisions and interventions.

Section 723 of the legislation was amended to add new subsection (c)(3) in the Chairman's substitute to clarify that plans would not be precluded from allowing non-physician health care

professionals to provide routine ob/gyn care. In addition, the entire section 723 was redrafted and adopted as part of the package of technical amendments offered by the Chairman. The purpose of the redrafting was to clarify the language of the section without changing the underlying intent of the provision.

Sec. 724. Patient access to pediatric care

Section 724 of the legislation requires a group health plan, other than a fully insured group health plan, to provide child enrollees with direct access to a pediatrician for routine pediatric care without requiring authorization by a gatekeeper, such as a referral from a primary care provider who is not a pediatrician. The committee intends for the term "routine care" to mean preventive and primary pediatric care and primary follow-up care provided by a pediatrician in an outpatient setting.

The committee is aware that many plans allow a pediatrician to be designated as a child's primary care provider and intends for this practice to be considered in compliance with the requirements of this section. The committee does not intend for this section to be interpreted as requiring the designation of a pediatrician as a child's primary care provider if a plan does not permit such a practice.

Section 724 was amended to add a new subsection (b)(2) to the Chairman's substitute, specifying that this provision does not prevent a plan from requiring the pediatrician to notify the designated primary care provider of any treatment decisions and interventions. It was also amended to add a new section (b)(3) in the Chairman's substitute to clarify that plans would not be precluded from allowing nonphysician health care professionals to provide routine pediatric care. In addition, the entire Section 724 was redrafted and adopted as part of the package of technical amendments offered by the Chairman. The purpose of the redrafting was to clarify the language of the section without changing the underlying intent of the provision.

Sec. 725. Access to specialists

Section 725 of the legislation was added by an amendment offered by Senators Frist and DeWine and adopted by voice vote in executive session. This section requires a group health plan, other than a fully insured group health plan, to ensure that plan enrollees have access to specialty care when such care is needed by an enrollee and covered under the plan and when such access is not otherwise available under the plan.

The committee recognizes that many plans provide differential benefits or cost-sharing based on whether services are obtained from a network or a non-network provider and does not intend for this section to disrupt this practice. The purpose of this section is to address situations in which a plan that does not provide any out-of-network benefit has an insufficient number and mix of specialists and subspecialists in its network to provide all the services covered under the plan without unreasonable delay. The committee is concerned that such a situation may create a barrier to care and can negatively impact patient health, particularly for patients with

complex or chronic medical conditions who require ongoing or frequent speciality care.

The committee also recognizes that, in some markets, it may not be feasible for a plan or its network to contract with a sufficient number and mix of specialists, for instance, a small community where there is only one nephrologist who does not participate in any networks. In such a situation, the committee intends that a plan providing benefits through a closed-panel network would take the necessary steps to secure the services of a nephrologist when a covered enrollee requires such services. This section should not be construed as requiring a plan to cover specific benefits or the services of a specific type or class of providers. However, the committee intends that when the plan covers a benefit or service that is appropriately provided by a particular type of specialist not in the network, the benefit will be provided using the "in-network" cost-sharing schedule.

This section defines specialty care as care and treatment provided by a health care practitioner, facility, or center that has adequate expertise through appropriate training and experience, including the training and qualifications to perform certain specialized procedures and/or treatments. The committee intends for the words "center" and "facility" to include, for example, a center of excellence. The committee believes that it is important for patients to have access to specialists with age appropriate expertise. Thus, in using the term "adequate expertise," the committee intends for this to include specialists with age appropriate expertise, such as pediatric and geriatric specialists.

The committee recognizes that disagreements about "adequate expertise" may often stem from an individual's personal preference or perception rather than from medical need. For instance, a plan may have ten qualified ob/gyn specialists in its network, but an enrollee insists that the plan should cover a non-network ob/gyn specialist that the enrollee believes is "the best" in the field. Or, a patient may prefer to receive an elective surgery at a center of excellence even though the plan's local network facilities routinely perform such procedures with good outcomes. The committee also recognizes that there may be some occasions when a plan's network providers may not, in fact, have adequate expertise. For instance, there may be just a few uniquely situated specialists across the country who have experience treating a certain rare form of stomach cancer and these specialists do not participate in the plan's network. In such a situation, the committee believes that a determination of "adequate expertise" can be made based on the comparative qualifications and credentials of the network and non-network specialists. In general, it is the committee's desire to apply the requirements of this section, and other provisions of this Act, primarily when disagreements about "adequate expertise" hinge on the actual qualifications, experience, and credentials of the specialist(s).

In arranging for specialty care, the committee anticipates that plans will negotiate a variety of arrangements. For example, a plan may seek to include the specialist in its network or it may negotiate an agreement with a specialist to provide care to an enrollee when the situation arises under the requirements of this provision.

Section 725 (a) of this section permits a plan to enter into a contractual arrangement with a specialist outside the network to meet the requirements of this section.

This section would not prevent a plan from requiring that the specialist adhere to a treatment plan if it: (1) is developed by the specialist in consultation with the patient and the patient's primary care provider; (2) is approved by the plan; and (3) meets the quality assurance and utilization review standards of the plan. In addition, this section would not prevent a plan from requiring the specialist to provide the patient's primary care provider with regular updates on the patient's health status and care, as well as all other necessary medical information.

This section would not prevent a plan from requiring authorization by the patient's primary care provider in order to obtain specialty services, so long as the authorization is for an adequate number of visits under an approved treatment plan, if required by the plan. For example, a breast cancer patient may require 8 chemotherapy treatments according to the treatment plan developed by the treating oncologist in consultation with the patient and the primary care provider. The committee anticipates that a plan might approve some portion or the entire block of 8 referrals before requiring the patient to seek authorization for additional visits, depending on factors such as the frequency of specialist visits required, the time span covered by the specialty visits under the authorization, and the frequency of primary care visits necessary to coordinate and ensure the quality of the patient's overall care. The committee's goal with respect to this provision is to prevent health plans from imposing unnecessarily burdensome requirements when ongoing care is medically necessary and appropriate for patients with complex and chronic conditions.

Sec. 726. Continuity of care

Section 726 of the legislation requires a group health plan, other than a fully insured group health plan, to provide continued benefits with the same provider for a patient who is undergoing a course of treatment (as described in this section) when his or her provider is terminated from the plan's network or when benefits or coverage are terminated because of a change in the terms of the provider's participation in the plan's network. It is the committee's intent that a change in the provider's participation in the network could be a result of the plan sponsor changing its relationship with an issuer or third party administrator. It is also the committee's intention that these requirements would not apply as a result of the patient's action, for example, if the patient voluntarily switched enrollment from coverage option A to coverage option B. In addition, this section requires a plan to give timely notice to patients who are undergoing a course of treatment when their provider has been terminated and to provide these patients with an opportunity to notify the plan of a need for transitional care.

The committee recognizes that employers periodically change their plan designs and/or relationships with services providers. The committee also recognizes that MCOs, physician group practices, and health care facilities negotiate and renegotiate provider relationships on an ongoing basis. The purpose of this section is to en-

sure that in such situations patients undergoing active treatment are able to make a smooth transition in care.

This section specifically requires a plan to continue coverage with a patient's provider, if the patient is undergoing a course of treatment that includes institutional care, care for a terminal illness, or care starting from the second trimester of pregnancy. Coverage duration is for up to 90 days for a patient who is terminally ill, or who is receiving institutional care. For a pregnant woman who is in her second or third trimester, coverage is required to be continued through the postpartum period. Section 726(b)(1) of the Chairman's substitute was amended to clarify that the extension of coverage under this section is available for up to 90 calendar days.

The committee intends for the requirements of this section to apply where a plan provides benefits through a network of providers or provides a greater benefit or higher level of coverage for the use of certain designated providers or facilities. If a plan is required under this section to provide continued coverage, it is the committee's intent that such coverage would be provided on the same basis as it was prior to the termination. For example, a plan providing coverage through a PPO or POS network arrangement must provide continued coverage under the terms of this section when it terminates a provider, even though access to that provider may be available at a reduced level of coverage (i.e., higher cost-sharing for the patient) under such arrangements.

The committee believes that a patient undergoing a course of treatment (as described in this section) should not have the terms of his or her coverage changed during the course of treatment due to a change in the provider relationship or contract. The committee does not intend for this interpretation to restrict in any manner a plan's ability to change its general cost-sharing requirements. For example, if a plan increases its co-payment structure for all similarly situated participants and beneficiaries, or the plan's third party administrator changes its cost-sharing requirements across a product or policy line, such a change would not trigger a requirement to provide continued coverage under this section.

The committee recognizes that, while some group health plans act as their own administrators and contract directly with providers, the vast majority simply purchase access to a third party administrator's network. The committee is also aware that most provider relationships and contracts are between providers and third party administrators or other service providers that provide services in connection with a group health plan. The committee intends that the requirements of this section would apply, regardless of whether a group health plan directly terminates the relationship with the provider, or a third party administrator acting on the plan's behalf terminates the relationship. For example, entities such as a managed care organization, a network management firm, or a physician practice management firm may be responsible for terminating a provider contract. To the extent such an organization is providing network management services to a group health plan and the termination of the provider relationship affects a participant or beneficiary in one of the three scenarios described in the paragraph above, the committee intends for the requirements of this section to apply. In addition, the requirements of this section

would also apply when a plan terminates its contract with a third party administrator (and the third party administrator's network), resulting in a patient's loss of access, or significant change in coverage, with respect to his or her provider.

This section defines "terminated" as, with respect to a contract, the expiration or nonrenewal of a contract by the plan, except for failure to meet the plan's quality standards or for fraud. The terminated contract could be a contract between a plan and a physician, a network, a group of physicians, and/or a facility. The committee intends for the word contract to encompass any arrangement, such as a contract or any arrangement that has a similar effect as a contract.

This section requires that, in order to receive continued payment by the plan (or its third party administrator), the terminated provider must agree to accept the rates in effect before the termination of the relationship or the rates provided under the replacement arrangement. The provider may not impose additional cost-sharing on the patient above the cost-sharing in effect under the old relationship. The provider must also agree to follow the plan's quality assurance standards and other policies previously in effect, such as prior authorization and referral requirements.

Notice Requirement: This section requires a plan to notify individuals undergoing a course of treatment (as described in this section) when the provider who is treating the individual is terminated from the network. The committee recognizes that plans will have to rely on providers in most situations to identify the patients who are undergoing courses of treatment described in this section. The committee intends that when a network terminates a provider from its network, it will include in its termination notice information about this right and the terms and conditions that the provider must accept to provide transitional care. In addition, the committee anticipates that if a provider is interested in continuing care for the patient that, in addition to agreeing to the terms and conditions under Section 726(c), the provider will notify the patient of his or her right to continued care. It is the committee's view that the provider and plan need not provide notice to the individual if the provider is unwilling or unable to provide transitional care under the terms outlined in Section 726(c).

The committee anticipates that a provider who is willing to accept the terms and conditions of providing transitional care will notify the plan of the patient's desire to have transitional care and that the plan will then notify the patient that it is providing such coverage with the same provider. Section 726(a)(1)(C) requires that a plan provide the individual with an opportunity to notify the plan of a need for transitional care; however, it is the committee's intention that, once a plan has been notified by the patient's provider of a need for transitional care, the plan may use its discretion to authorize continued coverage without first requiring the patient to notify the plan of a need for transitional care.

When the sponsor of a group health plan (i.e, employer or union) terminates a relationship with a third party administrator or service entity that results in participants and beneficiaries becoming eligible for continued care under this provision, the group health plan (or employer) may provide participants and beneficiaries with

notice about their rights to continued care as part of the open enrollment process. An individual may then notify the plan of his or her desire to receive continued care. The committee recognizes that whenever a group health plan (or employer) changes its relationship with a third party administrator, and therefore the third party administrator's network, there will be a number of individuals who qualify for transitional care under this section. The committee is aware that such changes are usually planned relatively far in advance of their implementation and that many provider contract terminations or non-renewals can also be anticipated in advance. In order to minimize the compliance burden of notice requirements under this section, the committee anticipates that the Secretary's guidance will include examples of situations in which a plan might satisfy the requirements of this section by providing notice sufficiently in advance of a change and continuing coverage throughout that period.

Sec. 727. Protection of patient-provider communications

Section 727 of the legislation prohibits a group health plan, other than a fully insured group health plan, from imposing any prohibition or restriction, contractual or otherwise, on a health care professional's ability to discuss freely with the patient information about the patient's health status, medical care, and treatment options. The committee intends for a health care professional to be able to discuss treatment alternatives with a patient and render good medical advice, regardless of whether the alternatives or recommended treatment are covered benefits or services under the plan.

The committee is aware that, as a result of this section, health care professionals may sometimes discuss or recommend treatment alternatives that may be excluded from coverage under the plan. However, this section does not require a plan to cover any benefits or services that are excluded from coverage under the plan. It is the committee's intent, with respect to a group health plan (other than a fully insured group health plan), that this section be consistent with the policy of the Federal Employees Health Benefits Program, as ordered by Executive Memorandum and executed by U.S. Office of Personnel Management rulemaking (Federal Register, August 10, 1998; Vol. 63; No. 153), specifically as such policy pertains to potential conflict regarding ethical, moral, or religious beliefs.

The committee intends that nothing in this section shall be construed as prohibiting a plan from requiring a health care provider to participate in, or cooperate with, programs and policies designed to monitor and improve the quality of health care services. Nor shall this section be construed as impeding payment and reimbursement arrangements, including capitated payment arrangements, that are negotiated between a plan and a health care provider.

Sec. 728. Patient's right to prescription drugs

Section 728 of the legislation was offered as an amendment by Senators Collins and Jeffords and adopted by rollcall vote in executive session. This section requires a group health plan, other than

a fully insured group health plan, that provides prescription drug benefits through a formulary to ensure that physicians and pharmacists participate in developing and reviewing the formulary. In addition, this section requires that a plan allow enrollees to access non-formulary prescription drugs through an exceptions process when medically necessary, appropriate, and consistent with quality assurance and utilization review standards of the plan, and when such drug would otherwise be a covered benefit.

The committee recognizes that formularies are an effective tool that health plans and their third party administrators, including managed care networks and pharmacy benefit managers, use to manage drug expenditures and promote safety. The committee is aware that managed care has generally expanded access to prescription drugs and helped to maintain their affordability for millions of Americans and is interested in ensuring that prescription drugs remain accessible and affordable, particularly in light of recent prescription drug cost trends. For a majority of people, the prescription drugs included in the plan's formulary will provide the desired therapeutic results. However, the committee is concerned that there may be occasions when a patient could be denied access to medication that is medically necessary and appropriate if a plan only provides coverage for medications on the formulary list and there is no medically necessary and appropriate prescription drug for the condition on that formulary list. In some situations, the only effective drug for a patient may not be on the formulary. For instance, a formulary might include 3 cholesterol-lowering medications, but a particular patient might only respond to, or be less likely to experience adverse side effects from, a fourth alternative that is not on the formulary. Thus, the purpose of this provision is to ensure that a plan's use of a formulary does not have an adverse impact on quality of care by hindering a patient's access to needed medication.

This section would require a group health plan to provide an exception to the formulary limitation, in accordance with the applicable quality and utilization review standards of the plan, when: (1) the plan's formulary does not include a medically necessary and appropriate medication for the patient's condition; (2) a non-formulary alternative is medically necessary and appropriate; and (3) the non-formulary medication is not otherwise excluded from coverage. Where a formulary and non-formulary drug are expected to achieve a similar outcome, it is the committee's intention that a plan need not provide coverage for the non-formulary medication unless the formulary medication is demonstrated to be ineffective or it is not appropriate for a specific patient.

The committee recognizes that many plans already provide access to medications that are not on the formulary in order to be responsive to consumer needs as well as preferences for medications that are not included on the formulary. Such arrangements, because they allow for consumer preferences and generally increase costs for all enrollees, typically provide such access at a higher cost-sharing level for the patient. For example, many plans use a multi-tiered cost-sharing structure that requires different cost-sharing or co-payments for brand name formulary drugs, generic

formulary drugs, and non-formulary drugs. Similarly, some plans also require different cost-sharing for mail order and retail drugs.

The committee recognizes that prescription drug benefit design is a rapidly evolving area and does not wish to interfere with the evolution of these programs or "lock-in" any particular approach. The committee believes that a prescription drug benefit that employs differential cost-sharing for formulary and non-formulary medications, including the use a multi-tiered cost-sharing structure or a similar arrangement, is consistent with the intent of this section, so long as the patient cost-sharing requirements for medically necessary and appropriate non-formulary medications do not undermine the committee's intent of providing a meaningful benefit for patients.

It is the committee's intent that a plan, in selecting to use a multi-tiered copayment structure, must set cost-sharing within a given policy, product or benefits package that is consistent across a category, communicated up front to participants and beneficiaries (in accordance with Section 714 (b)(2), (b)(11), and (16)(E) as added by Section 111 of this legislation), and does not vary by medication or patient.

The committee also intends for the requirements of this section to apply to each plan (and coverage option) that uses a formulary, including plans that provide benefits through a "carve-out" prescription drug program.

Sec. 729. Self-payment for behavioral health services

Section 729 of the legislation was offered as an amendment by Senator Wellstone and adopted by rollcall vote in executive session. This section bars a group health plan, other than a fully insured group health plan, from prohibiting or discouraging an enrollee from self-paying for behavioral health services once the plan has denied coverage. In addition, this section prohibits a plan from terminating a provider who permits an enrollee to self-pay for behavioral health services that are otherwise not covered or for which benefits are limited under the plan and for which the plan has denied coverage.

The committee recognizes that there are no existing laws that prohibit self-payment for behavioral health services in private-sector health coverage. However, there may be some cases in which a plan or a third party administrator that provides services to a plan (e.g., a MCO or managed behavioral health firm) may contractually prohibit participating providers from accepting self-payment for services provided outside the scope of plan coverage. In addition, plans often limit benefits for behavioral health services through utilization limitations, such as a cap on the number of covered inpatient days on outpatient visits.

A patient, in consultation with his or her treating health care professional, may determine that additional behavioral health services are needed, beyond any limits imposed by the plan or the plan's agent that manages the utilization of services for the plan. The purpose of this section is to allow a patient in this situation the right to seek and pay for such additional services from the same health care professional who had been treating the patient while such treatment was covered by the plan. The committee be-

lieves that thus maintaining a provider relationship can often have a positive impact on patient outcomes.

The committee feels strongly that a provider should disclose fully to the patient that such services are rendered by the provider acting in his or her individual capacity as a solo practitioner and outside the auspices (including the terms and conditions) of the plan. Although a plan may not terminate a provider for accepting self-payment under the terms of this section, the committee believes that nothing in this section would prevent a plan from imposing reasonable parameters on a provider who accepts self-payment. For instance, a plan may impose restrictions on a provider's use of plan resources and facilities and may require a provider to adhere to certain reporting requirements such as adverse drug events. Nothing in this section would require a provider to accept self-payment for such services.

This section would not prevent a plan from terminating a contract with a health care provider failing to meet applicable quality standards or for fraud. In using the term "self-pay," the committee intends that the plan will pay zero percent, and the enrollee will pay out of pocket the entire amount negotiated by the provider and the patient.

Sec. 730. Generally applicable provision

Section 730 of the legislation establishes that Subtitle A of Title I applies to group health plans other than fully insured group health plans. This section uses the definition of group health plan established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) in Section 733(a) of ERISA. It also adds a definition of a "fully insured group health plan" under Section 733(a)(3) of ERISA. The definition of fully insured group health plan under this section refers to a plan for which the benefits under the plan are provided pursuant to the terms of an arrangement between a group health plan and a health insurance issuer, and all of the benefits are guaranteed by the health insurance issuer under a contract or policy of insurance.

Section 730 also establishes that in the case of a group health plan that provides benefits under two or more coverage options, the requirements of Subtitle A, except for Section 722, would apply separately to each coverage option.

The committee intends for this section to ensure that group health plans that do not purchase insurance contracts or policies that are subject to State insurance regulations will be subject to the provisions of this Act. The purpose of this section is to apply important consumer protections to the segment of the market that is outside the reach of State authority, without disrupting or duplicating States' efforts to develop tailored patient protections that suit the needs of their populations through States' ability to regulate health insurance.

Sec. 102. Comprehensive independent study of patient access to clinical trials and coverage of associated routine costs

The willingness and ability of patients to participate in clinical trials is important both to patients seeking additional treatment options and to the continued success of biomedical research in the

United States. The committee is interested in information about the extent to which denials of coverage by health plans for services provided to members who wish to enroll in clinical trials is impacting treatment options and biomedical research. The committee is also concerned about the ability to differentiate the incremental costs associated with a patient's participation in a clinical trial from the routine costs of medical care which would otherwise have been provided.

For guidance on this issue, the committee adopted an amendment proposed by Senator Frist. Section 102 directs the Secretary of Health and Human Services to contract with the Institute of Medicine (IOM) to evaluate barriers to patient participation in clinical trials, the ability to account for routine costs during clinical trials, and the impact of coverage of routine costs associated with clinical trials on health insurance premiums. In conducting this study, the committee expects the IOM to seek input from a mix of key stakeholders on this issue. The Institute of Medicine will report findings, conclusions, and recommendations to the Senate Committee on Health, Education, Labor, and Pensions no later than 12 months after the date of execution of the contract.

The committee is also awaiting the results of a number of studies currently being conducted in the private sector which are seeking to answer similar questions about patient participation in clinical trials. The recent private-public collaborative agreement between the American Association of Health Plans and the National Institutes of Health is another development which pertains to this issue. The agreement encourages health plans to cover routine patient costs for specific clinical trials and proposes to answer unresolved questions about patient participation in clinical trials and the impact on health insurance premiums.

Subtitle B—Right to Information About Plans and Providers

Sec. 111. Information about plans

Section 111 of the legislation adds to ERISA Part 7 of Subtitle B of Title I, a new section 714 which applies to all group health plans and health insurance issuers that provide coverage in connection with a group health plan. This section requires these entities to provide participants, beneficiaries, and individuals eligible for coverage under the plan with a wide range of information about their health coverage options. Such information includes, for instance, a description of covered and excluded benefits, cost-sharing requirements, restrictions on accessing non-network providers and services, and prior authorization and referral requirements. The committee believes that access to information and the ability to choose among competing options are the hallmarks of an efficiently functioning market. The purpose of this provision is to give consumers information that will help them maximize their decision making.

The information specified in Section 714(b) must be provided automatically, 12 months after the enactment of this section. The information must be provided to participants and beneficiaries who do not live at the same address as the participant, as well as upon request to an individual who is eligible for coverage under the plan.

In addition, the Chairman's substitute added in Section 714(a)(1) that this information must also be provided "annually thereafter." The committee anticipates that, consistent with most current practices, this information will be provided in conjunction with an annual open enrollment period.

In adding these requirements under Part 7 of ERISA, rather than under Part 1, it is the committee's intention to establish information disclosure requirements that are more responsive to the needs of consumers and more consistent with how employers and health insurance issuers currently provide this type of information. The committee does not desire to establish redundant or burdensome information requirements and therefore added Section 714(e) to the Chairman's substitute, requiring the Secretary to issue conforming regulations to reduce or eliminate any duplication under Part 1 that was created by the addition of this section.

This section, under 714(b)(16) requires a statement by the plan that certain information will be be provided upon request, such as the names, addresses, and qualifications of providers, the summary description of the methods used for compensating providers, a summary description of utilization review procedures, and any information made public by accreditation organizations. Of course, the committee expects that in addition to providing a statement of availability, the plan will actually provide to the participant or beneficiary the information that has been requested.

This section specifies that information must be provided in a clear and accurate form and distributed in an accessible format that is understandable to the average plan participant or beneficiary.

In the general requirement under Section 714(a), the Chairman's substitute replaced the word "or" with "and," clarifying that this section applies to both group health plans and health insurance issuers that provide coverage in connection with a group health plan. The committee recognizes that a group health plan may not have direct access to the various pieces of information described in this section, but the committee does not desire to create redundant or burdensome requirements on plans and their service providers. Therefore, Section 714(a)(2) was added to the Chairman's mark, making clear that nothing in this section would prevent a plan or issuer from entering into an agreement under which the issuer agrees to assume responsibility for compliance and, thus, releases the plan from responsibility for such compliance.

Additional amendments were made to this section in the Chairman's substitute as follows:

• Section 714(a)(3) was added to clarify that information required under this section shall be provided to participants and beneficiaries at the address maintained by the plan or issuer. A related provision, Section 714(c), paragraph (2) and subparagraphs (A) and (B), were struck.

• The requirements of this section were added as a new Section 9813 to Subchapter B, Chapter 100 of the Internal Revenue Code of 1986. The addition of this section to the Internal Revenue Code allows for the assessment of penalties of $100 per day, per violation on plans that violate the terms of this section.

• The requirement to disclose specific exclusions under the plan, Section 714(b)(16)(F), was moved to Section 714(b)(1), to require this information to be provided routinely as part of the description of covered items and services, rather than upon request.

• Paragraph (9) was added to Section 714(b), requiring plans to disclose the definition of medical necessity used in making coverage determinations by the plan.

• Paragraph (11) was added to Section 714(b), requiring plans to disclose any provisions for obtaining off-formulary medications. A similar requirement was deleted from Section 714(b)(16)(E). This subparagraph now requires a plan to provide, upon request, the list of specific medications included on the formulary.

• Section 714(b)(13)(C), a reference to the legislation's subtitle on medical records confidentiality, was struck.

Sec. 112. Information about providers

The committee recognizes that for patients to make informed decisions about their health care options, they need valid and reliable information about the qualifications and competencies of health care professionals. Therefore, in Section 112, the committee has directed the Secretary of Health and Human Services to contract with the Institute of Medicine to study the availability and disclosure of information about health care professionals. The study will evaluate the current availability of such information on a State-by-State basis, examine patient preferences with respect to information, evaluate legal and other barriers to the disclosure of information, and make recommendations about the future disclosure of this information.

Subtitle C—Right To Hold Health Plans Accountable

Sec. 121. Amendment to Employee Retirement Income Security Act of 1974

This section of the legislation amends Section 503 of ERISA to create new procedures for grievances, coverage determinations, and appeals, including the right to an independent external review, that apply to all group health plans, including self-insured and fully insured plans, and health insurance issuers providing coverage in connection with group health plans. The committee also intends for this section to apply to utilization reviewers, managed care organizations, and other third party administrators to the extent that they contract with, act on behalf of, or provide services in connection with a group health plan. For simplicity, the remainder of this section will refer only to group health plans. The term "enrollee" was stricken throughout this section of the Chairman's substitute and replaced with participants and beneficiaries; however, for purposes of this report, the term "enrollee" refers to participants and beneficiaries.

Today, there are many structures, delivery systems, sources of coverage, and methods of financing for health care coverage. Various forms of managed care are now commonplace for the delivery of health care services. All of these changes, plus the complexity of the marketplace, have exposed a need for improved procedures governing coverage decisions, grievances, and appeals. The purpose of

this section is to improve the standards and time frames for these determinations and to ensure that the process for making coverage determinations is fair and reliable. The committee believes that timely utilization and coverage decisions, as well as a defined process for appealing such decisions, is key to ensuring that individuals have appropriate access to care. In addition, the committee believes that improving these procedures will impact positively the quality of care.

Initial coverage determinations

The legislation sets new standards and specific time frames for health plans' coverage determinations. A group health plan must ensure that procedures are in place to (i) determine eligibility, coverage, payment, and cost-sharing amounts; (ii) notify the enrollee and treating health care professional of the determination plus any additional payments the enrollee must make; and (iii) respond to written and oral requests for coverage or appeal determinations made by the enrollee or treating health care professional with the consent of the enrollee. "With the consent of the participant or beneficiary" was added to the Chairman's substitute. The committee believes that, because providers have interests of their own, it is important for the provider to act with the consent of the enrollee in these kinds of situations. For all of Section 121, the committee intends for any time frame requirement to be interpreted as "calendar days" unless otherwise specified.

The legislation requires a plan to make a non-emergency routine coverage determination for prior authorization within 30 calendar days from the date of the request. The Secretary may extend this period in certain circumstances determined by the Secretary to be beyond the control of the plan or issuer. A plan is required to provide notice of its decision to the individual and the treating health professional, if the medical circumstances indicate it is appropriate, no later than two working days after the date the determination is made.

A plan must have in place procedures to ensure that a retrospective determination is made within 30 working days of the plan's receipt of the necessary information. The committee considers a retrospective determination to be one in which the care or service has already been provided and for which there is a claim for payment or reimbursement. The plan is required to provide notice within five working days once it has made the determination.

Expedited determination

A plan must maintain procedures for expediting a prior authorization determination in cases when the normal time frame for making a determination would seriously jeopardize the life or health of the individual. In such a case, the plan is required to make an expedited prior authorization determination within 72 hours, in accordance with the medical exigencies of the case, after a request is received by the plan or issuer. The legislation requires a plan to provide an expedited determination when it receives a request for an expedited determination from an enrollee or when the treating health care professional has reasonably documented that the time frame for a routine coverage decision (i.e., 30 days) could

seriously jeopardize the life or health of the individual. Notice must be provided within the 72–hour period.

Concurrent review

A plan is required to have procedures to conduct concurrent review to approve an extended stay or additional services. The committee recognizes that concurrent review is a dynamic process that depends on the circumstances of the individual case. The committee does intend for a plan's concurrent review process to match the circumstances of the situation and provide for timely decisions that do not allow for disruption in care in a manner that adversely impacts health quality. Once a plan makes a concurrent determination, it must notify the participant and his or her treating health care professional within one working day.

Notice

When a plan makes an adverse coverage decision, regardless of whether such a decision is routine, expedited, or retrospective, it must provide notice. Notice of an adverse coverage determination is required to include: (i) the reasons for the determination (including the clinical or scientific evidence-based rationale used in making the determination) written in an understandable manner; (ii) procedures for obtaining additional information; and (iii) notice of the right to appeal and instructions on how to initiate an appeal.

Grievances

This section requires a plan to establish and maintain grievance procedures for addressing complaints between the plan, or a plan's third party administrator, and an enrollee concerning issues that are not related to a plan's denial of coverage. For instance, a grievance procedure would allow enrollees the opportunity to comment on telephone and appointment waiting times, facilities, or personnel, or complain that a preferred physician is not in the network. These complaints are non-appealable. The committee anticipates that the grievance procedures will provide plans with valuable information that will help plans and their service providers respond to customer concerns and preferences.

Internal appeals

Added to the Chairman's substitute was language that would allow a health plan enrollee, or the treating health professional with the consent of the enrollee, to appeal to the plan any adverse coverage decision up to 180 days after the enrollee has been notified of an adverse coverage determination. Any adverse coverage decision refers to routine coverage determinations, expedited decisions, retrospective determinations, and concurrent determinations, as described above.

The time frame for making a routine internal appeal determination is 30 working days from the request for the appeal. Notice must be provided not later than 2 working days after completion of the review. The time frame and standards for expedited internal appeals are the same as they are for the initial coverage decision—72 hours, in accordance with the medical exigencies of the case,

after a request is received by the plan or issuer. For expedited appeals, notice must be provided within the 72 hour period.

An adverse coverage determination that involves an issue of medical necessity or appropriateness is required to be reviewed by a physician who has appropriate expertise and who was not directly involved in the initial determination. Throughout this section, any use of the term "medical necessity" was stricken in the Chairman's substitute and replaced with "medical necessity or appropriateness."

Independent external review

A plan must have procedures providing an enrollee with the right to an independent external appeal, when the initial decision to deny coverage of the benefit is upheld by the internal reviewer. An enrollee has the right to appeal a decision to an independent medical reviewer in writing no later than 30 working days after the receipt of the final plan denial or the date on which the plan's time frame for making the internal appeal determination expired.

Participants must complete each phase of the appeals process, including the internal appeals process, before moving to the next. However, the Chairman's substitute includes a provision that stipulates that if a plan fails to meet the time frame for a determination, the coverage is deemed denied and the participant may pursue the next level of appeal.

The trigger for independent external review was modified as follows for the Chairman's substitute. An enrollee, or his or her authorized representative, which may be the treating health care professional, may request an independent, external review when the particular item or service involved:

1. Would be a covered benefit, when medically necessary and appropriate under the terms of the plan, except that the plan has determined that it is not medically necessary and appropriate; and the amount of the item involved exceeds a significant financial threshold, or there is a significant risk of placing the life or health of the individual in jeopardy; or

2. Would be a covered benefit, when not considered experimental or investigational under the terms of the plan, except that the plan has determined that the item or service is experimental or investigational.

The committee intends for adverse coverage determinations of covered benefits that involve a denial based on medical necessity and appropriateness, or a denial based on a determination about whether an item or service is experimental or investigational, to be eligible for external review. The committee recognizes that some coverage determinations involve an element of medical judgment or a determination of medical necessity and appropriateness. For instance, a plan might cover surgery that is medically necessary and appropriate, but exclude from coverage surgery that is performed solely to enhance physical appearance. In these cases, a plan must make a determination of medical necessity and appropriateness in order to determine whether the procedure is a covered benefit.

It is the committee's intention that coverage denials that involve a determination about medical necessity and appropriateness, such as the example above, would be eligible for external review. The

committee expects that a dispute would be a dispute between the plan, the plan's issuer or a plan's third party administrator, or any other entity that provides services for or acts on behalf of the group health plan, and the enrollee or the enrollee's treating health care professional acting under the consent of the enrollee. Throughout this section, the term "legal," when used before "representative," was stricken and replaced with "authorized" in the Chairman's substitute. The committee believes that this change will maintain the integrity of ERISA's fiduciary duties, but remove any undue legal barriers, such as having to obtain a legal power of attorney, for enrollees who require and authorize assistance.

The committee also recognizes that plan documents sometimes do not provide clear distinctions of what is, or is not, a covered benefit in the area of experimental or investigational treatment because of the constantly evolving nature of science. For instance, a plan might say that it does not cover any benefit or service that is experimental or investigational without listing any specific item or service by name and allowing the determination to be made on a case-by-case basis whether an item or service is experimental. Or, a plan might simply say that it covers all FDA-approved devices, or all FDA devices approved as of a certain date.

The committee does not intend to interfere with arrangements such as those above, or with a plan's or employer's general ability to define its coverage policy in the plan document. However, the committee is interested in ensuring that, in cases where a plan document's coverage policy on experimental or investigational treatment is not explicit or is linked to another policy that requires interpretation, disputes arising out of these kinds of situations will be eligible for external review. For instance, in making a coverage determination based on the current list of FDA-approved products, a plan administrator might mistakenly rely on out of date information and render an adverse coverage decision. The committee intends that such a dispute would be eligible for external review.

In cases where a plan or its agent would deny coverage based on both external review standards (i.e., not medically necessary and appropriate and experimental or investigational), the committee intends that such a determination cite both reasons in the initial denial and that the time frames and requirements for such a denial run concurrently. For example, a plan should not deny coverage on the grounds that it is experimental and then subsequently deny coverage on the grounds that it is not medically necessary and appropriate, after the decision has been appealed to an external reviewer who has overturned the plan's initial decision.

Once an external review has been requested, a plan must select a qualified external review entity, in accordance with the medical exigencies of the case, but not later than five working days after receipt of the request. The legislation requires a plan to select an entity in an unbiased manner and one that meets the qualifications of an external review entity established in this section of the legislation. A qualified external review entity must be: (I) an independent external review entity licensed or credentialed by a State; (II) a State agency established for the purpose of conducting independent external review; (III) an entity under contract with the Federal Government to provide independent external review serv-

ices; or (IV) any other entity meeting criteria established by the Secretary of Labor.

The external review entity then selects the independent expert medical reviewer(s), who would render an independent decision based on the valid, relevant, scientific, and clinical evidence. This selection of the external reviewer(s) must be made in accordance with the medical exigencies of the case but not later than 30 working days after the plan designates the external review entity. An external reviewer must be an independent medical expert, who has appropriate expertise and credentials and who does not have any material, professional, familial, or financial affiliation with the case or any of the parties involved. The reviewer must have expertise in the diagnosis or treatment under review and, when reasonably available, be of the same specialty as the treating physician. The committee intends for expertise to include age appropriate expertise such as pediatrics and geriatrics. Throughout this section, the term "external review" was stricken in the Chairman's substitute and replaced with "independent, external review." In making this change, it was the committee's wish to emphasize the importance of an impartial and unbiased process.

The health plan is required to forward the necessary information to the external reviewer, provide notice to the enrollee that the review has been initiated, and pay for the cost of the review. The external reviewer may receive reasonable and customary compensation and may not receive compensation that is contingent on the outcome of the decision. A reviewer may not be held liable for decisions regarding medical determinations, but may be held liable for actions that are arbitrary and capricious.

The committee adopted an amendment offered by Senator Frist that requires an external reviewer to make an independent determination based on the valid, relevant, scientific, and clinical evidence. In so doing, an external review shall take into consideration appropriate and available information, including any evidence-based decision making or clinical practice guidelines used by the group health plan; evidence or information submitted by the plan, issuers, patient, or patient's physician; the patient's medical record; expert consensus; and peer reviewed medical literature as defined in Section 556(5) of the Federal Food, Drug, and Cosmetic Act.

The committee believes that requiring the external reviewer to make an assessment that takes into account the spectrum of appropriate and available information illustrates the committee's intent that the reviewer make an independent determination and not be bound by any one particular element. The committee believes that the bill's independent standard of review cannot, and should not, be interpreted as an "arbitrary and capricious" standard of review. The only reference to an "arbitrary and capricious" standard of proof in this bill pertains to the reviewer's liability. Should either party—the plan or the patient—sue the external reviewer, that party must prove that the external reviewer's actions were arbitrary and capricious. The committee believes that this high bar provides an additional guarantee that the external reviewer will be able to make a truly independent decision.

For purposes of this section, the committee intends that "scientific and clinical evidence" means the following sources:

"(1) Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and submit most of their published articles for review by experts who are not part of the editorial staff.

"(2) Peer-reviewed literature, biomedical compendia, and other medical literature that meet the criteria of the National Institutes of Health's National Library of Medicine for indexing in Index Medicus, Excerpta (EMBASE), Medline, and MEDLARS database Health Services Technology Assessment Research (HSTAR).

"(3) Medical journals recognized by the Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act.

"(4) The following standard reference compendia: The American Hospital Formulary Service-Drug Information, the American Dental Association Accepted Dental Therapeutics, and the United States Pharmacopoeia-Drug Information.

"(5) Findings, studies, or research conducted by or under auspices of Federal Government agencies and nationally recognized Federal research institutes including the Agency for Healthcare Research and Quality, National Institutes of Health, National Academy of Sciences, Health Care Financing Administration, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services."

The external reviewer is required to complete the review in a time frame that is in accordance with the medical exigencies of the case but no later than 30 working days after the date the reviewer is designated or the date on which all information necessary to complete the review is received. An external review decision is binding on the plan, if the procedures of this subsection were followed.

The committee interprets "expert consensus" as including both what is generally accepted medical practice and recognized best practice. The independent external reviewer is required to consider information from the treating physician, the patient's medical record, expert consensus, and peer-reviewed medical literature to assure that standards of care are reviewed in a manner that takes into account the unique medical needs of the patient.

Enforcement

Plans that fail to comply with a coverage determination by an independent, external reviewer are subject to new enforcement provisions under ERISA, including financial penalties that heretofore have not been available for violations under Section 503 of ERISA. Specifically, a participant or beneficiary may sue a plan for a violation under this provision, and if the court decides in favor of the participant, assess a financial penalty of up to $100/day from the date of the violation and award other relief as the court deems proper. The committee also intends for the court to have the option of requiring the plan to provide the benefit, awarding attorney fees, costs, and expert witness fees, and other relief the court deems appropriate under the circumstances. This new remedy will be in addition to remedies already available under ERISA, including equitable and injunctive relief for a violation of ERISA's requirements.

TITLE II—GENETIC INFORMATION AND SERVICES

The intent of the legislation in Title II is to provide patients with protections against discrimination in certain health insurance practices based on predictive genetic information.

The legislation amends the Employee Retirement Income Security Act of 1974, the Public Health Service Act, and the Internal Revenue Code of 1986. The legislation prohibits group health plans and health insurance issuers offering health insurance coverage in connection with a group health plan from conditioning enrollment or adjusting premium or contribution amounts for a group on the basis of predictive genetic information concerning an individual or a family member of the individual (including information about a request for or receipt of genetic services).

The legislation prohibits health insurance issuers in the individual market from using predictive genetic information as a condition of eligibility for the individual market. The legislation prohibits health insurance issuers in the individual market from adjusting premium rates for individuals based on predictive genetic information concerning enrollees or their family members.

The legislation prohibits group health plans or health insurance issuers from requesting or requiring predictive genetic information concerning an individual or a family member. The legislation allows for the request of predictive genetic information for diagnosis, treatment, or payment purposes but requires health plans or health insurance issuers to provide a description of the procedures in place to safeguard the confidentiality of such information. The committee intends to address the full range of issues with respect to the confidentiality of all medical information this year. A separate legislative proposal will be undertaken to enact a comprehensive Federal law to protect patients' medical records as stipulated by the statutory deadline of August, 1999, mandated in the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

The term "genetic information" is defined as information about genes, gene products, or inherited characteristics that may derive from an individual or family member (including information about a request for or receipt of genetic services). "Genetic services" are defined as health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

The term "predictive genetic information" is defined as, in the absence of symptoms, clinical signs, or a diagnosis of the condition related to that information, information about an individual's genetic tests; information about genetic tests of family members of that individual; or information about the occurrence of a disease or disorder in family members. This definition does not include the following: information about the sex or age of the individual; information derived from physical tests, such as chemical, blood, or urine analyses of the individual, including cholesterol tests and information about physical exams of the individual.

The term "genetic test" means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed indi-

viduals. Such term does not include information derived from physical tests, such as the chemical, blood, or urine analyses of the individual, including cholesterol tests, and information about physical exams of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease.

Because scientists believe that most individuals carry genetic mutations that may place them at risk for future disease, the legislation is intended to prohibit discrimination against individuals who are currently healthy but may carry a genetic mutation or have a family history of a genetic disease. The legislation does not prohibit health plans and issuers from medical underwriting based on an individual's current health status. If an individual has been diagnosed with breast cancer or has exhibited symptoms or clinical signs of the disease, this is not considered predictive genetic information. If the individual carries a mutation for breast cancer but is not symptomatic or diagnosed with the disease, this is considered to be predictive genetic information that may not be utilized for determining eligibility or setting premiums in health insurance coverage.

Title II is intended to be applicable to group health plans, health insurance issuers offering group health insurance in connection with group health plans, and health insurance issuers offering health insurance coverage in the individual market. The approach taken in Title II is intended to model the approach taken in the Health Insurance Portability and Accountability Act of 1996 [P.L. 104–191]. This title is not intended to be applicable to life insurance, disability income insurance, long-term care insurance, or any of the other forms of insurance coverage described as "Excepted Benefits" in Section 733 of the Employee Retirement Income Security Act of 1974, Section 2791 of the Public Health Service Act, or Section 9832 of the Internal Revenue Code of 1986.

TITLE III—HEALTH CARE RESEARCH AND QUALITY

Part A—Establishment and General Duties

The legislation changes the name of the Agency for Health Care Policy and Research to the Agency for Healthcare Research and Quality (AHRQ). The mission statement retains much of the current statute but adds language regarding the Agency's responsibility to promote health care quality through: (1) research; (2) synthesizing and disseminating available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and (3) advancing private and public efforts to improve health care quality. The list of General Duties continues to recognize the Agency's unique role in supporting and conducting research on the ways that health care services are organized, managed, and financed, the productivity, efficiency, and effectiveness of the ways health care is delivered, and the forces that shape the healthcare marketplace. The Committee believes that the Agency's work on the cost and appropriate use of and access to health care services is essential for addressing the types of patient protection issues raised in this bill and will be essential for the long-term stability of the Medicare program.

The legislation adds a clarifying disclaimer and rule of construction to the statute which prohibits the Agency from mandating "national standards of clinical practice or quality healthcare standards." The committee intent is that nothing in this section shall be construed to imply that the Agency's role is to mandate a national standard or specific approach to quality measurement and reporting. These two provisions are intended to reinforce the point that the Agency has no regulatory authority; the Agency's role is to build the science of health care and quality and let private- and public-sector purchasers, professional groups, and accreditation agencies set quality "standards."

The committee has expanded the list of priority populations in the statute to encourage research pertaining to children and people with special health care needs, such as chronic care, care for persons with disabilities, and end-of-life care. While the Agency has increased its commitment to child health research in recent years, children have not been a major focus of health services research, reflecting a shortage of child health services researchers, methodological issues, and the fact that children account for only a small portion of total health expenditures. The committee strongly believes that the nation will receive a significant return from an increased investment in research on children's health. The Agency should support the training of additional child health researchers and expand the focus on child health throughout its research portfolio. Recognizing that the critical need in this area is to build the knowledge base about what works best for children in daily practice, the committee has included provisions in the bill to foster the development of interdisciplinary Healthcare Improvement Research Centers and provider-based research networks. This new authority will facilitate the development of that knowledge and its prompt translation into improved practice for all patients.

The committee is also supportive of the Agency's past research related to end-of-life care and its current emphasis on chronic care. The committee believes that current demographic trends warrant an ongoing emphasis on such special health care needs, including disabilities, and has added this category to the list of priority populations. People with disabilities interact with the health care system at a higher rate than many other populations, and so research on their experience in accessing and receiving health care provides valuable insight into the overall effectiveness of the nation's health care system. The Agency should address those with special health care needs throughout its research portfolio, with special attention to the most effective ways of managing care for those with multiple chronic conditions and disabilities, the burden of disease for individual patients and the demands on care givers, for instance, with respect to pain management and end-of-life care.

The committee expects the Agency to stress to the research community the importance of addressing the challenges faced by all of the groups listed in this section—those living in rural areas and each of these priority populations—in its general grant solicitations and, as appropriate, in more targeted solicitations.

The committee strongly supports the Agency's role as the major source of Federal funding for pre- and postdoctoral training in health services research. As a major sponsor and consumer of

health services research, the Federal Government has a continuing interest in fostering the development of a vital health services research work force, and the Agency must be a leader in that effort. We understand that limited resources have restricted the Agency's ability to support the level of training envisioned in the Institute of Medicine's 1995 report on the health services research work force, however, the committee urges the Director to make support for training a high priority. As additional funding becomes available, the Committee also urges the Director to supplement the training funds the Agency receives under the National Research Service Award program with appropriated funds.

In administering these training programs, the committee expects the Director to take into account shortages in the number of researchers addressing priority populations. This has long been recognized as a problem in minority and rural health, and more recently, as a problem in child health. In fact, it was an Agency-funded conference on Improving the Quality of Care for Children that recently noted that no Federal agencies have child health services research training initiatives. Training new researchers in these shortage areas is an important long-term investment in improving the health of each of these priority populations.

Part B—Health Care Improvement Research

Sec. 911. Health care outcome improvement research

The legislation requires the Agency to identify and disseminate the evidence rating methods or systems that it uses to assess health care research results. Any Agency publications containing health care recommendations will indicate, using such methods or systems, the level of substantiating evidence for its clinical recommendations. The committee included this provision to ensure that the processes used by the Agency and its contractors are understood by and can be used by others.

The Agency is also required to employ research strategies and dissemination mechanisms that will assist in translating health services and quality improvement research into practice through grants to Healthcare Improvement Research Centers, multidisciplinary research centers linked with relevant sites of care, e.g., Provider-based Research Networks, and similar innovative organizational constructs. The committee believes that through this provision promising research findings can be translated more rapidly into improvements in daily practice.

Sec. 912. Private-public partnerships to improve organization and Delivery

The legislation outlines 6 roles for the Agency to provide scientific and technical support for private and public research relating to health care quality, including: (1) identification and assessment of methods for the evaluation of health of enrollees in health plans and those receiving long-term care services; (2) development and testing of quality measures; (3) compilation and dissemination of measures; (4) assistance in the development of information systems; (5) development of survey tools; and (6) research on the ways

that purchasers and consumers use quality information in making decisions.

The legislation eliminates the demonstration status of the Centers for Education and Research on Therapeutics (CERTs), which was added to the Agency's statute by the Food and Drug Administration Modernization Act of 1997. The CERTs program was established to conduct research and increase awareness of products and ways to improve their effective use, and to increase awareness of risks of both new uses and combinations of therapies. These centers will evaluate, develop options and methods, and conduct state-of-the-art clinical, laboratory, and health services research. The committee intends that the important clinical and safety information gained through this program will be provided on an ongoing basis to consumers as well as health care practitioners and insurers.

The committee is gravely concerned about preventable health care errors and resulting patient injury. Therefore, the legislation further directs the Agency to conduct and support research and build partnerships to support research on reducing errors in medicine. The legislation states that this research shall include the identification of the causes of preventable health care errors and patient injury in health care delivery; strategies for reducing errors and improving patient safety; and promoting the implementation of effective strategies throughout the health care industry.

Sec. 913. Information on quality and cost of care

The Agency's current Medical Expenditure Panel Survey (MEPS) is a unique resource for information about the cost, use, and access of Americans to health care services. The Committee has recognized the importance of the survey by providing a statutory mandate for MEPS. The legislation also builds upon MEPS by directing the Agency to support a nationally representative survey and to expand its sample size, beginning in FY 2001, so that MEPS can provide information on the quality of patient care and outcomes for frequently occurring conditions. The Agency is required to develop information on children and persons with special health care needs through over-sampling or periodic updates. Beginning in FY 2003, the Secretary, acting through the Director, is to submit an annual report on national trends in health care quality, drawing upon the enhanced MEPS survey and other available data. The Committee expects the Agency to use a variety of measures to develop this annual picture of how health care quality is faring. The legislation directs the Agency to take into account any outcomes measurements generally collected by private-sector accreditation organizations to assure that the reported information is not inconsistent with what is being collected through other programs. The committee hopes that this annual report will provide an opportunity for quality performance comparisons.

Sec. 914. Information systems for health care improvement

The committee recognizes the importance of supporting the development of health care information systems to enable the collection and dissemination of information. Therefore, the legislation directs the Agency to support research to evaluate and support initia-

tives to advance: (1) the use of information systems for the study of health care quality; (2) training for health care researchers and practitioners in the use of information systems; (3) creation of effective linkages between various sources of health care information, including development of health care information networks; (4) the linking of health care information networks and real-time decision support systems; (5) the utility and comparability of health information data and medical vocabularies; (6) evaluation of the use of computer-based records to create a personal health record and to monitor public health and outcomes of care for particular populations; and (7) the protection of individually identifiable information in health services research and quality improvement. The committee believes that the Federal Government should encourage patient participation in clinical decision making and notes that the legislation directs the Agency to support demonstrations on the use of new information tools to improve shared decision making between patients and care givers.

Sec. 915. Research supporting primary care delivery and access in underserved areas

The legislation codifies current activities of the Agency, including support for the work of a Preventive Services Task Force and a mandate to maintain a Center for Primary Care Research, focusing on several areas of primary care research.

Sec. 916. Clinical practice and technology innovation

During its hearings, the committee heard testimony urging that the Agency's technology assessment process and the Health Care Financing Administration (HCFA) Medicare coverage process needed to be more transparent, open, and conducted within clearly defined time frames. The committee strongly concurs. That is why the committee has directed the Agency to make available, i.e., post on its web site and update as needed, a description of the process and methodology that the Agency and its contractors use for practice and technology assessments. The committee understands that HCFA's upcoming Federal Register notice outlining proposed regulation governing the Medicare coverage process will provide public notice when a technology assessment is commissioned, and the notice will indicate the proposed time frame for each assessment. The committee expects AHRQ to complement this effort by ensuring that an adequate description of the planned assessment and the time frame for completing it can also be accessed through its web site, providing an opportunity for the submission of pertinent data and analyses for consideration during the assessment, and making the text of completed technology assessments available in a reasonable and timely manner.

Sec. 917. Coordination of Federal Government quality improvement efforts

The committee envisions the Agency for Healthcare Research and Quality (AHRQ) as the hub and driving force for Federal health care quality improvement efforts. Therefore, this legislation directs the Secretary, acting through the Director, to coordinate all research, evaluations, and demonstrations related to health services

research and health care quality measurement and improvement supported by the Federal Government. The Director is to develop and manage a process to improve interagency coordination, strengthen the Federal health care research infrastructure, set specific goals for Federal support and furthering of health services research and quality improvement, and strengthen the management of Federal health care quality improvement programs. The legislation also requires the Secretary to contract with the Institute of Medicine to develop two reports on the organization and coordination of the health care quality research, improvement, and oversight activities of the Federal Government, with particular attention to DHHS activities under Titles XVIII, XIX, and XXI of the Social Security Act, and recommendations on how to improve the efficiency and effectiveness of quality improvement activities.

Part C—General Provisions

Part C governs the day-to-day functioning of the Agency. Most of these subsections are a restatement of current law with the following changes.

Section 921 makes several modifications to the Agency's existing National Advisory Committee. The name of the Council is changed to reflect the renaming of the Agency, the statement of its mission is altered to reflect the changes in the Agency's overall mission outlined in Part A of the legislation, the size of the Council is increased by four members to permit a broader representation of the Agency's stakeholders, and there are minor changes in the requirements for the composition of the Council and the list of designated ex officio members.

The Committee has added language to section 922, governing the Agency's peer review process, to codify Agency practice requiring recusal of any study section member where there is even the appearance of a potential conflict-of-interest and requiring that all information received by study section members, other than public records or public information, must be treated as confidential information. At the same time, the Committee has eliminated overly prescriptive language in current statute regarding the types of study sections that the Agency needs to maintain and has adjusted the maximum level of small grant awards to reflect changes in inflation.

The Committee has made a number of technical changes to the language in Section 923 dealing with the development, collection, and dissemination of data. The Committee broadened the Agency's authority to "tabulate and analyze statistics" on a reimbursable basis to conducting research or analyses otherwise authorized under this title.

Among other changes, the Agency is directed to ensure that the information disseminated is science-based and useful and appropriate to the target audience (sec. 924).

To improve the quality of health care, the committee stresses the importance of translating biomedical research into clinical practice. Therefore, the legislation expresses the intent of Congress to provide a proportionate increase in translational, interdisciplinary health care research as funding for biomedical research increases.

The legislation establishes a funding level of $250 million for FY 2000 and "such sums as necessary" for FY 2001–FY 2006. The separate authorization for the Centers for Education and Research on Therapeutics (CERTs) is eliminated. The committee assumes CERTs will be funded by the Agency's main authorization and that elimination of the separate line item will allow the Agency greater flexibility to support this program.

V. Cost Estimate

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

Summary: Title I of the Patients' Bill of Rights Act would amend the Employee Retirement Income Security Act (ERISA) to give members of self-insured health plans rights to obtain certain services, require group health plans and health insurance issuers to provide certain information to enrollees and potential enrollees, and establish internal and external review procedures for group health plans and health insurance issuers. Title II would prohibit health plans from discriminating on the basis of genetic information. Title III would redesignate the Agency for Health Care Policy and Research as the Agency for Healthcare Research and Quality and would reauthorize the agency.

The proposed patient protections and grievance procedures would increase the premiums for employer-sponsored health insurance, substitute nontaxable fringe benefits for taxable wages, and reduce federal receipts from income and payroll taxes. The Congressional Budget Office (CBO) estimates that these provisions would reduce federal tax revenues by $15 million in 2000 and by $1.0 billion over the 2000–2004 period.

S. 326 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). State, local, and tribal governments either would be exempt from the bill's requirements governing health care benefits and insurance or would be able to opt out of the requirements.

Estimated cost to the Federal Government: The estimated effect of the bill on direct spending and receipts is shown in Table 1. The costs of this legislation fall within budget function 550 (health).

TABLE 1.—ESTIMATE OF THE BUDGETARY EFFECTS OF THE PATIENTS' BILL OF RIGHTS ACT

	By fiscal years, in millions of dollars—									
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
REVENUES										
Income and HI Payroll Taxes	−10	−70	−140	−210	−260	−290	−310	−320	−340	−360
Social Security Payroll Taxes	−5	−30	−65	−90	−110	−130	−130	−140	−150	−160
Total	−15	−100	−205	−300	−370	−420	−440	−460	−490	−520
AUTHORIZATIONS OF APPROPRIATIONS										
Study of Access to Clinical Trials	1	([1])	0	0	0	0	0	0	0	0
Healthcare Research and Quality	25	138	217	247	261	267	272	250	123	37

TABLE 1.—ESTIMATE OF THE BUDGETARY EFFECTS OF THE PATIENTS' BILL OF RIGHTS ACT—Continued

	By fiscal years, in millions of dollars—									
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Total	26	138	217	247	261	267	272	250	123	37

[1] Less than $500,000.
Note.—HI=Hospital Insurance.
Source: Congressional Budget Office.

Basis of estimate

Revenues

The proposed rights to medical care and advice, informational requirements, and grievance procedures would affect the federal budget through their effect on premiums for employer-sponsored health insurance. Although the rights to medical advice and care would apply only to self-insured ERISA plans, other plans are likely to be affected by them as well. Federal legislation to regulate a significant part of the health insurance market could stimulate action by states and health plans to develop consistent policies on coverage. Taking such spillover effects into account, CBO estimates that the provisions for medical care and advice, patient information, grievance procedures, and confidentiality of patient information would raise average premiums by about 0.8 percent. Table 2 shows the estimated effect of each provision on premiums, before employers modify their behavior to offset some of the increase. The effects are expressed as a percentage of total premiums for all nonfederal employer-sponsored plans, including plans that would face no increase in costs.

TABLE 2.—ESTIMATED EFFECT OF THE PATIENTS' BILL OF RIGHTS ACT ON PREMIUMS FOR EMPLOYER-SPONSORED HEALTH INSURANCE

[In percent]

Provision	Increase in premiums
TITLE I	
Subtitle A—Right to Medical Advice and Care:	
Access to emergency care	0.2
Offering choice of coverage options	(1)
Access to obstetric and gynecological care	(1)
Access to pediatric care	(1)
Access to specialists	(1)
Continuity of care	0.2
Protection of patient-provider communications	(1)
Right to prescription drugs	(1)
Self-payment for behavioral health care services	(1)
Subtitle B—Right to Information About Plans and Providers	0.1
Subtitle C—Right to Hold Health Plans Accountable	0.3
TITLE II	
Genetic Information and Services	(1)
Total	0.8

[1] Less than 0.05 percent.

The estimate assumes that about 60 percent of the increase in premiums would be offset through decreases in fringe benefits and that about 40 percent would be passed on to employees as lower

wages. CBO estimates that the increase in premiums would reduce federal tax revenues by $15 million in 2000 and by $1.0 billion over the 2000–2004 period. Social Security payroll taxes, which are off-budget, account for $300 million of the five-year total.

Right to Medical Advice and Care. Subtitle A of title I contains a number of patient protections for enrollees in self-insured ERISA health plans. Those provisions include:

- a prohibition of interference by health plans with medical communications between physicians and their patients;
- a requirement that plans pay for hospital emergency services—until the patient is stabilized—when the prudent layperson standard is met, and that beneficiaries be charged no more than would be required if such services were furnished by a participating provider;
- a requirement for direct access to an obstetrical and gynecological specialist for covered routine obstetrical and gynecological care;
- a requirement for direct access to pediatricians for covered routine pediatric services;
- a requirement that beneficiaries have access to specialty care when such care is covered by the plan;
- the right to continue care for 90 days with a provider whose contract has been terminated by a health plan;
- a requirement that plans with a formulary for prescription drugs involve physicians and pharmacists in the development of the formulary and provide for exceptions from the formulary limitation;
- prohibitions on discouraging beneficiaries from paying for behavioral health care services not covered by the plan and terminating providers because they permit beneficiaries to pay for such services; and
- a requirement that health plans offer employees a point-of-service option when the existing health plan offerings do not provide choice among provider groups.

CBO estimates that those rights to medical care and advice would ultimately increase costs across all nonfederal employer-sponsored health plans by about 0.4 percent.

Right to Information About Plans and Providers. Subtitle B of title I would require all ERISA group health plans to provide certain kinds of information on plan provisions to enrollees and to make other kinds available on request. Most of the required information is typically provided now as part of a plan's handbook or could easily be incorporated into that document. Although some documents would have to be amended to meet the requirements of this provision, such documents are continually changed to reflect new terms. Plans would be responsible for making available to participants any data on quality or performance that they collect, but they would not be required to collect such data. Plans would have to make minor investments in personnel and systems to assure and monitor compliance with those requirements. CBO estimates that the informational requirements would increase costs across all nonfederal employee-sponsored health plans by 0.1 percent.

Right to Hold Health Plans Accountable. Subtitle C of title I would require all ERISA group health plans to abide by specific

time limits for making coverage determinations and to have an internal review process for reconsidering coverage decisions within defined time limits at the request of the enrollee. For those coverage decisions involving medical necessity or investigational treatments, a physician with the appropriate expertise would have to conduct the internal review. Plans would also have to provide for external review of medical necessity decisions involving claims exceeding a significant dollar threshold or investigational treatments for life threatening illnesses. The findings of the external review would be binding on the health plan.

Most plans today have a functioning internal appeals process, but they operate with more flexibility on timing than they might have under this provision. Consequently, a few plans would have to invest in more review personnel to meet the specified time limits. Costs would also increase because of the requirement for external review, which would be new to most plans. CBO estimates that the net cost of this subtitle would be about 0.3 percent of employer-sponsored health plan costs.

Genetic Information and Services. Title II would prohibit all health plans and health insurers from using predictive genetic information in setting premiums for groups or individuals. It would also prohibit plans from requesting such information except when the information was needed for diagnosis, treatment, or payment relating to the provision of health services. Even then, plans could not require such information and would have to provide the individual with a description of the procedures in place for protecting the confidentiality of such information. Although this provision would keep health insurers and health plans from reducing their costs through favorable risk selection based on genetic information, its cost to private employer-sponsored health plans as a whole would be negligible.

Authorizations of appropriations

Clinical Trials. Title I would require the Secretary of Health and Human Services to contract with the Institute of Medicine to conduct a study of access by patients to clinical trials and the coverage of routine health care costs by private health plans and insurers. CBO estimates that this provision would increase discretionary spending by $1 million in 2000.

Healthcare Research and Quality. Title III would redesignate the Agency for Healthcare Policy and Research as the Agency for Healthcare Research and Quality and respecify its mission. To support the activities of AHRQ, S. 326 would authorize $250 million in fiscal year 2000 and such sums as may be necessary for fiscal years 2001–2006. Assuming appropriations of the authorized amounts, CBO estimates that this title would increase discretionary spending by $25 million in fiscal year 2000 and $888 million over the 2000–2004 period.

Pay-as-you-go Considerations: Section 252 of the Balanced Budget and Emergency Deficit Control Act sets up pay-as-you-go procedures for legislation affecting direct spending and receipts. The net changes in outlays and governmental receipts that are subject to pay-as-you-go procedures are shown in Table 3. For purposes of en-

forcing pay-as-you-go procedures, only the effects in the current year, the budget year, and the succeeding four years are counted.

TABLE 3.—SUMMARY OF PAY-AS-YOU-GO EFFECTS

	By fiscal years, in millions of dollars—									
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Change in outlays	0	0	0	0	0	0	0	0	0	0
Change in receipts	−10	−70	−140	−210	−260	−290	−310	−320	−340	−360

Estimated impact on state, local, and tribal governments: The bill's amendments to ERISA and to the Public Health Services Act would establish a number of new requirements governing health care benefits and insurance. However, plans offered by state, local, and tribal governments are exempt from the requirements of ERISA, and they may opt out of the requirements of the Public Health Service Act. Consequently, the new provisions would not be intergovernmental mandates as defined by UMRA, and they would have an impact on the budgets of states, local, or tribal governments only if those governments chose to comply.

Estimated impact on the private sector: The bill would impose several private-sector mandates as defined in UMRA. They include the rights to medical care and advice and requirements for plans to establish appeals procedures for handling patients' grievances. CBO estimates that the direct costs of those mandates to private-sector entities would significantly exceed the threshold specified in UMRA ($100 million in 1996, adjusted annually for inflation) every year after 2000.

Previous CBO Estimate: On March 17, 1999, CBO provided an estimate of S. 326, as introduced on January 28, 1999. This estimate reflects changes in the bill as reported by the committee on March 18, 1999, more recent information on the health care system, and reanalysis of the impact of certain provisions in light of new information. In total, the estimated effect on premiums for employer-sponsored health insurance has increased from 0.5 percent to 0.8 percent.

The committee added a new standard for external review of denials of coverage to subtitle C. That standard would require independent external reviewers to take into account information submitted by the patient's physician and the medical records as well as scientific and clinical literature. The standard would substitute those criteria for the plan's own definition of medical necessity and would therefore lead to more decisions favorable to patients. That change adds 0.2 percentage points to the estimate.

The estimate of the prudent layperson standard for emergency care has been increased by 0.1 percentage point because the committee added a new restriction on health plans' ability to charge patients higher copayments when they seek emergency care at nonparticipating providers.

New provisions involving prescription drugs and the right to receive behavioral health care at the participant's expense add little to the estimate. In addition, the title regarding privacy of medical records and access to medical records was removed.

New information obtained about the frequency with which employers, especially those with few employees, switch plans has led to a slight increase in the estimate of the effect of the provision involving continuity of care. New data also led to a slight decrease in the estimate of the costs of offering a choice of coverage options.

Estimate prepared by: Federal Cost Estimate: Linda Bilheimer, Tom Bradley, Jeanne De Sa, and Judith Wagner. Impact on State, Local, and Tribal Governments: Leo Lex. Impact on the Private Sector: Judith Wagner.

Estimate approved by: Paul N. Van de Water, Assistant Director for Budget Analysis.

VI. Application of Law to the Legislative Branch

Section 102(b)(3) of Public Law 104–1, the Congressional Accountability Act (CAA), requires a description of the application of this bill to the legislative branch. S. 326 amends various Federal laws and reauthorizes a federal agency, but does not amend any act that applies directly to the legislative branch. However, Title II of the Act, Genetic Information and Services, applies to insurance issuers and thus would apply indirectly to the Federal Employees Health Benefits Program (FEHBP) which contracts with insurance issuers. The impact of this provision on the FEHBP may not be relevant, however, given that the FEHBP has broad non-discrimination rules already in place.

VII. Regulatory Impact Statement

Title I of the bill will impose several new mandates on the private-sector, including the mandatory provision of care or access to providers in certain situations, new information disclosure requirements, and new procedures for coverage determination and appeals, including the requirement to provide independent, external review. For the most part, these mandates build on existing regulatory structures and private-sector practices. Thus, the committee has determined that the overall regulatory impact of Title I will be modest. This view is consistent with the CBO cost estimate of 0.8 percent.

Through voluntary measures and private-sector accreditation programs, many private-sector health plans have already adopted the kinds of access provisions contained in subtitle A. The committee believes that the impact of this subtitle is further limited by the fact that self insured group health plans do not as frequently employ the techniques targeted by some provisions in this bill and characteristic of, for example, a fully insured HMO. For instance, a plan, other than a fully insured plan, that does not require the authorization or referral of a primary care physician in order to access speciality care, is likely to experience less regulatory burden as a result of this bill. Consequently, specific requirements, such as the notice and time frame requirements contained in the continuity of care section and the prudent layperson standard for emergency room coverage are likely to have only a modest regulatory impact.

Subtitle B, Right to Information About Plans and Providers, requires all group health plans to provide a range of information on plan provisions to participants and beneficiaries. The information

requirements in this bill significantly exceed ERISA's existing information requirements, particularly with respect to the range, quantity, depth, and timing of the information. However, much of the information required by this provision is currently provided as part of the plan's member handbook or the employer's open enrollment process. Therefore, the committee believes that plans may experience some new regulatory burdens as a result of this provision, but the impact will be minor.

ERISA currently contains procedures for coverage determinations and internal appeals, but does not require independent, external review. Most, if not all plans, already have a functioning internal appeals process, and some have implemented external review on a voluntary basis. However, plans operate with considerably more flexibility in the current environment than they might under this provision, particularly with respect to time frames and the standards governing decisions that involve a determination of medical necessity or investigational treatment. Therefore, the committee has determined that this provision will have a modest regulatory impact, particularly for plans that do not currently offer independent, external review.

The committee believes that policy gains derived from Title I of this bill—better consumer information, improved access to care and services, and procedures to ensure that care promised by the plan is delivered—far outweigh the modest regulatory impact of these provisions.

The committee has determined that the regulatory impact of Title II will be negligible and that Title III of this bill will result in no increase in the regulatory burden.

VIII. Section-by-Section Analysis

Section 1. Short Title; Table of Contents. This Act may be cited as the "Patients' Bill of Rights Act," and includes a table of contents.

TITLE I—PATIENTS' BILL OF RIGHTS

Subtitle A—Right to Advice and Care

SECTION 101. PATIENT RIGHT TO MEDICAL ADVICE AND CARE

Subsection (a). In General. Part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185 et seq.) is amended to include a new Subpart C, as follows:

Subpart C—Patient Right to Medical Advice and Care

SECTION 721. PATIENT ACCESS TO EMERGENCY MEDICAL CARE

Subsection (a). In General. To the extent that the group health plan (other than a fully insured group health plan) provides coverage for benefits consisting of emergency medical care (except for items or services specifically excluded), the plan must meet the following two requirements:

(1) The plan must provide coverage for benefits, without requiring preauthorization, for appropriate emergency medical screening examinations (within the capability of the emergency facility) to

the extent that a prudent layperson, who possesses an average knowledge of health and medicine, would determine such examinations to be necessary to determine whether emergency medical care is necessary.

(2) The plan must provide coverage for benefits, without requiring preauthorization, for additional emergency care to stabilize an emergency medical condition following an emergency medical screening examination.

Subsection (b). Uniform Cost-Sharing Required. Nothing in this section should be construed as preventing a group health plan from imposing any form of cost-sharing (including coinsurance, copayments, and deductibles) on any participant or beneficiary for coverage of benefits described above, so long as the following condition is met:

> Cost-sharing must be uniformly applied with respect to similarly situated participants and beneficiaries, and to all benefits consisting of emergency medical care provided to such participants and beneficiaries under the plan.

The plan must cover emergency medical care that is provided to a participant by a nonparticipating health care provider in an amount that does not exceed the liability that would have been incurred for services provided by a participating provider.

Subsection (c). Definition of Emergency Medical Care. In this section:

(1) The term "emergency medical care" relates to a participant or beneficiary under a group health plan and refers to covered inpatient and outpatient services that:

(A) are furnished by a provider that is qualified to furnish such services; and

(B) are needed to evaluate or stabilize an emergency medical condition.

(2) The term "emergency medical care" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in:

(A) placing the health of the participant or beneficiary (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

(B) serious impairment to bodily functions, or

(C) serious dysfunction of any bodily organ or part.

SECTION 722. OFFERING OF CHOICE OF COVERAGE OPTIONS

Subsection (a). Requirement. Except as provided in the next paragraph, if a group health plan provides coverage for benefits only through a defined set of participating health care professionals, the plan must offer the participant the option to purchase point-of-service coverage for all such benefits for which coverage is otherwise so limited. This option must be made available to the participant at the time of enrollment under the plan and at such other times as the plan offers the participant a choice of coverage options.

Exception in the case of multiple issuer or coverage options. This requirement does not apply with respect to a participant in a group health plan if the plan offers the participant two or more coverage options that differ significantly with respect to the use of participating health care professionals or the networks of such professionals that are used.

Subsection (b). Point-of-Service Coverage Defined. In this section, the term "point-of-service coverage" means, with respect to benefits covered under a group health plan, coverage of such benefits when provided by a nonparticipating health care professional.

Subsection (c). Small Employer Exemption. The point-of-service option requirement does not apply to any group health plan of a small employer. Here, the term "small employer" means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least two but not more than 50 employees on business days during the preceding calendar year and who employs at least two employees on the first day of the plan year. For purposes of this paragraph, the provisions of subparagraph (C) of section 712(c)(1) of ERISA shall apply in determining employer size.

Subsection (d). Rule of Construction. Nothing in this section should be construed:

(1) as requiring coverage for benefits for a particular type of health care professional;

(2) as requiring an employer to pay any costs as a result of this section or to make equal contributions with respect to different health coverage options;

(3) as preventing a group health plan from imposing higher premiums or cost-sharing on a participant for the exercise of a point-of-service coverage option; or

(4) to require that a group health plan include coverage of health care professionals that the plan excludes because of fraud, quality of care, or other similar reasons with respect to such professionals.

SECTION 723. PATIENT ACCESS TO OBSTETRIC AND GYNECOLOGICAL CARE

Subsection (a). General Rights. A group health plan must waive any referral requirement in the case of a female participant who seeks coverage for routine obstetrical or gynecological care. The plan must treat the ordering of other routine obstetrical or gynecological care by a physician who specializes in obstetrics and gynecology as authorization by the primary care provider for such other routine care.

Subsection (b). Application of Section. A group health plan described in this section:

(1) provides coverage for routine obstetric care (such as pregnancy-related services) or routine gynecologic care (such as preventive women's health examinations); and

(2) requires the designation by a participant or beneficiary of a participating primary care provider who is not a physician in obstetrics or gynecology.

Subsection (c). Rules of Construction. Nothing in this section:

(1) waives any coverage requirements relating to medical necessity or appropriateness with respect to coverage of obstetric or gynecological care;

(2) precludes the plan from requiring that the specialist in obstetric or gynecology notify the designated primary care provider or the plan of treatment decisions; or

(3) precludes a group health plan from allowing health care professionals other than physicians to provide routine obstetric or gynecologic care.

SECTION 724. PATIENT ACCESS TO PEDIATRIC CARE

Subsection (a). In General. In the case of a group health plan that provides coverage for routine pediatric care and requires the designation by a participant or beneficiary of a participating primary care provider, if the designated primary care provider is not a physician who specializes in pediatrics:

(1) the plan may not require authorization or referral by the primary care provider in order for a participant to obtain coverage for routine pediatric care; and

(2) the plan must treat the ordering of other related routine pediatric care by such a specialist as authorized by the designated primary care provider.

Subsection (b). Rules of Construction. Nothing in this section:

(1) waives any coverage requirements relating to medical necessity or appropriateness with respect to coverage of pediatric care;

(2) precludes the plan from requiring that a pediatric specialist notify the designated primary care provider or the plan of treatment decisions; or

(3) precludes a group health plan from allowing health care professionals other than physicians to provide routine pediatric care.

SECTION 725. ACCESS TO SPECIALISTS

Subsection (a). In General. A group health plan must ensure that participants and beneficiaries have access to specialty care when such care is covered under the plan. Allows such access to be provided through contractual arrangements with specialized providers outside the plan network.

Subsection (b). Treatment Plans. A group health plan is not prohibited from requiring that specialty care be provided under a treatment plan so long as the plan is: (1) developed by the specialist, in consultation with the primary care provider, and the participant or beneficiary; (2) approved by the plan; and (3) in accordance with applicable quality assurance and utilization review standards. A plan may require the specialist to notify the primary care provider with regular updates on the specialty care provided, as well as all other necessary medical information.

Subsection (c). Referrals. A plan is not prohibited from requiring an authorization by the primary care provider of the participant or beneficiary in order to obtain coverage for specialty services so long as such authorization is for an adequate number of referrals under an approved treatment plan.

Subsection (d). Specialty Care Defined. "Specialty care" means, with respect to a condition, care and treatment provided by a health care practitioner, facility, or center (such as a center of excellence) that has adequate expertise (including age-appropriate expertise) through appropriate training and experience.

SECTION 726. CONTINUITY OF CARE

Subsection (a). In General.

Termination of provider. If a contract between a group health plan and a health care provider is terminated (see definition below), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in a group health plan, and an individual who is a participant or beneficiary in the plan is undergoing a course of treatment from the provider at the time of such termination, the plan must:

(A) notify the individual on a timely basis of such termination;

(B) provide the individual with an opportunity to notify the plan of a need for transitional care; and

(C) in the case of termination described in paragraph (2), (3), and (4) of subsection (b), and subject to subsection (c), permit the individual to continue or be covered with respect to the course of treatment with the provider's consent during a transitional period (as provided under subsection (b)).

Termination. In this section, the term "terminated" includes, with respect to a contract, the expiration or nonrenewal of the contract by the group health plan, but does not include a termination of the contract by the plan for failure to meet applicable quality standards or for fraud.

Subsection (b). Transitional Period.

(1) General rule. Except as provided in paragraph (3), the transitional period under this subsection shall extend for up to 90 days from the date of the notice of the provider's termination (described above).

(2) Institutional care. Subject to paragraph (1), the transitional period under this subsection for institutional or inpatient care from a provider shall extend until the discharge or termination of the period of institutionalization and also shall include institutional care provided within a reasonable time of the date of termination of the provider status if the care was scheduled before the date of the notice of the provider's termination (described above) or if the individual on such date was on an established waiting list or otherwise scheduled to have such care.

(3) Pregnancy. Notwithstanding paragraph (1), if:

(A) a participant or beneficiary has entered the second trimester of pregnancy at the time of a provider's termination of participation; and

(B) the provider was treating the pregnancy before the date of the termination; the transitional period under this subsection with respect to provider's treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

(4) Terminal illness. Subject to paragraph (1), if:

(A) a participant or beneficiary was determined to be terminally ill (as determined under Medicare law) prior to a provider's termination of participation; and

(B) the provider was treating the terminal illness before the date of termination; and the care is directly related to the treatment of the terminal illness.

Subsection (c). Permissible Terms and Conditions.—A group health plan may condition coverage of continued treatment by a provider upon the provider agreeing to the following terms and conditions:

(1) The provider agrees to accept reimbursement from the plan and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or, in the case described in subsection (b)(2), at the rates applicable under the replacement plan after the date of the termination of the contract with the group health plan) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in subsection (a)(1) had not been terminated.

(2) The provider agrees to adhere to the quality assurance standards of the plan responsible for payment under paragraph (1) and to provide to such plan necessary medical information related to the care provided.

(3) The provider agrees otherwise to adhere to such plan's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan.

Subsection (d). Rule of Construction. Nothing in this section shall be construed to require the coverage of benefits which would not have been covered if the provider involved remained a participating provider.

Subsection (e). Definition. In this section, the term "health care provider" or "provider" means: (1) any individual who is engaged in the delivery of health care services in a state and who is required by state law or regulation to be licensed or certified by the state to engage in the delivery of such services in the state; and (2) any entity that is engaged in the delivery of health care services in a state and that, if it is required by state law or regulation to be licensed or certified by the state to engage in the delivery of such services in the state, is so licensed.

SECTION 727. PROTECTION OF PATIENT-PROVIDER COMMUNICATIONS

Subsection (a). In General. A group health plan may not prohibit or otherwise restrict a health care professional, acting within the lawful scope of practice, from advising a participant who is a patient of the professional about the health status of the participant or medical care or treatment for the condition or disease of the participant, regardless of whether coverage for such care or treatment are provided under the plan.

Subsection (b). Rule of Construction. Nothing in this section requires a group health plan to provide specific benefits under the terms of such plan.

SECTION 728. PATIENT'S RIGHT TO PRESCRIPTION DRUGS

To the extent that a group health plan provides coverage for benefits with respect to prescription drugs, and limits such coverage to drugs included in a formulary, the plan must:

(1) ensure the participation of physicians and pharmacists in developing and reviewing such formulary; and

(2) in accordance with applicable quality assurance and utilization review standards, provide for exceptions from the formulary limitation when a non-formulary alternative is medically necessary and appropriate.

SECTION 729. SELF-PAYMENT FOR BEHAVIORAL HEALTH CARE SERVICES

Subsection (a). In General. A group health plan may not:

(1) prohibit or otherwise discourage a participant or beneficiary from self-paying for behavioral health care services once the plan has denied coverage for such services;

(2) terminate a health care provider because such provider permits participants or beneficiaries to self-pay for behavioral health care services that are not otherwise covered or for which the plan provides limited coverage, to the extent that the plan denies coverage of the services.

Subsection (b). Rule of Construction. Nothing in subsection (a)(2) prohibits a group health plan from terminating a contract with a health care provider for failure to meet applicable quality standards or for fraud.

SECTION 730. GENERALLY APPLICABLE PROVISIONS

Subsection (a). In the case of a group health plan that provides benefits under 2 or more coverage options, the requirements of this subpart, other than section 722, shall apply separately with respect to each coverage option.

Subsection (b). Definition. Section 733(a) of the Employee Retirement Income Security Act of 1974 (ERISA) is amended by adding a definition for "fully insured group health plan" to mean a plan where benefits under the plan are provided pursuant to the terms of an arrangement between a group health plan and a health insurance issuer and are guaranteed by the health insurance issuer under a contract or policy of insurance.

Subsection (c). Conforming Amendment. Amends the table of contents in section 1 of ERISA.

SECTION 102. COMPREHENSIVE INDEPENDENT STUDY OF PATIENT ACCESS TO CLINICAL TRIALS AND COVERAGE OF ASSOCIATED ROUTINE COSTS

Subsection (a). Study by the Institute of Medicine. The Secretary of Health and Human Services is directed to enter into a contract with the Institute of Medicine to conduct a comprehensive study of patient access to clinical trials and the coverage of routine patient care costs by private health plans and insurers.

Subsection (b). Matters to be Assessed. The study must assess the following: (1) factors that hinder patient participation in clinical trials, including health plan and insurance policies and prac-

tices; (2) the ability of health plans and investigators to distinguish between routine patient care costs and costs associated with clinical trials; and (3) the potential impact of health plan coverage of routine costs associated with clinical trials on health care premiums.

Subsection (c). Report. The Institute of Medicine must submit a report on the study to the Senate Committee on Health, Education, Labor and Pensions and the Secretary of Health and Human Services not later than 12 months after the date of execution of a contract under subsection (a). The report must set forth the findings, conclusions, and recommendations of the Institute for increasing patient participation in clinical trials, encouraging collaboration between the public and private sectors, and improving analysis of determining routine costs associated with the conduct of clinical trials.

Subsection (d). Funding. The Secretary must provide for funding of the report and study out of funds appropriated to the Department of Health and Human Services for FY2000.

SECTION 103. EFFECTIVE DATE AND RELATED RULES

Subsection (a). In General. The amendments made by this subtitle apply with respect to plan years beginning on or after January 1 of the second calendar year following the date of the enactment of this Act. The Secretary must issue all regulations necessary to carry out the amendments made by this section before the effective date.

Subsection (b). Limitation on Enforcement Actions. No enforcement action shall be taken, pursuant to the amendments made by this subtitle, against a group health plan with respect to a violation of a requirement imposed by such amendments before the date of issuance of regulations issued in connection with such requirement, if the plan has sought to comply in good faith with such requirement.

Subtitle B—Right to Information About Plans and Providers

SECTION 111. INFORMATION ABOUT PLANS

Subsection (a). Employee Retirement Income Security Act of 1974. Amends subpart B of part 7 of subtitle B of Title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185 et seq.) by adding at the end the following:

SECTION 714. HEALTH PLAN COMPARATIVE INFORMATION

Subsection (a). (1). General Requirement. A group health plan, and a health insurance issuer that provides coverage in connection with group health insurance coverage, shall, not later than 12 months after the date of enactment of this section, and at least annually thereafter, provide for the disclosure, in a clear and accurate form to each participant and each beneficiary who does not reside at the same address as the participant, or upon request to an individual eligible for coverage under the plan, or plan sponsor with which the plan or issuer has contracted, of the information described in subsection (b).

(2). Rule of Construction. Nothing in this section shall be construed to prevent a plan or issuer from entering into any agreement under which the issuer agrees to assume responsibility for compliance with the requirements of this section and the plan is released from liability for such compliance.

(3). Provision of Information. Information shall be provided to participants and beneficiaries under this section at the address maintained by the plan or issuer with respect to such participants or beneficiaries.

Subsection (b). Required Information. The informational materials to be distributed under this section shall include for each package option available under a group health benefit plan the following:

(1) A description of the covered items and services under each such plan and any in- and out-of-network features of each such plan, including a summary description of the specific exclusions from coverage under the plan.

(2) A description of any cost-sharing, including premiums, deductibles, coinsurance, and copayment amounts, for which the participant or beneficiary will be responsible, including any annual or lifetime limits on benefits, for each such plan.

(3) A description of any optional supplemental benefits offered by each such plan and the terms and conditions (including premiums or cost-sharing) for such supplemental coverage.

(4) A description of any restrictions on payments for services furnished to a participant or beneficiary by a health care professional that is not a participating professional and the liability of the participant or beneficiary for additional payments for these services.

(5) A description of the service area of each such plan, including the provision of any out-of-area coverage.

(6) A description of the extent to which participants or beneficiaries may select the primary care provider of their choice, including providers both within the network and outside the network of each such plan (if the plan permits out-of-network services).

(7) A description of the procedures for advance directives and organ donation decisions if the plan maintains such procedures.

(8) A description of the requirements and procedures to be used to obtain preauthorization for health services (including telephone numbers and mailing addresses), including referrals for specialty care.

(9) A description of the definition of medical necessity used in making coverage determinations by each such plan.

(10) A summary of the rules and methods for appealing coverage decisions and filing grievances (including telephone numbers and mailing addresses), as well as other available remedies.

(11) A summary description of any provisions for obtaining off-formulary medications if the plan utilizes a defined formulary for providing specific prescription medications.

(12) A summary of the rules for access to emergency room care. Also, any available educational material regarding proper use of emergency services.

(13) A description of whether or not coverage is provided for experimental treatments, investigational treatments, or clinical trials

and the circumstances under which access to such treatments or trials is made available.

(14) A description of the specific preventative services covered under the plan if such services are covered.

(15) A statement regarding the manner in which a participant or beneficiary: (a) may access an obstetrician, gynecologist, or pediatrician; and (b) obtains continuity of care.

(16) A statement that the following information, and instructions on obtaining such information (including telephone numbers and, if available, Internet websites), shall be made available upon request:

(A) The names, addresses, telephone numbers, and state licensure status of the plan's participating health care professionals and participating health care facilities, and, if available, the education, training, speciality qualifications or certifications of such professionals.

(B) A summary description of the methods used for compensating participating health care professionals, such as capitation, fee-for-service, salary, or a combination thereof. (The requirement of this subparagraph shall not be construed as requiring plans to provide information concerning proprietary payment methodology.)

(C) A summary description of the methods used for compensating health care facilities, including per diem, fee-for-service, capitation, bundled payments, or a combination thereof. (The requirement of this subparagraph shall not be construed as requiring plans to provide information concerning proprietary payment methodology.)

(D) A summary description of the procedures used for utilization review.

(E) The list of the specific prescription medications included in the formulary of the plan, if the plan uses a defined formulary.

(F) A description of the specific exclusions from coverage under the plan.

(G) Any available information related to the availability of translation or interpretation services for non-English speakers and people with communication disabilities, including the availability of audio tapes or information in Braille.

(H) Any information that is made public by accrediting organizations in the process of accreditation if the plan is accredited, or any additional quality indicators that the plan makes available.

Subsection (c) Manner of Distribution. The information described in this section must be distributed in an accessible format that is understandable to an average plan participant or beneficiary.

Subsection (d) Rule of Construction. Nothing in this section may be construed to prohibit a group health plan, or health insurance issuer in connection with group health insurance coverage, from distributing any other additional information determined by the plan or issuer to be important or necessary in assisting participants and beneficiaries (or upon request, potential participants) in the selection of a health plan or from providing information under subsection (b)(15) as part of the required information.

Subsection (e) Conforming Regulations. The Secretary must issue regulations to coordinate the requirements on group health plans and health insurance issuers under this section with the require-

ments imposed under part 1 of ERISA, to reduce duplication of information required to be provided.

Subsection (f). Health care professional. In this section, the term 'health care professional' means a physician (as defined in Section 1861(r) of the Social Security Act) or other health care professional if coverage for the professional's services is provided under the health plan involved for the services of the professional. Such term includes a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

Subsection (b). Internal Revenue Code. The Internal Revenue Code is amended to include the following new section:

SECTION 9813. HEALTH PLAN COMPARATIVE INFORMATION

Subsection (a). (1). General Requirement. A group health plan must, not later than 12 months after the date of enactment of this section and, at least annually thereafter, disclose in a clear and accurate form to each participant and beneficiary who does not reside at the same address as the participant, or upon request to an individual eligible for coverage under the plan, the information described in subsection (b).

(2). Rule of Construction. Nothing in this section shall be construed to prevent a plan or issuer from entering into any agreement under which the issuer agrees to assume responsibility for compliance with the requirements of this section and the plan is released from liability for such compliance.

(3). Provision of Information. Information shall be provided to participants and beneficiaries under this section at the address maintained by the plan or issues with respect to such participants or beneficiaries.

Subsection (b) through subsection (f). Provisions are the same as subsection (b) through subsection (f) under Section 714 of the Employee Retirement Income Security Act of 1974, as added by Section 111 of this Act.

SECTION 112. INFORMATION ABOUT PROVIDERS

Subsection (a). Study. The Secretary of Health and Human Services must enter into a contract with the Institute of Medicine for a study, and the submission to the Secretary of a report, that includes:

(1) an analysis of information concerning health care professionals that is currently available to patients, consumers, states, and professional societies, nationally and on a state-by-state basis, including patient preferences with respect to information about such professionals and their competencies;

(2) an evaluation of the legal and other barriers to the sharing of information concerning health care professionals; and

(3) recommendations for the disclosure of information on health care professionals, including the competencies and pro-

fessional qualifications of such practitioners, to better facilitate patient choice, quality improvement, and market competition.

Subsection (b). Report. Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall forward to the appropriate committees of Congress a copy of the report and study.

SUBTITLE C—RIGHT TO HOLD HEALTH PLANS ACCOUNTABLE

SECTION 121. AMENDMENT TO EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

Subsection (a). In General. Section 503 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1133) is amended as follows:

SECTION 503. CLAIMS PROCEDURE, COVERAGE DETERMINATION, GRIEVANCES AND APPEALS

Subsection (a). Claims Procedure. In accordance with regulations of the Secretary, every employee benefit plan must:

(1) provide adequate notice in writing to *a covered participant or beneficiary* whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant, and

(2) afford a reasonable opportunity to any *covered participant or beneficiary* whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim.

Subsection (b). Coverage Determinations Under Group Health Plans.

(1) Procedures.

(A) In general. A group health plan or health insurance issuer conducting utilization review shall ensure that procedures are in place for:

(i) making determinations regarding whether a participant or beneficiary is eligible to receive a payment or coverage for health services under the plan or coverage involved and any cost-sharing amount that the enrollee is required to pay with respect to such service;

(ii) notifying a covered participant or beneficiary (or their authorized representatives) and the treating health care professionals involved regarding determinations made under the plan or issuer and any additional payments that the participant or beneficiary may be required to make with respect to such service; and

(iii) responding to requests, either written or oral, for coverage determinations or for internal appeals from a participant or beneficiary (or the legal representative of such enrollee) or the treating health care professional with consent.

(B) Oral requests. With respect to an oral request described in subparagraph (A)(iii), a group health plan or health insurance issuer may require that the requesting individual provide written evidence of such request.

(2) Timeline for making determinations.

(A) Routine determination. A group health plan or a health insurance issuer shall maintain procedures to ensure that prior authorization determinations concerning the provision of non-emergency items or services are made within 30 days from the date on which the request for a determination is submitted, except that such period may be extended where certain circumstances exist that are determined by the Secretary to be beyond control of the plan or issuer.

(B) Expedited determination.

(i) A prior authorization determination under this subsection shall be made within 72 hours after a request is received by the plan or issuer under clause (ii) or (iii).

(ii) A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection upon the request of a participant or beneficiary if, based on such a request, the plan or issuer determines that the normal time for making such a determination could seriously jeopardize the life or health of the participant or beneficiary.

(iii) A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection if the request involved indicates that the treating health care professional has reasonably documented, based on the medical exigencies, that a determination under the procedures described in subparagraph (A) could seriously jeopardize the life or health of the participant or beneficiary.

(C) Concurrent determinations. A plan or issuer shall maintain procedures to certify or deny coverage of an extended stay or additional services.

(D) Retrospective determination. A plan or issuer shall maintain procedures to ensure that, with respect to the retrospective review of a determination made under paragraph (1), the determination shall be made within 30 working days of the date on which the plan or issuer receives necessary information.

(3) Notice of determinations.

(A) Routine determination. With respect to a coverage determination of a plan or issuer under paragraph (2)(A), the plan or issuer shall issue notice of such determination to the enrollee (or the authorized representative), and consistent with the medical exigencies of the case, to the treating health care professional involved not later than 2 working days after the date on which the determination is made.

(B) Expedited determination. With respect to a coverage determination of a plan or issuer under paragraph (2)(B), the plan or issuer shall issue notice of such determination to the participant or beneficiary (or the authorized representative), and consistent with the medical exigencies of the case, to the treating health care professional involved within the 72 hour period described in paragraph (2)(B).

(C) Concurrent reviews. With respect to the determination under a plan or issuer to certify or deny coverage of an extended stay or additional services, the plan or issuer shall issue notice of such determination to the treating health care professional and to the participant or beneficiary involved (or the authorized representative) within 1 working day of the determination.

(D) Retrospective reviews. With respect to the retrospective review under a plan or issuer of a retrospective determination, the plan or issuer shall issue written notice of an approval or disapproval of a determination under this subparagraph to the participant or beneficiary (or the authorized representative) and health care provider involved within 5 working days of the date on which such determination is made.

(E) A written notice of an adverse coverage determination under this subsection, or of an expedited adverse coverage determination, shall be provided to the participant or beneficiary (or the authorized representative) and treating health care professional (if any) involved and shall include:

(i) the reasons for the determination (including the clinical or scientific-evidence based rationale used in making the determination) written in a manner to be understandable to the average enrollee;

(ii) the procedures for obtaining additional information concerning the determination; and

(iii) notification of the right to appeal the determination and instructions on how to initiate an appeal in accordance with subsection (d).

Subsection (c). Grievances. A group health plan or issuer offering health insurance coverage in connection with a group health plan shall have written procedures for addressing grievances between the plan or issuer and a participant or beneficiary. Determinations under such procedures shall be non-appealable.

Subsection (d). Internal Appeal of Coverage Determinations.

(1) Right to Appeal. (A) In general. A participant or beneficiary (or the authorized representative) and the treating health care professional with the consent of the enrollee (or the legal representative of the enrollee), may appeal any adverse coverage determination under the procedures described in this subsection.

(B) Time for Appeal. A participant or beneficiary must be ensured of not less than 180 days, beginning on the date of an adverse coverage determination, to appeal such determination.

(C) Failure to Act. The failure of a plan or issuer to issue a coverage within applicable timelines shall be treated as an adverse coverage determination for purposes of proceeding to internal review.

(2) Records. A group health plan and a health insurance issuer shall maintain written records, for at least 6 years, with respect to any appeal under this subsection for purposes of internal quality assurance and improvement.

(3) Routine determinations. A group health plan or a health insurance issuer shall complete the consideration of an appeal of an adverse routine determination not later than 30 working days after the date on which a request for such appeal is received.

(4) Expedited determination.

(A) In general. An expedited determination with respect to an appeal shall be made in accordance with the medical exigencies of the case, but in no case more than 72 hours after the request for such appeal is received by the plan or issuer.

(B) Request by participant or beneficiary. A plan or issuer shall maintain procedures for expediting a prior authorization deter-

mination upon the request of an participant or beneficiary if, based on such a request, the plan or issuer determines that the normal time for making such a determination could seriously jeopardize the life or health of the participant or beneficiary.

(C) Documentation by health care professional. A plan or issuer shall maintain procedures for expediting a prior authorization determination if the request involved indicates that the treating health care professional has documented, based on the medical exigencies that a routine determination could seriously jeopardize the life or health of the enrollee.

(5) Conduct of review. A review of an adverse coverage determination shall be conducted by an individual with appropriate expertise who was not directly involved in the initial determination.

(6) Lack of medical necessity. An appeal under this subsection relating to a determination to deny coverage based on a lack of medical necessity or appropriateness, or based on an experimental or investigational treatment, shall be made only by a physician with appropriate expertise in the field of medicine involved who was not involved in the initial determination.

(7) Notice.

(A) In general. Written notice of a determination made under an internal review process shall be issued to the participant or beneficiary (or the authorized representative) and the treating health care professional not later than 2 working days after the completion of the review (or within the 72–hour period, if applicable).

(B) Adverse coverage determinations. With respect to an adverse coverage determination made under this subsection, the notice described in subparagraph (A) shall include:

(i) the reasons for the determination (including the clinical or scientific-evidence based rationale used in making the determination) written in a manner to be understandable to the average participant or beneficiary;

(ii) the procedures for obtaining additional information concerning the determination; and

(iii) notification of the right to an external review under subsection (e) and instructions on how to initiate such a review.

Subsection (e). Independent External Review.

(1) Access to Review.

(A). In General. A group health plan or a health insurance issuer offering health insurance coverage in connection with a group health plan shall have written procedures to permit a participant or beneficiary (or the authorized representative) access to an independent external review with respect to an adverse coverage determination concerning a particular item or service ((including a circumstance treated as an adverse coverage determination) under subparagraph (B)) where:

(i) the particular item or service involved,

(I) (aa) would be a covered benefit when medically necessary and appropriate, under the terms of the plan, and the item or service has been determined not to be medically necessary and appropriate under the internal appeals process required; or there has been a failure to issue a timely coverage determination; and

(bb) (AA) the amount of the item or service exceeds a significant financial threshold, or

(BB) or there is a significant risk of placing the life or health of the participant or beneficiary in jeopardy, or

(II) would be a covered benefit, when not considered experimental or investigational under the terms and conditions of the plan, and the item or service has been determined to be experimental or investigational under the internal appeals process or there has been a failure to issue a timely coverage determination; and

(ii) the participant or beneficiary has completed the internal appeals process under subsection (d) with respect to such determination.

(B) The failure to issue a coverage determination within the applicable timeline shall be treated as an adverse coverage determination for purposes of proceeding to independent external review.

(2) Initiation of the external review process.

(A) Filing of request. A participant or beneficiary (or the authorized representative) who desires to have an external review conducted shall file a written request for such review with the plan or issuer involved not later than 30 working days after the receipt of a final denial of a claim. Any such request shall include the consent of the participant or beneficiary (or the authorized representative) for the release of medical information and records to independent external reviewers.

(B) Information and notice. Not later than 5 working days after the receipt of a request, the plan or issuer involved shall select an external appeals entity that shall be responsible for designating an external reviewer.

(C) Provision of information. The plan or issuer involved shall forward necessary information (including medical records, any relevant review criteria, the clinical rationale consistent with the terms and conditions of the contract between the plan or issuer and the participant or beneficiary for the coverage denial, and evidence of the enrollee's coverage) to the independent, external reviewer.

(D) Notification. The plan or issuer involved shall send a written notification to the participant or beneficiary (or the authorized representative) and the plan administrator, indicating that an external review has been initiated.

(3) Conduct of external review.

(A) Designation of external appeals entity by plan or issuer. A plan or issuer that receives a request for an external review shall designate a qualified external appeals entity that will make a decision in an unbiased manner. Describes a qualified entity as: (i) one licensed or credentialed by a state; (ii) a state agency established for the purpose of conducting independent external reviews; (iii) any entity under contract with the federal government to provide external review services; (iv) any entity accredited as an external review entity by an accrediting body recognized by the Secretary for such purpose; or (v) any other entity meeting criteria established by the Secretary.

(B) Designation of external reviewer by external appeals entity. The external appeals entity shall designate one or more individuals

to serve as external reviewers. Such reviewers shall be independent medical experts who shall:

(i) be appropriately credentialed or licensed in any state to deliver health care services;

(ii) not have any material, professional, familial, or financial affiliation with the case under review, the participant or beneficiary involved, the treating health care professional, the institution where the treatment would take place, or the manufacturer or any drug, device, procedure, or other therapy proposed for the participant or beneficiary whose treatment is under review;

(iii) have expertise (including age-appropriate expertise) in the diagnosis or treatment under review and, when reasonably available, be of the same specialty as the physician treating the participant or beneficiary or recommending or prescribing the treatment in question;

(iv) receive only reasonable and customary compensation from the group health plan or health insurance issuer in connection with the external review that is not contingent on the decision rendered by the reviewer; and

(v) not be held liable for decisions regarding medical determinations (but may be held liable for actions that are arbitrary and capricious).

(4) Standard of review.

(A) In general. An independent external reviewer shall:

(i) make an independent determination based on the valid, relevant, scientific and clinical evidence to determine the medical necessity, appropriateness, experimental or investigational nature of the proposed treatment; and

(ii) take into consideration appropriate and available information including any evidence-based decision making or clinical practice guidelines used by the group health plan or health insurance issuer; timely evidence or information submitted by the plan, issuer, patient or patient's physician; the patient's medical record; expert consensus; and medical literature.

(B) Notice. The plan or issuer involved shall ensure that the participant or beneficiary receives notice, within 30 days after the determination of the independent medical expert, regarding the actions of the plan or issuer with respect to the determination of such expert under the independent external review.

(5) Timeframe for review. An independent external reviewer shall complete a review of an adverse coverage determination in accordance with the medical exigencies of the case, but in no case later than 30 working days after the later of:

(A) the date on which such reviewer is designated; or

(B) the date on which all information necessary to completing such review is received.

(6) Binding determination. The determination of an external reviewer under this subsection shall be binding upon the plan or issuer if the provisions of this subsection or the procedures implemented under such provisions were complied with by the independent external reviewer.

(7) Study. Not later than 2 years after the date of enactment of this section, the General Accounting Office shall conduct a study of

a statistically appropriate sample of completed independent external reviews. Such study shall include an assessment of the process involved during an independent external review and the basis of decision making by the independent external reviewer. The results of such study shall be submitted to the appropriate committees of Congress.

(8) Effect of certain provisions. Nothing in this section shall be construed as affecting or modifying the Employee Retirement Income Security Act provisions governing supersedure of state law with respect to a group health plan.

Subsection (f). Rule of Construction. Nothing in this section shall be construed to prohibit a plan administrator or plan fiduciary or health plan medical director from requesting an independent external review by an independent external reviewer without first completing the internal review process.

Subsection (g). Definitions. In this section:

The term adverse coverage determination means a coverage determination under the plan which results in a denial of coverage or reimbursement.

The term coverage determination means with respect to items and services for which coverage may be provided under a health plan, a determination of whether or not such items and services are covered or reimbursable under the coverage and terms of the contract.

The term grievance means any complaint made by a participant or beneficiary that does not involve a coverage determination.

The term group health plan means an employee welfare benefit plan to the extent that the plan provides medical care to employees or their dependents directly or through insurance, reimbursement, or otherwise.

The term health insurance coverage means benefits consisting of medical care under any hospital or medical service policy or certificate, hospital or medical service plan contract, or health maintenance organization (HMO) contract offered by a health insurance issuer.

The term health insurance issuer means an insurance company, insurance service, or insurance organization (including an HMO) which is licensed to engage in the business of insurance in a state and which is subject to state law which regulates insurance. The term does not include a group health plan.

The term prior authorization determination means a coverage determination prior to the provision of the items and services as a condition of coverage of the items and services under the coverage.

The term treating health care professional with respect to a group health plan, health insurance issuer or provider sponsored organization means a practitioner who is acting within the scope of their state licensure or certification for the delivery of health care services and who is primarily responsible for delivering those services to the enrollee.

The term utilization review with respect to a group health plan or health insurance coverage means a set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings. Techniques may include ambulatory review, pro-

spective review, second opinion, certification, concurrent review, case management, discharge planning or retrospective review.

Subsection (b). Enforcement. Amends the Employee Retirement Income Security Act of 1974 to provide for a civil penalty for plan failures to comply with coverage determinations.

Subsection (c). Conforming Amendment. Amends the table of contents in Section 1 of the Employee Retirement Income Security Act of 1974.

Subsection (d). Effective Date. The amendments made by this section are effective for plan years beginning on or after one year after the date of enactment of this Act. The Secretary must issue all regulations necessary to carry out such amendments before the effective date.

TITLE II—GENETIC INFORMATION AND SERVICES

SECTION 201. SHORT TITLE

This title may be cited as the "Genetic Information Nondiscrimination in Health Insurance Act of 1999."

SECTION 202. AMENDMENTS TO EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

Subsection (a). Prohibition of Health Discrimination on the Basis of Genetic Information or Genetic Services.

(1). No Enrollment Restriction For Genetic Services. ERISA is amended by extending the prohibition against discrimination based on genetic information to include information about a request for or receipt of genetic services

(2). No Discrimination in Group Premiums Based on Predictive Genetic Information. ERISA (as amended by Section 111(a) of this bill) is amended further by adding a new Section 715, which follows:

SECTION 715. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION

Group health plans or health insurance issuers offering insurance coverage in connection with a group health plan are prohibited from adjusting premium or contribution amounts for a group on the basis of predictive genetic information concerning an individual (including a dependent) or family member of the individual (including information about a request for or receipt of genetic services).

(3). Conforming Amendment. Section 702(b) of ERISA of 1974 is amended by adding the following:

(3) Reference to Related Provision. "For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group health plan on the basis of predictive genetic information (including information about a request for or receipt of genetic services), see Section 715.

Subsection (b). Limitation on Collection of Predictive Genetic Information. This subsection amends Section 702 of ERISA by adding the following new subsection.

Subsection (c). Collection of Predictive Genetic Information.

(1). Limitation on Requesting or Requiring Predictive Genetic Information. Group health plans or health insurance issuers offering insurance coverage in connection with a group health plan are prohibited from requesting or requiring predictive genetic information concerning an individual (including a dependent) or family member of the individual (including information about a request for, or, receipt of, genetic services), except as provided in paragraph (2) which follows.

(2). Information Needed For Diagnosis, Treatment, or Payment.

(A). In General. This paragraph permits group health plans or health insurance issuers that provide health care to an individual or dependent to request (but not require) that individuals or dependents disclose or authorize the collection of predictive genetic information for diagnosis, treatment, or payment purposes relating to the provision of health care.

(B). Notice of Confidentiality Practices and Description of Safeguards. As part of a request of subparagraph (A), group health plans or health insurance issuers that provide health care to an individual or dependent must provide them with a description of the procedures in place to safeguard confidentiality of such predictive genetic information.

Subsection (d). Confidentiality with Respect to Predictive Genetic Information.

(1) Notice of Confidentiality Practices.

(A) Preparation of Written Notice. A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, must post or provide, in writing and in a clear and conspicuous manner, notice of the plan or issuer's confidentiality practices, including: a description of an individual's rights with respect to predictive genetic information; the procedures established by the plan or issuer for the exercise of the individual's rights; and the right to obtain a copy of the notice of the required confidentiality practices.

(B) Model Notice. The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, is required to develop and disseminate model notices of confidentiality practices.

(2) Establishment of Safeguards. A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, must establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information.

Subsection (c). Definitions. This subsection amends Section 733(d) of ERISA by adding at the end the following definitions:

Family Member.—means, with respect to an individual, the spouse or a dependent child of that individual, including a child who is born to, or placed for adoption with, the individual, and all other individuals related by blood to that individual, spouse, or child.

Genetic Information.—information about genes, gene products, or inherited characteristics that may derive from an individual or a

family member (including information about a request for, or, receipt of, genetic services).

Genetic Services.—health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

Predictive Genetic Information.—in the absence of symptoms, clinical signs, or a diagnosis of the condition related to such information: information about an individual's genetic tests; information about genetic tests of family members of the individual; or information about the occurrence of a disease or disorder in family members. The term does not include the following: information about the sex or age of the individual; information derived from routine physical tests, such as chemical, blood, or urine analyses of the individual including cholesterol tests; and information about physical exams of the individual.

Genetic Test.—the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals. The term provides the same exclusions as the term predictive genetic information.

Subsection (d). Effective Date. This subsection and its amendments will go into effect, with respect to group health plans, for plan years beginning 1 year after enactment of this bill.

SECTION 203. AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT

Subsection (a). Amendments Relating to the Group Market.

The Public Health Service Act is amended by adding provisions prohibiting health discrimination on the basis of predictive genetic information in the group market. Such provisions are very similar to those above (Section 202 of this Act) that amended ERISA. The changes create a new section:

"SECTION 2707. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION IN THE GROUP MARKET"

Subsection (b). Amendment Relating to the Individual Market. The Public Health Service Act is amended by adding provisions prohibiting health discrimination on the basis of genetic information in the individual market. The provisions prohibit the use of predictive genetic information as a condition of eligibility and for setting premium rates in the individual market. Such provisions are very similar to those above (Section 202 of this Act) that amended ERISA. The changes create a new section:

"SECTION 2753. PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF PREDICTIVE GENETIC INFORMATION"

SECTION 204. AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986

Subsection (a). Prohibition of Health Discrimination on the Basis of Genetic Information or Genetic Services. The Internal Revenue Code of 1986 is amended by adding provisions prohibiting health discrimination on the basis of genetic information in the group market. Such provisions very similar to those above (section 202 of

this Act) that amended ERISA. The amendments apply to group health plans and create a new section:

"SECTION 9814. PROHIBITING HEALTH DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION"

TITLE III—HEALTHCARE RESEARCH AND QUALITY

SECTION 301. SHORT TITLE

This section cites the title as "Healthcare Research and Quality Act of 1999".

SECTION 302. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT

Title IX of the Public Health Service (PHS) Act is amended to read as follows:

TITLE IX—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

Part A—Establishment and General Duties

SECTION 901. MISSION AND DUTIES

Subsection (a). In General. This subsection redesignates the Agency for Health Care Policy and Research as the Agency for Healthcare Research and Quality (hereinafter referred to as "the Agency".

Subsection (b). Mission. The purpose of the Agency is to enhance the quality, appropriateness, and effectiveness of healthcare services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical practice, including the prevention of diseases and other health conditions. The Agency is required to promote healthcare quality improvement by:

(1) conducting and supporting research that develops and presents scientific evidence regarding all aspects of healthcare, including—

(A) methods of enhancing patient participation in their own care and for facilitating shared patient-physician decision-making;

(B) the outcomes, effectiveness, and cost-effectiveness of healthcare practices, including preventive measures and long-term care;

(C) existing and innovative technologies;

(D) the costs, utilization, and access to healthcare;

(E) the ways in which healthcare services are organized, delivered, and financed and the interaction and impact of these factors on the quality of patient care;

(F) methods for measuring and strategies for improving quality; and

(G) ways in which patients, consumers, and practitioners acquire and use new information about best practices and health benefits;

(2) synthesizing and disseminating available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

(3) advancing private and public efforts to improve healthcare quality.

Subsection (c). Requirements With Respect to Rural Areas and Priority Populations. The Director of the Agency is required to undertake and support research, demonstration projects, and evaluations with respect to the delivery of health services (a) in rural areas (including frontier areas); (b) for low-income groups, and minority groups; (c) for children; (d) for the elderly; and (e) for people with special healthcare needs, including disabilities, chronic care, and end-of-life healthcare.

Subsection (d). Appointment of Director. This subsection designates the head of the Agency as appointed by the Secretary to be known as the Director for Healthcare Research and Quality. The Secretary, acting through the Director, is required to carry out the authorities and duties established under this title of the bill.

SECTION 902. GENERAL AUTHORITIES

The Director is required to support demonstration projects, conduct and support research, evaluations, training, research networks, multidisciplinary centers, technical assistance, and the dissemination of information, on healthcare, and on systems for the delivery of such care, including activities with respect to—

(1) the quality, effectiveness, efficiency, appropriateness and value of healthcare services;

(2) quality measurement and improvement;

(3) the outcomes, cost, cost-effectiveness, and use of healthcare services and access to such services;

(4) clinical practice, including primary care and practice-oriented research;

(5) healthcare technologies, facilities, and equipment;

(6) healthcare costs, productivity, and market forces;

(7) health promotion and disease prevention, including clinical preventive services;

(8) health statistics, surveys, database development, and epidemiology, and

(9) medical liability.

Subsection (b). Health Services Training Grants. The Director may provide training grants in the field of health services research to include pre- and post-doctoral fellowships and training programs, young investigator awards, and other programs and activities as appropriate. Training funds for carrying out these activities are made available under Section 487 as well as funds appropriated directly to the Agency. In developing priorities for the allocation of such funds, the Director is required to take into consideration shortages of trained researchers addressing priority populations.

Subsection (c). Multidisciplinary Centers. The Director may provide financial assistance toward the costs of planning, establishing and operating centers for multidisciplinary health services research, demonstration projects, evaluations, training, and policy analysis.

Subsection (d). Relation to Certain Authorities Regarding Social Security. Activities of the Agency should be appropriately coordinated with experiments, demonstration projects, and other related activities authorized by the Social Security Act and the Social Security Amendments of 1967. Activities that affect Medicare, Medicaid, and the State Child Health Insurance Program are required to be carried out consistent with provisions of the Social Security Act affecting outcomes research.

Subsection (e). Disclaimer. The Agency is prohibited from mandating national standards of clinical practice or healthcare quality. Published recommendations that result from the Agency's projects shall include a disclaimer to that effect.

Subsection (f). Rule of Construction. This section clarifies that the provisions are not to be construed to imply that the Agency's role is to mandate a national standard or specific approach to quality measurement and reporting. In determining research and quality improvement activities, the Agency must consider a wide range of choices, providers, healthcare delivery systems, and individual preferences.

Part B—Healthcare Improvement Research

SECTION 911. HEALTHCARE OUTCOME IMPROVEMENT RESEARCH

Subsection (a). Evidence Rating Systems. The Agency shall collaborate with experts from the public and private sector to identify and disseminate methods or systems to assess health care research results, and to rate the strength of the scientific evidence behind healthcare practice, recommendations in the research literature, and technology assessments. The Agency is required to make such evidence assessment methods and systems widely available. Agency publications containing recommendations must indicate the level of substantiating evidence using such methods or systems.

Subsection (b). Healthcare Improvement Research Centers and Provider-Based Research Networks. Requires the Agency to use research strategies and mechanisms to link research directly with clinical practice in geographically diverse locations including Health Improvement Research Centers that provide access to multidisciplinary expertise in outcomes or quality improvement research; Practice-based Research Networks, including plan, facility, or delivery systems sites of care (especially primary care), that can evaluate and promote quality improvement; and other innovative mechanisms or strategies.

SECTION 912. PRIVATE-PUBLIC PARTNERSHIPS TO IMPROVE ORGANIZATION AND DELIVERY

Subsection (a). Support for Efforts to Develop Information on Quality.

(1) Scientific and Technical Support. As the principal agency for healthcare quality research, the Agency may provide scientific and technical support for public and private efforts to improve healthcare quality, including accrediting organizations.

(2) Role of the Agency. The role of the Agency is to:

(A) identify and assess methods for evaluating the health of health plan enrollees by type of plan, provider, and provider

arrangements; and of other populations, including those receiving long-term care services;

(B) develop, test, and disseminate quality measures, including measures of health and functional outcomes;

(C) compile and disseminate healthcare quality measures developed in the private and public sector;

(D) assist in the development of improved healthcare information systems;

(E) develop survey tools to measure enrollee assessments of their healthcare; and

(F) identify and disseminate information on mechanisms to integrate quality information into purchaser and consumer decision-making.

Subsection (b). Centers for Education and Research on Therapeutics.

(1) In General. Requires the Secretary, acting through the Director and in consultation with the Commissioner of Food and Drugs, to establish a program for making one or more grants to establish centers to conduct research to: (i) increase awareness of new uses, improvements in the use, and risks of drugs, biological products, and devices, (ii) provide objective clinical information to healthcare providers, insurers, government agencies, patients and consumers; and (iii) improve the quality of healthcare while reducing the cost of healthcare through the appropriate use of drugs, biological products, or devices; and prevent adverse effects. In addition, requires the conduct of research on the comparative effectiveness, cost-effectiveness, and safety of drugs, biological products, and devices and such other activities as the Secretary determines to be appropriate.

Subsection (c). Reducing Errors in Medicine. This section directs the Secretary to conduct and support research and build public-private partnerships to identify the causes of preventable errors and patient injury in healthcare delivery to: develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and promote implementation of strategies for improving patient safety.

SECTION 913. INFORMATION ON QUALITY AND COST OF CARE

Subsection (a). This section requires the Director to:

(1) conduct a survey to gather data on the cost and use of healthcare services and, beginning in FY 2001 and subsequent years, quality of health care, including the types of healthcare services Americans use, their access to healthcare services, frequency of use, how much is paid for the services used, the source of those payments, the types and costs of private health insurance, access, satisfaction, and quality of care for the general population including rural residents and also for children, the uninsured, poor and near-poor individuals, and persons with special healthcare needs; and

(2) develop databases and tools that enable States to track the quality, access, and use of healthcare services.

Subsection (b)(1). This section further requires that the above survey: (A) identify determinants of health outcomes and functional status, the needs of special populations with respect to such variables as well as an understanding of these changes over time, rela-

tionships to healthcare access and use, and to monitor the overall national impact of Federal and State policy changes on healthcare; (B) provide information on the quality of care and patient outcomes for frequently occurring clinical conditions for a nationally representative sample of the population; and (C) provide reliable national estimates for children and persons with special healthcare needs through the use of supplements or periodic expansions of the survey.

(2). Beginning in fiscal year 2003, an annual report is required to be submitted to Congress on national trends in the quality of healthcare.

SECTION 914. INFORMATION SYSTEMS FOR HEALTHCARE IMPROVEMENT

This section directs the agency to support research, initiatives on:

(1) the use of information systems for the study of healthcare quality;

(2) training for healthcare practitioners and researchers in the use of information systems;

(3) the creation of linkages between various sources of health information;

(4) the delivery and coordination of evidence-based healthcare services, including the use of real-time decision-support programs;

(5) the utility and comparability of health information data and medical vocabularies by addressing issues related to the structure, content, definition, and coding of health information and data in consultation with other Federal, State and Private entities;

(6) the evaluation and use of computer-based health records; and

(7) the protection of confidential patient information.

In addition, the Agency is directed to support demonstrations into the use of new information tools for improving shared decision-making between patients and providers.

SECTION 915. RESEARCH SUPPORTING PRIMARY CARE DELIVERY AND ACCESS IN UNDERSERVED AREAS

Subsection (a). Preventive Services Task Force. This section defines a Preventive Services Task Force to review the evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations, regarding the usefulness in daily clinical practice. The Agency is directed to provide ongoing administrative, research, and technical support for the operation of the Preventive Services Task Force and to coordinate and support the dissemination of the Preventive Services Task Force recommendations.

Subsection (b). Primary Care Delivery Research.

This section establishes a Center for Primary Care Delivery Research within the Agency (referred to in this subsection as the "Center") to serve as the principal source of funding for primary care delivery research in the Department of Health and Human Services. Specifies the focus of primary care delivery research as the first contact when illness or health concerns arise, the diag-

nosis, treatment or referral to specialty care, preventive care, and the relationship between the clinician and the patient in the context of the family and community.

The Center is required to conduct and support research on the nature and characteristics of primary care delivery practice; producing evidence for the management of common clinical problems; the management of undifferentiated clinical problems; and the continuity and coordination of health services.

SECTION 916. CLINICAL PRACTICE AND TECHNOLOGY INNOVATION

Subsection (a). In General. Requires the Director to promote innovation in evidence-based clinical practice and healthcare technologies by: conducting and supporting research; developing, evaluating, and disseminating methodologies for assessments; and conducting and supporting assessments of healthcare practices and technologies; promoting education, training, and providing technical assistance; and working with the National Library of Medicine and the public and private sector to develop an electronic clearinghouse of currently available assessments and those in progress.

Subsection (b). This section specifies the process for clinical practice and technology assessment. It requires the Director to develop and publish a description of the methods used by the Agency and its contractors in conducting such assessments not later than December 31, 2000. It requires the Director to cooperate and consult with the administrators of other federal agencies, professional societies, and other private and public entities and it requires methods used in such assessments to consider safety, efficacy, and effectiveness; legal, social, and ethical implications; costs, benefits, and cost-effectiveness; comparisons to alternative technologies and practices; and requirements of the Food and Drug Administration.

Subsection (c). Specific Assessments. Requires the Director to conduct and support specific assessments of healthcare technologies and practices and allows the Director to conduct or support assessments on a reimbursable bases for other federal agencies. In addition, the Director may make grants to, or enter into cooperative agreements or contracts for the purpose of conducting assessments of experimental, emerging, existing, or potentially outmoded healthcare technologies, and for related activities with entities determined to be appropriate by the Director. Such entities can include academic medical centers, research institutions, professional organizations, third party payers, other governmental agencies, and consortia of appropriate research entities established for the purpose of conducting technology assessments.

SECTION 917. COORDINATION OF FEDERAL GOVERNMENT QUALITY IMPROVEMENT EFFORTS

Subsection (a). This section requires the Secretary, acting through the Director, to coordinate all federal research, evaluations, and demonstrations related to health services research and quality measurement and improvement activities. The Director, in collaboration with the appropriate federal officials, is required to develop and manage a process to improve interagency coordination, priority setting, and the use and sharing of research findings;

strengthen the research information infrastructure, including databases, set specific goals; and strengthen the management of Federal healthcare quality improvement programs.

Subsection (b)(1). Study by the Institute of Medicine. This section directs the Secretary to enter into a contract with the Institute of Medicine to describe and evaluate current quality improvement, quality research and quality monitoring processes to identify options and make recommendations to improve the efficiency and effectiveness of such quality improvement programs.

(2) Requirements. This section describes the requirements of the contract to include the preparation of (i) not later than 12 months after the date of enactment of this title, a report providing an overview of the quality improvement programs of the Department of Health and Human Services for the Medicare, Medicaid, and CHIP programs under Titles XVIII, XIX, and XXI of the Social Security Act; and (ii) not later than 24 months after the date of enactment of this title, of a final report containing recommendations for a comprehensive system and public-private partnerships for healthcare quality improvement. The Secretary is required to submit the reports to the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Commerce of the House of Representatives.

Part C—General Provisions

SECTION 921. ADVISORY COUNCIL FOR HEALTHCARE QUALITY RESEARCH.

This section establishes the Advisory Council for Healthcare Quality Research. The Advisory Council is required to advise the Secretary and the Director with respect to activities to carry out the purpose of the Agency under Section 901(b) and to make recommendations to the Director regarding:

(A) healthcare research priorities, especially studies related to quality, outcomes, cost and the utilization of, and access to, healthcare services;

(B) the field of healthcare research and related disciplines, especially issues related to training needs, and dissemination of information on quality; and

(C) the appropriate role of the Agency in each of these areas in light of private sector activity and identification of opportunities for public-private sector partnerships.

Membership is to be comprised of appointed members, who are voting members, and ex-officio members. The Secretary will appoint 21 members and ensure that they represent professions and entities concerned with, or affected by, activities under this title and under Section 1142 of the Social Security Act. The appointed members must include 4 distinguished researchers, four individuals distinguished in the practice of medicine of which at least one is a primary care practitioner; three individuals distinguished in other health professions; four individuals either representing the private healthcare sector, including health plans, providers, and purchasers or individuals distinguished as health care administrators; four individuals distinguished in the fields of healthcare qual-

ity, economics, information systems, law, ethics, business, or public policy; and two individuals representing the interests of patients and consumers. At least 17 members are required to be representatives of the public who are not officers or employees of the United States.

The Secretary is required to designate as ex officio members of the Advisory Council the Assistant Secretary for Health, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, the Administrator of the Health Care Financing Administration, the Assistant Secretary of Defense (Health Affairs), and the Under Secretary for Health of the Department of Veterans Affairs; and such other Federal officials as the Secretary considers appropriate.

Members of the Advisory Council appointed are required to serve for a term of 3 years and may continue to serve after the expiration of the term until a successor is appointed. If a member of the Advisory Council does not serve the full term, the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the predecessor's term. The Director is required to designate an individual, from among the membership, to serve as the chair of the Advisory Council. The Advisory Council will meet not less than once during each discrete 4–month period and shall otherwise meet at the call of the Director or the chair.

Members of the Advisory Council shall receive compensation for each day (including travel time) engaged in carrying out the duties of the Advisory Council unless declined by the member. Such compensation may not be in an amount in excess of the Executive Level IV of the General Schedule. Ex officio members may not receive compensation for service on the Advisory Council in addition to the compensation otherwise received for duties carried out as officers of the United States.

The Director is required to provide to the Advisory Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.

SECTION 922. PEER REVIEW WITH RESPECT TO GRANTS AND CONTRACTS

Subsection (a). Requires that appropriate technical and scientific peer review be conducted with respect to each application for a grant, cooperative agreement, or contract under this title. Each peer review group to which an application is submitted shall report its finding and recommendations respecting the application to the Director in such form and in such manner as the Director shall require.

Subsection (b). Approval as Precondition of Awards. The Director may not approve an application described above unless the application is recommended for approval by a peer review group established under subsection (c).

Subsection (c). Establishment of Peer Review Groups. The Director is required to establish technical and scientific peer review groups to carry out this section. Such groups shall be established without regard to the provisions of Title 5, United States Code, that govern appointments in the competitive service, and without regard to the provisions of chapter 51, and subchapter III of chap-

ter 53, of such title that relate to classification and pay rates under the General Schedule.

Peer review group members are to be eminently qualified individuals. Not more than 25% of such groups' membership are to be officers and employees of the United States and such officers and employees may not receive additional compensation for service. Such groups shall continue in existence until otherwise provided by law.

Peer review group members shall agree in writing to (A) treat information received, records, reports, and recommendations as confidential information and (B) recuse themselves from participation in the peer-review of specific applications which present a potential personal conflict of interest or appearance of such conflict.

In the case of applications for financial assistance whose direct costs will not exceed $100,000, the Director can make adjustments in the peer review procedures to encourage the entry of individuals into the field of research and to encourage clinical practice-oriented research, and for such other purposes as the Director may determine to be appropriate.

The Secretary shall issue regulations for the conduct of peer review under this section.

SECTION 923. CERTAIN PROVISIONS WITH RESPECT TO DEVELOPMENT, COLLECTION, AND DISSEMINATION OF DATA

Subsection (a). Standards With Respect to Utility of Data. Requires the Director to establish standard methods to assure the utility, accuracy, and sufficiency of data collected by or for the Agency. Requires the Director to take into account other Federal data collection requirements and differences among health care plans, delivery systems, providers, and provider arrangements. If the methods affect the administration of other programs, including the programs under titles XVIII, XIX or XXI of the Social Security Act, they shall be in the form of recommendations to the Secretary.

Subsection (b). Statistics. Requires the Director to take appropriate action to assure that statistics developed under this title are of high quality, timely, and comprehensive, as well as specific, standardized, and adequately analyzed and indexed; and make such information available on as wide a basis as is practicable.

Subsection (c). Authority Regarding Certain Requests. Upon request of a public or private entity, the Director may undertake research or analyses otherwise authorized under this title, the cost of which would be paid by the entity and such funds would remain available to the Agency until expended.

SECTION 924. DISSEMINATION OF INFORMATION

Subsection (a). The Director is required to (a) promptly publish, or make broadly available, in an understandable form, the results of research, demonstration projects, and evaluations; (b) ensure that information disseminated by the agency is science-based, objective, and useful; (c) promptly make data available to the public; (d) provide, in collaboration with the National Library of Medicine where appropriate, indexing, abstracting, translating, publishing, and other services leading to a more effective dissemination of research information, and undertake programs to develop new or im-

proved methods for making such information available; and (e) as appropriate, provide technical assistance to State and local government and health agencies and conduct liaison activities to such agencies to foster dissemination.

Subsection (b). The Director may not restrict the publication or dissemination of data or results from projects conducted or supported under this title except for those limitations described below.

Subsection (c). Information that allows one to identify a person or establishment supplying the information or allows one to identify a person or establishment described if it cannot be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented to its use for such other purpose and it may not be published or released in any form unless any person identified therein or the person who supplied the data has consented to its publication or release.

Subsection (d). Establishes a civil monetary penalty of not more than $10,000 for violation of the above rule.

SECTION 925. ADDITIONAL PROVISIONS WITH RESPECT TO GRANTS AND CONTRACTS

Subsection (a). Financial Conflicts of Interest. The Director is required to define by regulation the circumstances under which financial interests in projects may be reasonably expected to create a bias in favor of obtaining results that are consistent with such interests and the actions the Director will take in response to such interests.

Subsection (b). Requirement of Application. Applications for grants, cooperative agreements, or contracts, may not be approved unless the application is submitted to the Secretary in the required form and contains such agreements, assurances, and information as determined by the Director to be necessary to carry out the program involved.

Subsection (c). Provision of Supplies and Services in Lieu of Funds.

(1) In general. Upon request of an entity receiving a grant, cooperative agreement, or contract, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding an entity in carrying out the project involved and, for such purpose, may detail to the entity any officer or employee of the Department of Health and Human Services.

(2) Corresponding reduction in funds. With respect to a request described for services supplies or equipment, the Secretary is required to reduce the amount of the financial assistance involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Director. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

Subsection (e). Applicability of Certain Provisions With Respect to Contracts. Contracts may be entered into under this part without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

SECTION 926. CERTAIN ADMINISTRATIVE AUTHORITIES

Subsection (a). Deputy Director and Other Officers and Employees.

(1) Deputy director. The Director may appoint a deputy director for the Agency.

(2) Other officers and employees. The Director may appoint and fix the compensation of such officers and employees as may be necessary to carry out this title. Except as otherwise provided by law, such officers and employees shall be appointed in accordance with the civil service and compensation laws.

Subsection (b). Facilities. Authorizes the Secretary to lease or otherwise acquire through the Director of General Services, buildings or portions of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed 10 years; and acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other real or personal property (including patents) as the Secretary deems necessary.

Subsection (c). Provision of Financial Assistance. Authorizes the Director to make grants to public and nonprofit entities and individuals, and enter into cooperative agreements or contracts with public and private entities and individuals.

Subsection (d). Utilization of Certain Personnel and Resources. Authorizes the Director to utilize personnel and equipment, facilities, and other physical resources of the Department of Health and Human Services, permit appropriate (as determined by the Secretary) entities and individuals to utilize the physical resources of such Department, and provide technical assistance and advice. In addition, the Director, may use, with their consent, the services, equipment, personnel, information, and facilities of other federal, state, or local public agencies, or of any foreign government, with or without reimbursement of such agencies.

Subsection (e). Consultants. Authorizes the Secretary to engage consultants from time to time and for such periods as the Director deems advisable in accordance with provisions of section 3109 of Government Organization and Employees on the assistance and advice of consultants from the United States or abroad.

Subsection (f). Experts. (1). Authorizes the Secretary to obtain the services of not more than 50 experts or consultants who have appropriate scientific or professional qualifications.

(2) Travel expenses. Experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed for their expenses associated with traveling to and from their assignment location in accordance with sections of Government Organization and Employees (Title 5, United States Code) on travel, transportation and subsistence expenses for government employees. Expenses may not be allowed in connection with an expert or consultant unless the expert agrees in writing to complete the entire period of assignment, or 1 year, whichever is shorter, unless separated or reassigned for reasons that are beyond the control of the expert or consultant and that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable

from the expert or consultant as a debt of the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

Subsection (g). Voluntary and Uncompensated Services. Allows the Director to accept voluntary and uncompensated services.

SECTION 937. FUNDING

Subsection (a). This section states that the intent of the writers Committee is to ensure that the United States' investment in biomedical research is rapidly translated into improvements in the quality of patient care, with a corresponding investment in research on the most effective clinical and organizational strategies for use of these findings in daily practice is necessary, and notes that funds provided allow for a proportionate increase in healthcare research as the United State's States' investment in biomedical research increases.

Subsection (b). Authorization of Appropriations. For the purpose of carrying out this title, there are authorized to be appropriated $250,000,000 for fiscal year 2000, and such sums as may be necessary for each of the fiscal years 2001 through 2006.

Subsection (c). Evaluations. In addition to appropriated amounts available above, there shall be made available for each fiscal year an amount equal to 40% of the maximum amount authorized in Section 241 (relating to evaluations).

SECTION 928. DEFINITIONS

Defines advisory council, agency and director.

SECTION 303. REFERENCES

Effective upon the date of enactment of this Act, any reference in law to the "Agency for Health Care Policy and Research" shall be deemed to be a reference to the "Agency for Healthcare Research and Quality".

TITLE VI—MISCELLANEOUS PROVISIONS

SECTION 401. SENSE OF THE COMMITTEE

This section expresses the sense of the Committee that Congress should take measures to further the purposes of this Act, including making any necessary changes to the Internal Revenue Code of 1986 or other Acts to (1) promote equity and prohibit discrimination based on genetic information with respect to the availability of health benefits; (2) provide for the full deduction of health insurance costs for self-employed individuals; (3) provide for the full availability of medical savings accounts; (4) provide for the carryover of unused benefits from cafeteria plans, flexible spending arrangements and health flexible spending accounts; and (5) permit contributions towards medical savings account through the federal employees health benefits program.

XI. ADDITIONAL VIEWS OF MAJORITY

The Patients' Bill of Rights Act (S. 326) passed by the Committee on Health, Education, Labor, and Pensions is a strong and responsible patient protection bill that improves the quality of care and ensures that patients get the medical care they need. We stand by this bill and our interpretation of its provisions.

Although S. 326 was ultimately passed along party lines, the Committee has a long standing tradition of reporting out bills with honesty, integrity, and in a manner that adds value to the policy debate. Additional and minority views are common practice and afford committee members with the opportunity to add additional and opposing policy perspectives. The minority is entitled to their views and we respect that their views are different from the majority's on certain issues in the Patients' Bill of Rights debate.

Unfortunately, the minority has chosen to submit inflammatory views that go well beyond expressing an opposing policy position. These views not only attack the integrity of the majority, but they also misrepresent a number of critical facts. We feel compelled to comment on these errors because, if they should become part of the legislative history, they could have detrimental implications for consumers and patients, the very people we are trying to protect with this legislation. Although their views contain many inaccuracies, we only focus on a few key errors and examples where the minority directly contradicts the committee interpretation.

First, the minority views incorrectly state that under S. 326 denials for emergency room care are ineligible for external review, and that the only recourse a patient has is to go to court. S. 326 makes independent, external review available for any denial or dispute based on medical necessity, regardless of whether the denial is for emergency or non-emergency care (Sec. 503(e)(1)(A)(i)(I)(aa)). Moreover, the bill also provides expedited procedures, including expedited appeal procedures, for emergency situations.

Second, the minority views state that under S. 326, the external reviewer cannot overrule a plan decision unless the plan actions have been "arbitrary and capricious." The minority views also provide an example about cosmetic surgery that directly contradicts an example in the committee report (Section IV; Sec. 121; Independent, external review). The minority interpretation is wrong—S. 326 has a standard of review that requires independent medical judgment. An independent reviewer must make an independent determination based on the valid, relevant, scientific, and clinical evidence. (Sec. 503(e)(4)(A)(i)). Although plan information, such as evidence-based decisionmaking and clinical practice guidelines, are some of the factors that a reviewer must consider, there are many additional factors that a reviewer is required to consider under S. 326. For example, a reviewer is also required to consider the treating physician's recommendation, peer review literature, and the pa-

tient's medical record. The reviewer makes an independent determination and is not bound by any particular element.

Perhaps the most egregious misrepresentation of facts in the minority views is their reference to a CBO score of 4.8 percent. In fact, CBO has scored the star print of S. 6, the bill that was introduced in the Senate and offered as a complete substitute to S. 326 during markup, as increasing premiums by an average of 6.1 percent (see attached letter from CBO). The committee is aware that the Democrats are proposing to amend S. 6 in order to receive a score of 4.8 percent from CBO. Such a substantial premium increase, whether it be 6.1 percent, as introduced and offered during markup, or 4.8 percent, if amended in some future debate, will have serious consequences for consumers, particularly when added to already increasing health care premiums.

As mentioned in the report, the primary goals of S. 326, The Patients' Bill of Rights Act, are to improve health care quality through better information; improve procedures and rights to help consumers and patients access benefits and services; reduce barriers to coverage based on genetic information; and support federal investments in health quality research. An equally important goal is to provide these new protections without significantly increasing the cost of health coverage and causing more Americans to become uninsured.

Whether S. 6 increases premiums by 6.1 percent or 4.8 percent, based on a GAO report it will result in approximately 1.8 to 1.5 million Americans losing their health insurance coverage. Enacting legislation that will significantly increase the number of the uninsured is an unacceptable outcome for the majority and one that we will consistently oppose.

JIM JEFFORDS.
JUDD GREGG.
BILL FRIST.
SUSAN COLLINS.
MIKE DEWINE.
MICHAEL B. ENZI.
TIM HUTCHINSON.
CHUCK HAGEL.
JEFF SESSIONS.
SAM BROWNBACK.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 15, 1999.

Hon. DON NICKLES,
Assistant Majority Leader, U.S. Senate,
Washington, DC.

DEAR SENATOR: You have asked CBO to clarify its estimate of the effect of the introduced version (star print) of S. 6 on health insurance premiums. As stated in our cost estimate of April 23, CBO estimates that the version of S. 6 introduced on January 19 would increase premiums for empoyer-sponsored health plans by an average of 6.1 percent.

Sincerely,

DAN L. CRIPPEN, *Director.*

ADDITIONAL VIEWS OF SENATOR ENZI

During the Health, Education, Labor and Pensions Committee consideration of S. 326, I asserted strong positions on several key components of the managed care reform debate. These additional views are intended to reiterate my support for S. 326, provide the Committee with a cohesive explanation of my position on specific policy, and express my appreciation to the Committee for reporting to the full Senate a good bill for health care consumers.

S. 326 offers a series of patient protections to consumers in Employee Retirement Income Security Act (ERISA) regulated health plans. Direct access to OB/GYN and pediatric providers, a ban on gag clauses, a prudent layperson standard for emergency services, a point-of-service option, continuity of care and access to specialists will provide consumers in self-funded plans the same protections being offered to state-regulated plan participants. Additionally, all ERISA regulated plans will be required to disclose extensive comparative information about coverage, networks and cost-sharing. This requirement is complemented by the establishment of a new binding, independent external appeals process, the lynch pin of any successful consumer protection effort.

I believe the two most contentious elements of the managed care reform debate are addressed favorably for consumers in S. 326. The first is holding health plans accountable for medical versus coverage decisions; the second is ensuring that health plans cannot manipulate the definition of "medical necessity" to deny patient care.

S. 326 does not expand the liability of ERISA plans by exposure to state tort laws, which has been proposed as a way to hold health plans accountable for medical decisions. Rather, S. 326 gets patients the medical treatment they need right away through a timely appeals process. It doesn't require them to earn it through a lawsuit. I do understand the frustration expressed by physicians who are held liable for their medical decisions. It is for that very reason that the bill I support securely places the responsibility for medical decisions in the hands of independent medical experts. These decisions are binding on health plans, who run the risk of losing their accreditation, daily fines and, ultimately, their stake in the market.

Likewise, the external appeals process in S. 326 prohibits plans from hiding behind an arbitrary definition of medical necessity to deny care. S. 326 expressly establishes a standard of review, including: the medical necessity and appropriateness, experimental or investigational nature of the coverage denial; and, any evidence-based decision making or clinical practice guidelines, including, but not limited to, those used by the health plan (Subtitle C.Sec.503(e)(4)). In other words, the independent external reviewer—required by the bill to have appropriate medical expertise—will have access to the patient's medical record, evidence of-

fered by the treating physician and all other documents introduced during the internal review process. Additionally, the reviewer will consider expert consensus and peer-reviewed literature, thus incorporating standards of "medical necessity" clearly outside those prescribed by the plan. The bill also requires that, during the internal appeals process, the medical necessity determination is made by an independent physician with the appropriate medical expertise—not by the plan.

Since its inception in 1974, this is the first major reform effort of ERISA as it pertains to the regulation of group health plans. The focus of the mission—regardless of politics—should be to protect patients. Protecting patients means not only improving the quality of care but expanding access to care and allowing consumers and purchasers the flexibility to acquire the care that best fits their needs. The contention has been how to do this in the context of our health delivery system. I believe S. 326 is a responsible approach to protecting consumers in the managed care market.

While bipartisanship was in short order during Committee consideration of S. 326, it is my hope that we can continue discussions among all members to advance needed patient protections without jeopardizing access to health care. I look forward to my continued role in the process.

MICHAEL B. ENZI.

X. MINORITY VIEWS

More than 75 percent of privately insured Americans are enrolled in managed care health plans. Managed care at its best offers the opportunity to improve care and keep patients healthy while controlling spending. However, too often managed care has been mismanaged care. Too many HMOs put profits before patients. Congress has delayed far too long in correcting the abuses of managed care, and this legislation further delays the prospect of essential reform.

For 2 years, this committee has contemplated whether it should approve legislation to establish needed patient protections. Unfortunately, the measure reported out of this committee fails to meet the test of real reform. Most of its meager protections are extended to only those patients who work for large private companies that do not actually purchase private insurance. it leaves out more than 100 million Americans, approximately two-thirds of those with private health insurance. It falls short of the recommendations of President Clinton's nonpartisan blue ribbon advisory commission. It does not reflect the comparable model laws created by the National Association of Insurance Commissioners and enacted by many States. It does not even require HMOs to follow the Code of Conduct designed and advocated by their own trade association.

The result, if this inadequate bill is enacted, is that most Americans will continue to wait for the protections they deserve. Each day that Congress delays meaningful reform, health plan abuses cause unnecessary suffering, financial loss, and major frustration for millions of families.

The legislation approved by the committee fails to grant key protections for children, women, persons with disabilities, and those with chronic conditions or special health care needs. Above all, it fails to ensure that medical decisions are made by physicians and patients, rather than insurance company executives. It sum, its flaws are deep and its gaps are numerous.

Republicans attempt to justify their decisions to limit protections to the minority of Americans who work for employers that self-fund their plans by saying that state laws should cover the rest. They say they want to "protect the unprotected." But they are more interested in protecting insurance companies, and the authority and bureaucracy of state regulatory agencies than protecting patients. It is a travesty that the majority of the provisions of the committee bill cover only 48 million of the 161 million Americans covered by private insurance plans. There is no justification for denying these protections to the other 113 million Americans in private plans.

The committee claims that our approach embodies a "one size fits all" philosophy and would shift insurance administration from state capitals to Washington. Nothing could be farther from the truth. Our proposal follows a time-tested principle that does not

violate the historical division of Federal-State responsibility. The Federal Government would establish a national floor of protection, with States free to go farther, if they choose. The program would be implemented and administered by State. The Federal Government would step in only if a state fails to act.

This approach received strong bipartisan support in the past, when Congress enacted legislation establishing continuation coverage under COBRA in 1986, health insurance portability and accountability under the Kassebaum-Kennedy Act in 1996, mental health parity, minimum protections for mothers and newborns, and, last year, reconstructive surgery coverage following a mastectomy. And, of course, the approach of establishing a Federal floor of protection with States free to go farther if they choose is common in areas as diverse as civil rights, the minimum wage, and occupational safety requirements. The committee majority even uses this model for their genetic discrimination provisions. Yet they continue to insist that all constituents are not created equal when it comes to patient protections.

The following table shows the number of people left behind under the Republican proposal.

TABLE 1.—THE REPUBLICAN BILL LEAVES TWO-THIRDS OF AMERICANS OUT—STATE-BY-STATE IMPACT

State	Number of privately insured persons	Number of persons not covered under the Republican bill	% of persons not covered under the Republican bill
Alabama	2,700,000	1,745,000	65
Alaska	400,000	313,000	78
Arizona	2,400,000	1,705,000	71
Arkansas	1,400,000	934,000	67
California	18,400,000	13,162,000	72
Colorado	2,600,000	1,873,000	72
Connecticut	2,200,000	1,430,000	65
Delaware	500,000	325,000	65
Florida	7,700,000	5,194,000	67
Georiga	4,500,000	2,899,000	64
Hawaii	700,000	497,000	71
Idaho	800,000	597,000	75
Illinois	8,100,000	5,282,000	65
Indiana	4,100,000	2,596,000	63
Iowa	2,100,000	1,461,000	70
Kansas	1,700,000	1,137,000	67
Kentucky	2,300,000	1,493,000	65
Louisiana	2,300,000	1,507,000	66
Maine	800,000	524,000	66
Maryland	3,500,000	2,453,000	70
Massachusetts	4,100,000	2,561,000	62
Michigan	6,700,000	4,287,000	64
Minnesota	3,300,000	2,220,000	67
Mississippi	1,700,000	1,174,000	69
Missouri	3,400,000	2,329,000	69
Montana	500,000	365,000	73
Nebraska	1,100,000	762,000	69
Nevada	1,100,000	758,000	69
New Hampshire	800,000	529,000	66
New Jersey	5,500,000	3,815,000	69
New Mexico	900,000	682,000	76
New York	10,600,000	7,243,000	68
North Carolina	4,600,000	2,985,000	65
North Dakota	400,000	274,000	69

TABLE 1.—THE REPUBLICAN BILL LEAVES TWO-THIRDS OF AMERICANS OUT—STATE-BY-STATE IMPACT—Continued

State	Number of privately insured persons	Number of persons not covered under the Republican bill	% of persons not covered under the Republican bill
Ohio	7,500,000	5,813,000	78
Oklahoma	1,900,000	1,323,000	70
Oregon	2,100,000	1,492,000	71
Pennsylvania	8,100,000	5,391,000	67
Rhode Island	600,000	399,000	67
South Carolina	2,400,000	1,611,000	67
South Dakota	500,000	360,000	72
Tennessee	3,200,000	2,121,000	66
Texas	11,000,000	7,250,000	66
Utah	1,500,000	1,119,00	75
Vermont	400,000	273,000	68
Virginia	4,100,000	2,670,000	65
Washington	3,900,000	2,879,000	74
West Virginia	1,000,000	686,000	69
Wisconsin	3,800,000	2,490,000	66
Wyoming	300,000	225,000	75

Source: Estimates based on data provided by the United States Department of Labor.

Republicans justify this extraordinary omission by saying that State laws should cover these persons. But, while some states have acted, significant gaps remain. Thirty States have no continuity of care protections; 30 States do not require that consumers be offered a point-of-service option; 13 States do not use a prudent layperson or similar standard for coverage of emergency services; and 12 States do not provide direct access to ob-gyn care. These are the same rights that the majority grants to people in self-funded plans—yet millions will be left out because of an ideological decision to protect states instead of patients.

Doesn't hard-working policeman who puts his life on the line every day deserve protections equal to that of his neighbor, who works for a large corporation? Democrats say yes, but Republicans say no. Doesn't a young mother who works at a small business for the minimum wage deserve the same assurances as the salesman for a large corporation? Democrats say yes. Republicans say no. Doesn't a worker at a large firm who joins an HMO deserve the same protection as the co-worker at the next desk who happens to be in the company's self-funded plan? Doesn't the struggling small businessman who buys a policy to protect his family and his two employees deserve strong protections? Senators are elected to represent all of the people in our states. It is abundantly clear that individuals and families across the country strongly support key patient protections. They want to know that their health insurance will be there when they need it.

During the course of the committee's actions, we had hoped to be able to agree on bipartisan legislation that would have assured all patients in the private market the protections they need and deserve.

First, we offered our alternative legislation as a substitute. The Democratic Patients' Bill of Rights (S. 6) is the original patient protection legislation. It is a responsible and effective answer to the widespread problems that patients and their families face every day. It is supported by a coalition of 200 organizations that rep-

resent doctors, nurses, patients, small businesses, religious organizations and advocates for children, women, and working families. The coalition includes the American Medical Association, the Consortium of Citizens with Disabilities, Families USA, the American Cancer Society, the American Heart Association, the National Alliance for the Mentally III, the National Partnership for Women and Families, the American Nurses Association, the National Association of Children's Hospitals, and the AFL–CIO.

It is rare for such a broad and diverse group to come together in support of legislation. But they have done so to end the flagrant abuses that hurt so many families. In contrast, the committee legislation is not supported by a single organization that speaks for patients or the people who care for them.

The committee repeatedly rejected our attempts to improve the legislation. More than 20 strengthening amendments were voted down on party lines. We offered numerous amendments to simply guarantee that S. 326 follows through on its claims, including those that would:

—extend protections to all 161 million Americans with private insurance;

—correct the flaws in the independent appeal system by expanding the scope of decisions eligible for external review and by assuring that the review is fair, binding on the plan, truly independent, and resolved in a timely fashion;

—assure that patients with on-going health needs can keep their doctor during a transition period if their doctor is dropped from the plan's network or their employer changes plans;

—protect patients who go to the emergency room with the symptoms of heart attack, stroke, or other serious condition from facing thousands of dollars in medical bills for medical care given by an emergency room doctor but turned down by their health plan; and

—assure a meaningful opportunity for all patients, including those who operate or work for small businesses, to choose a real point-of-service option.

The majority rejected every Democratic attempt to clarify or improve the provisions in the committee bill. Democrats also tried to address the gaps in the bill by offering amendments to add provisions from the original Democratic Patients' Bill of Rights (S. 6), including those that would:

—guarantee access to needed specialty care for those with serious illnesses and disabling conditions, including access to pediatric specialists and doctors outside the plan if the plan does not have the appropriate specialist in its network;

—allow patients with cancer, Parkinson's disease, epilepsy, Alzheimer's disease, and other serious illnesses to participate in clinical trials if conventional therapy offers no hope;

—restore the right of all patients in HMOs to hold their plans accountable in state courts for abuses that result in injury or death;

—prevent HMOs from arbitrarily interfering with a doctor's decision to treat patients in the hospital rather than in an out-

patient clinic, or to recommend additional days in the hospital following surgery;

—assure that women with breast cancer are not forced to undergo drive-through mastectomies;

—protect health providers from retaliation for supporting their patients in the appeal process, or reporting quality of care concerns to a supervisor, a private accreditation organization or a regulatory authority;

—establish an independent state-level consumer assistance program to help patients understand and exercise their rights and responsibilities under their health insurance plans;

—prohibit insurance companies from denying coverage by falsely declaring that FDA-approved products are "experimental;" and

—ensure that managed care plans have an adequate number, distribution and variety of health providers to care for their patients.

The basic proposals are strongly supported by the American people. Virtually all are provided to millions of elderly and disabled citizens by Medicare. Many have been recommended by the insurance industry itself. Yet, the committee majority refused to accept or support any of these proposals.

The right to appeal decisions by a plan to deny care or coverage to an independent entity is the cornerstone of any patient protection proposal. Today, if a health plan breaks its promise, there is no recourse that can provide relief in time to save a life or prevent a disability. Instead, when the issues are sickness or health, and are often as serious as life or death, health insurance companies are allowed to be both judge and jury. A strong independent review mechanism is needed to assure that patients receive the care recommended by their doctors and covered by their premiums, without having to resort to litigation.

Independent review was recommended unanimously by the President's Commission. It has worked successfully in Medicare for more than thirty years. Families deserve the basic fairness that only impartial appeals can provide. Without such a remedy, any "rights" of patients exist on paper only—and they are often worth no more than the paper on which they are printed when a health plan ignores its responsibilities.

Both the Democratic and the committee proposals provide for an appeal to a third party for resolution of disputes. The appeal right is one area in which the Republican bill extends protection beyond employer self-funded plans. Even here, however, millions of Americans are left out under the Republican bill. This provision only applies to people in private employment-based health plans. Employees of state and local governments—such as teachers, policemen, firemen, nurses in public hospitals—are left out. So are self-employed small businessmen— such as farmers, home day care providers, entrepreneurs and others—who purchase their insurance as individuals, rather than as part of an employment group. A total of almost 40 million Americans would be denied independent appeal rights under the Republican bill.

Even for those fortunate enough to be included in the provision, the protection is more illusory than real—because the process in

the Republican bill is full of loopholes. It stacks the deck against patients and in favor of health plans.

Without a realistic right of external appeal, a patient's only option in the case of an unfair plan decision is to go to court—a slow, expensive, and often unsatisfactory procedure.

We all recognize that a good, independent external review is critical to fully protect patients. Unfortunately, the committee legislation has five fundamental flaws in its review section.

First, it does not provide "de novo" review. The independent reviewer is not entitled to take a fresh look at all the evidence in the case and make a fair decision. Under current ERISA law, which is not changed by the Republican proposal, the reviewer can only overrule the plan if its actions have been "arbitrary and caprcious"—a very high standard for a patient to meet. To be fair to patients, the independent review should take a fresh look at the case and decide based on the best medical evidence and unique position of the patient, not just whether the plan's actions are or are not arbitrary and capricious.

Second, the Republican plan nullified the promise of fair dispute resolution by limiting the decisions eligible for external review to issues where the plan says the basis of its denial is whether care is medically necessary or experimental. This limitation would prevent reviewers from overruling plan decisions that are based on contract provisions. For example, if a plan falsely claimed that reconstructive surgery for a deformed child was "cosmetic," and thus not covered by the contract, there would be no appeal. If a plan falsely claimed that a life-saving piece of medical equipment recommended by physician was not durable medical equipment as defined in the contract and therefore not covered, there would be no appeal. It is especially ironic that third-party review is not available for the rights supposedly granted under the committee bill. For example, if patients go to the emergency room with symptoms that they believe are caused by a heart attack, the committee proposal says that if the patients acted as a prudent layperson would act, the plan is supposed to pay the bill. This is the right thing to do. No one's life should be put at risk because they are afraid to go to the nearest emergency room. But, if the plan says, "Your chest didn't hurt enough. You don't qualify under the prudent layperson standard," there is no recourse under this proposal, except going to court. Your case would not be eligible for third-party review.

To add insult to injury, the plan determines whether or not a denial is based on medical necessity. As a result, the plan ultimately decides whether a case even qualifies for third-party review. Clearly, the plan has a conflict of interest in making such decisions.

Third, the review under the Republican proposal is far from independent. That plan chooses the review organization, which then selects the reviewer who will decide the case. This also creates an obvious conflict of interest. No other dispute resolution system allows one of the parties to the dispute to make a unilateral choice of the decision-maker because such a selection procedure is inherently unfair. It doesn't happen under Medicare. Fifteen out of 18 states that have established independent review programs do not allow it. The standards for arbitration of the American Arbitration Association,

the American Bar Association, and the Federal Arbitration Act all reject this inherently unfair approach. But health plans want to stack the deck—and so this unfair approach was included in the committee bill.

Fourth, the Republican plan allows HMOs and insurance companies to go to court to avoid or delay an otherwise binding decision by challenging whether the external review entity correctly followed the guidelines.

Finally, and perhaps most critical, the committee bill has no definition of medical necessity. It therefore requires the reviewer to accept the plan's definition. As a result, insurance companies can write their contracts in ways to make external review meaningless. An external reviewer would have to decide whether a procedure was medically necessary based on the definition in the plan's contract, no matter how narrow or unfair to patients. For example, if a plan defined medially necessary care as care that had been proven by double-blind clinical trials to be safe and effective, 80 percent or more of medicine would not meet the standard and the plan would have almost total discretion to deny care it felt would cost too much. Such a provision makes a mockery of the right to fair review.

Our proposal would correct each of these defects. It would provide full, fair, timely, and truly independent review. Yet the committee rejected it. Instead, the committee legislation offers the appearance of patient protection without the reality.

In addition, when the misconduct of managed care plans actually results in serious injury or death, patients and their families should be able to hold the plan liable in court. Our legislation would shield employers from liability, unless they intervene to make the decision to deny or delay care that results in injury or death. The concept is clear-accountability follows decision-making. Every other industry in America can be held responsible in this way for its actions. HMOs, whose decisions truly can mean life or death, do not deserve this unique and unfair immunity—an immunity that creates a systematic bias against providing patients necessary but costly care.

Some say that you cannot sue your way to better health. But it is obvious that the fear of liability is a powerful incentive for HMOs to do the right thing when decisions on health care are being made.

The bottom line is that our alternative would guarantee patients and physicians the rights that every honorable insurance company already grants— and provide effective, timely mechanisms to enforce these rights. These protections are essential components of good health care that every family believes that were promised when they purchased health insurance and paid their premiums.

No patient with symptoms of a stroke should be forced to delay treatment to the point where paralysis and disability are permanent, because a managed care accountant does not respond promptly and correctly. Yet that would be allowed under the committee legislation.

No patient should question whether their doctor, nurse or therapist can practice medicine as they know best. Gag clauses and improper incentive arrangements should have no place in American

medicine. Doctors and other providers must be able to give every patient their best possible advice, without fear of retaliation or financial penalties. Our plan bans abusive insurance industry practices that undermine the integrity of the doctor-patient relationship. The committee legislation does not.

No woman with breast cancer should be forced to endure a "drive-through" mastectomy against the advice of her doctor. No children with cancer should be told that only the physicians in the plan's network can treat them, when those physicians have no experience or expertise with children or with that type of cancer. Yet these situations will continue to occur under the committee plan.

No patient with a serious illness—like cancer or Alzheimer's disease or osteoporosis or rheumatoid arthritis—who cannot be helped by standard treatments should be denied access to the clinical trials that may be the only hope for a cure or improvement. Traditionally, health insurance has given patients this opportunity—but managed care plans today are often saying "no"—and both patients and medical research are suffering. The committee legislation does nothing to assure access to life-saving clinical trials.

Every family knows that it will some day have to confront the challenge of serious illness for a parent, or a grandparent, or a child. When that day comes, all of us want the best possible medical care for our loved ones. Members of the Senate deserve good medical care for their loved ones—and we generally get it. Every other family is equally deserving of high quality care—but too often they do not get it.

The committee has also included in its legislation a proposal to stop health insurers from discriminating on the basis of predictive genetic information. While we support this concept, the committee heard from experts in a hearing last May that such legislation must take additional precautions beyond those that included in the committee plan if it is to be effective.

Most important, such legislation must also prohibit employers from using predictive genetic information to discriminate in hiring or firing of employees. A recent survey of management professionals found that 5 percent of responding companies engage in genetic testing in the workplace, and nearly 20 percent of those companies have not hired someone because of their genetic information. Clearly, this information is being used against men and women in the workplace. If we want to encourage Americans to take advantage of new opportunities to test for genetic conditions that have not yet become manifest and to obtain preventive treatment or gene therapy, we must act to prohibit genetic discrimination in the workplace as well as in health insurance. Otherwise, employers will fire or refuse to hire those who may have a genetic predisposition to a particular disease. Democrats offered an amendment to provide this protection, but the committee rejected it.

Unfortunately, our legislation has been subjected to a relentless campaign of disinformation and distortion by those who profit from the abuses of the status quo. Insurance companies, HMOs and their allies spent more than $100 million on advertising and lobbying against it last year. And they are at it again this year.

Our opponents make unsubstantiated allegations that our Patients' Bill of Rights will dramatically raise costs and increase the

number of uninsured. The same groups that have for years charged excessive premiums and opposed attempts to expand insurance coverage now weep crocodile tears about the effects of actually having to deliver the benefits they have promised. When the General Accounting Office (GAO/HEHS–98–203R) examined the potential interaction between premium increases and insurance status, they concluded that patient protection legislation could actually increase coverage.

Every independent estimate of the impact of our Patients' Bill of Rights on medical costs has found it to be minimal. The Congressional Budget Office said that the expected increase in average health insurance premiums after five years would be 4.8 percent. This is an increase that averages less than one percent per year, split between the employer and employee. A typical worker would pay less than the cost of a McDonald's Happy Meal for these much needed protections, and much less than the 6–10 percent average annual increase that insurance companies are currently imposing to improve their bottom line. If the groups opposed to our legislation are serious in their concern for the uninsured, we invite them to join us in supporting protections that will give every American affordable and genuine health insurance.

The votes by the committee were a litmus test that determined whether the Patients' Bill of Rights should protect profits or patients. Unfortunately, patients lost this round. But we will continue to seek strong patient protections for all Americans until they are signed into law. We will not give up this struggle until every American is able to receive the best care that American medicine can provide.

EDWARD KENNEDY.
CHRIS DODD.
TOM HARKIN.
BARBARA A. MIKULSKI.
JEFF BINGAMAN.
PAUL D. WELLSTONE.
PATTY MURRAY.
JACK REED.

XI. SUPPLEMENTAL VIEWS

We wish to clarify one issue surrounding the cost of enacting the Patients' Bill of Rights that we support. The substitute amendment offered by Senator Kennedy during the Executive Session reflected legislative language in S. 1890 from the 105th Congress and in S. 6, which was introduced earlier this year. At the time of the Executive Session, on March 17 and 18, the Congressional Budget Office (CBO) had not provided an estimate of S. 6. However, the CBO analysis of S. 1890 estimated that the legislation would ultimately result in a 4.0 percent increase in premiums after 10 years.

On April 23, at the request of Chairman Jeffords, CBO released an estimate that S. 6 would result in a premium increase of 6.1 percent when the costs are fully phased in, but the accompanying letter from CBO indicated that the estimate would drop to 4.8 percent if the sponsors provided clarifying language. A copy of this letter follows. In reviewing the Patients' Bill of Rights, CBO assumed an interpretation of our legislation that did not reflect our intent. We provided CBO with language to clarify our intent, and CBO has formally reduced the estimate of the premium increase to 4.8 percent.

The 6.1 percent increase does not refer to any legislation that will be considered by the Senate. Use of this number is irresponsible and misleading, and serves only to distort the discussion of managed care reform.

EDWARD KENNEDY.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, April 23, 1999.

Hon. JAMES M. JEFFORDS,
Chairman, Committee on Health, Education, Labor, and Pensions, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: At your request, the Congressional Budget Office (CBO) has prepared the enclosed cost estimate for S. 6, the Patients' Bill of Rights Act of 1999, as introduced (Star Print) on January 19, 1999.

CBO estimates that the ultimate effect, over a period of years, would be to increase premiums for employer-sponsored health insurance by an average of 6.1 percent. However, the sponsors have indicated their intention to clarify the bill in ways that could reduce the premium increase to 4.8 percent.

Sincerely,

DAN L. CRIPPEN, *Director.*

XII. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

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Section 1. * * *

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Sec. 714. Health plan comparative information.
Sec. 715. Prohibiting premium discrimination against groups on the basis of predictive genetic information.

SUBPART C—PATIENT RIGHT TO MEDICAL ADVICE AND CARE

Sec. 721. Patient access to emergency medical care.
Sec. 722. Offering of choice of coverage options.
Sec. 723. Patient access to obstetric and gynecological care.
Sec. 724. Patient access to pediatric care.
Sec. 725. Access to specialists.
Sec. 726. Continuity of care.
Sec. 727. Protection of patient-provider communications.
Sec. 728. Patient's right to prescription drugs.
Sec. 729. Self-payment for behavioral health care services.
Sec. 730. Generally applicable provisions.

[SUBPART C] SUBPART D—GENERAL PROVISIONS

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SEC. 502. (a) A civil action may be brought—(1) by a participant or beneficiary—

* * * * * * *

(c)(1) Any administrator (A) who fails to meet the requirements of paragraph (1) or (4) of section 606 or section 101(e)(1), *or fails to comply with a coverage determination as required under section 503(e)(6),* with respect to a participant or beneficiary, or (B) who fails or refuses to comply with a request for any information which such administrator is required by this title to furnish to a participant or beneficiary (unless such failure or refusal results from matters reasonably beyond the control of the administrator) by mailing the material requested to the last known address of the requesting participant or beneficiary within 30 days after such request may in the court's discretion be personally liable to such participant or beneficiary in the amount of up to $100 a day from the date of such failure or refusal, and the court may in its discretion order such other relief as it deems proper. For purposes of this paragraph,

each violation described in subparagraph (A) with respect to any single participant, and each violation described in subparagraph (B) with respect to any single participant or beneficiary, shall be treated as a separate violation.

[SEC. 503. In accordance with regulation of the Secretary, every employee benefit plan shall—

[(1) provide adequate notice in writing to any participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant, and

[(2) afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim.]

SEC. 503. CLAIMS PROCEDURE, COVERAGE DETERMINATION, GRIEVANCES AND APPEALS.

(a) CLAIMS PROCEDURE.—In accordance with regulations of the Secretary, every employee benefit plan shall—

(1) provide adequate notice in writing to any participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant; and

(2) afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim.

(b) COVERAGE DETERMINATIONS UNDER GROUP HEALTH PLANS.—

(1) PROCEDURES.—

(A) IN GENERAL.—A group health plan or health insurance issuer conducting utilization review shall ensure that procedures are in place for—

(i) making determinations regarding whether a participant or beneficiary is eligible to receive a payment or coverage for health services under the plan or coverage involved and any cost-sharing amount that the participant or beneficiary is required to pay with respect to such service;

(ii) notifying a covered participant or beneficiary (or the authorized representative of such participant or beneficiary) and the treating health care professionals involved regarding determinations made under the plan or issuer and any additional payments that the participant or beneficiary may be required to make with respect to such service; and

(iii) responding to requests, either written or oral, for coverage determinations or for internal appeals from a participant or beneficiary (or the authorized representative of such participant or beneficiary) or the treating health care professional with the consent of the participant or beneficiary.

(B) ORAL REQUESTS.—With respect to an oral request described in subparagraph (A)(iii), a group health plan or

health insurance issuer may require that the requesting individual provide written evidence of such request.

(2) TIMELINE FOR MAKING DETERMINATIONS.—

(A) ROUTINE DETERMINATION.—A group health plan or a health insurance issuer shall maintain procedures to ensure that prior authorization determinations concerning the provision of non-emergency items or services are made within 30 days from the date on which the request for a determination is submitted, except that such period may be extended where certain circumstances exist that are determined by the Secretary to be beyond control of the plan or issuer.

(B) EXPEDITED DETERMINATION.—

(i) IN GENERAL.—A prior authorization determination under this subsection shall be made within 72 hours, in accordance with the medical exigencies of the case, after a request is received by the plan or issuer under clause (ii) or (iii).

(ii) REQUEST BY PARTICIPANT OR BENEFICIARY.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection upon the request of a participant or beneficiary if, based on such a request, the plan or issuer determines that the normal time for making such a determination could seriously jeopardize the life or health of the participant or beneficiary.

(iii) DOCUMENTATION BY HEALTH CARE PROFESSIONAL.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection if the request involved indicates that the treating health care professional has reasonably documented, based on the medical exigencies, that a determination under the procedures described in subparagraph (A) could seriously jeopardize the life or health of the participant or beneficiary.

(C) CONCURRENT DETERMINATIONS.—A plan or issuer shall maintain procedures to certify or deny coverage of an extended stay or additional services.

(D) RETROSPECTIVE DETERMINATION.—A plan or issuer shall maintain procedures to ensure that, with respect to the retrospective review of a determination made under paragraph (1), the determination shall be made within 30 working days of the date on which the plan or issuer receives necessary information.

(3) NOTICE OF DETERMINATIONS.—

(A) ROUTINE DETERMINATION.—With respect to a coverage determination of a plan or issuer under paragraph (2)(A), the plan or issuer shall issue notice of such determination to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and, consistent with the medical exigencies of the case, to the treating health care professional involved not later than 2 working days after the date on which the determination is made.

(B) EXPEDITED DETERMINATION.—With respect to a coverage determination of a plan or issuer under paragraph (2)(B), the plan or issuer shall issue notice of such determination to the participant or beneficiary (or the authorized representative of the participant or beneficiary), and consistent with the medical exigencies of the case, to the treating health care professional involved within the 72 hour period described in paragraph (2)(B).

(C) CONCURRENT REVIEWS.—With respect to the determination under a plan or issuer under paragraph (2)(C) to certify or deny coverage of an extended stay or additional services, the plan or issuer shall issue notice of such determination to the treating health care professional and to the participant or beneficiary involved (or the authorized representative of the participant or beneficiary) within 1 working day of the determination.

(D) RETROSPECTIVE REVIEWS.—With respect to the retrospective review under a plan or issuer of a determination made under paragraph (2)(D), the plan or issuer shall issue written notice of an approval or disapproval of a determination under this subparagraph to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and health care provider involved within 5 working days of the date on which such determination is made.

(E) REQUIREMENTS OF NOTICE OF ADVERSE COVERAGE DETERMINATIONS.—A written notice of an adverse coverage determination under this subsection, or of an expedited adverse coverage determination under paragraph (2)(B), shall be provided to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and treating health care professional (if any) involved and shall include—

(i) the reasons for the determination (including the clinical or scientific-evidence based rationale used in making the determination) written in a manner to be understandable to the average participant or beneficiary;

(ii) the procedures for obtaining additional information concerning the determination; and

(iii) notification of the right to appeal the determination and instructions on how to initiate an appeal in accordance with subsection (d).

(c) GRIEVANCES.—A group health plan or a health insurance issuer shall have written procedures for addressing grievances between the plan or issuer offering health insurance coverage in connection with a group health plan and a participant or beneficiary. Determinations under such procedures shall be non-appealable.

(d) INTERNAL APPEAL OF COVERAGE DETERMINATIONS.—

(1) RIGHT TO APPEAL.—

(A) IN GENERAL.—A participant or beneficiary (or the authorized representative of the participant or beneficiary) or the treating health care professional with the consent of the participant or beneficiary (or the authorized representative

of the participant or beneficiary), may appeal any adverse coverage determination under subsection (b) under the procedures described in this subsection.

(B) TIME FOR APPEAL.—A plan or issuer shall ensure that a participant or beneficiary has a period of not less than 180 days beginning on the date of an adverse coverage determination under subsection (b) in which to appeal such determination under this subsection.

(C) FAILURE TO ACT.—The failure of a plan or issuer to issue a determination under subsection (b) within the applicable timeline established for such a determination under such subsection shall be treated as an adverse coverage determination for purposes of proceeding to internal review under this subsection.

(2) RECORDS.—A group health plan and a health insurance issuer shall maintain written records, for at least 6 years, with respect to any appeal under this subsection for purposes of internal quality assurance and improvement. Nothing in the preceding sentence shall be construed as preventing a plan and issuer from entering into an agreement under which the issuer agrees to assume responsibility for compliance with the requirements of this section and the plan is released from liability for such compliance.

(3) ROUTINE DETERMINATIONS.—A group health plan or a health insurance issuer shall complete the consideration of an appeal of an adverse routine determination under this subsection not later than 30 working days after the date on which a request for such appeal is received.

(4) EXPEDITED DETERMINATION.—

(A) IN GENERAL.—An expedited determination with respect to an appeal under this subsection shall be made in accordance with the medical exigencies of the case, but in no case more than 72 hours after the request for such appeal is received by the plan or issuer under subparagraph (B) or (C).

(B) REQUEST BY PARTICIPANT OR BENEFICIARY.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection upon the request of a participant or beneficiary if, based on such a request, the plan or issuer determines that the normal time for making such a determination could seriously jeopardize the life or health of the participant or beneficiary.

(C) DOCUMENTATION BY HEALTH CARE PROFESSIONAL.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection if the request involved indicates that the treating health care professional has reasonably documented, based on the medical exigencies of the case that a determination under the procedures described in paragraph (2) could seriously jeopardize the life or health of the participant or beneficiary.

(5) CONDUCT OF REVIEW.—A review of an adverse coverage determination under this subsection shall be conducted by an individual with appropriate expertise who was not directly involved in the initial determination.

(6) LACK OF MEDICAL NECESSITY.—A review of an appeal under this subsection relating to a determination to deny coverage based on a lack of medical necessity and appropriateness, or based on an experimental or investigational treatment, shall be made only by a physician with appropriate expertise, including age-appropriate expertise, who was not involved in the initial determination.

(7) NOTICE.—

(A) IN GENERAL.—Written notice of a determination made under an internal review process shall be issued to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and the treating health care professional not later than 2 working days after the completion of the review (or within the 72-hour period referred to in paragraph (4) if applicable).

(B) ADVERSE COVERAGE DETERMINATIONS.—With respect to an adverse coverage determination made under this subsection, the notice described in subparagraph (A) shall include—

(i) the reasons for the determination (including the clinical or scientific-evidence based rationale used in making the determination) written in a manner to be understandable to the average participant or beneficiary;

(ii) the procedures for obtaining additional information concerning the determination; and

(iii) notification of the right to an independent external review under subsection (e) and instructions on how to initiate such a review.

(e) INDEPENDENT EXTERNAL REVIEW.—

(1) ACCESS TO REVIEW.—

(A) IN GENERAL.—A group health plan or a health insurance issuer offering health insurance coverage in connection with a group health plan shall have written procedures to permit a participant or beneficiary (or the authorized representative of the participant or beneficiary) access to an independent external review with respect to an adverse coverage determination concerning a particular item or service (including a circumstance treated as an adverse coverage determination under subparagraph (B)) where—

(i) the particular item or service involved—

(I)(aa) would be a covered benefit, when medically necessary and appropriate under the terms and conditions of the plan, and the item or service has been determined not to be medically necessary and appropriate under the internal appeals process required under subsection (d) or there has been a failure to issue a coverage determination as described in subparagraph (B); and

(bb)(AA) the amount of such item or service involved exceeds a significant financial threshold; or

(BB) there is a significant risk of placing the life or health of the participant or beneficiary in jeopardy; or

(II) would be a covered benefit, when not considered experimental or investigational under the terms and conditions of the plan, and the item or service has been determined to be experimental or investigational under the internal appeals process required under subsection (d) or there has been a failure to issue a coverage determination as described in subparagraph (B); and

(ii) the participant or beneficiary has completed the internal appeals process under subsection (d) with respect to such determination.

(B) FAILURE TO ACT.—The failure of a plan or issuer to issue a coverage determination under subsection (d) within the applicable timeline established for such a determination under such subsection shall be treated as an adverse coverage determination for purposes of proceeding to independent external review under this subsection.

(2) INITIATION OF THE INDEPENDENT EXTERNAL REVIEW PROCESS.—

(A) FILING OF REQUEST.—A participant or beneficiary (or the authorized representative of the participant or beneficiary) who desires to have an independent external review conducted under this subsection shall file a written request for such a review with the plan or issuer involved not later than 30 working days after the receipt of a final denial of a claim under subsection (d). Any such request shall include the consent of the participant or beneficiary (or the authorized representative of the participant or beneficiary) for the release of medical information and records to independent external reviewers regarding the participant or beneficiary.

(B) INFORMATION AND NOTICE.—Not later than 5 working days after the receipt of a request under subparagraph (A), or earlier in accordance with the medical exigencies of the case, the plan or issuer involved shall select an external appeals entity under paragraph (3)(A) that shall be responsible for designating an independent external reviewer under paragraph (3)(B).

(C) PROVISION OF INFORMATION.—The plan or issuer involved shall forward necessary information (including medical records, any relevant review criteria, the clinical rationale consistent with the terms and conditions of the contract between the plan or issuer and the participant or beneficiary for the coverage denial, and evidence of the coverage of the participant or beneficiary) to the independent external reviewer selected under paragraph (3)(B).

(D) NOTIFICATION.—The plan or issuer involved shall send a written notification to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and the plan administrator, indicating that an independent external review has been initiated.

(3) CONDUCT OF INDEPENDENT EXTERNAL REVIEW.—

(A) DESIGNATION OF EXTERNAL APPEALS ENTITY BY PLAN OR ISSUER.—

(i) IN GENERAL.—A plan or issuer that receives a request for an independent external review under paragraph (2)(A) shall designate a qualified entity described in clause (ii), in a manner designed to ensure that the entity so designated will make a decision in an unbiased manner, to serve as the external appeals entity.

(ii) QUALIFIED ENTITIES.—A qualified entity shall be—

(I) an independent external review entity licensed or credentialed by a State;

(II) a State agency established for the purpose of conducting independent external reviews;

(III) any entity under contract with the Federal Government to provide independent external review services;

(IV) any entity accredited as an independent external review entity by an accrediting body recognized by the Secretary for such purpose; or

(V) any other entity meeting criteria established by the Secretary for purposes of this subparagraph.

(B) DESIGNATION OF INDEPENDENT EXTERNAL REVIEWER BY EXTERNAL APPEALS ENTITY.—The external appeals entity designated under subparagraph (A) shall, not later than 30 days after the date on which such entity is designated under subparagraph (A), or earlier in accordance with the medical exigencies of the case, designate one or more individuals to serve as independent external reviewers with respect to a request received under paragraph (2)(A). Such reviewers shall be independent medical experts who shall—

(i) be appropriately credentialed or licensed in any State to deliver health care services;

(ii) not have any material, professional, familial, or financial affiliation with the case under review, the participant or beneficiary involved, the treating health care professional, the institution where the treatment would take place, or the manufacturer of any drug, device, procedure, or other therapy proposed for the participant or beneficiary whose treatment is under review;

(iii) have expertise (including age-appropriate expertise) in the diagnosis or treatment under review and, when reasonably available, be of the same specialty as the physician treating the participant or beneficiary or recommending or prescribing the treatment in question;

(iv) receive only reasonable and customary compensation from the group health plan or health insurance issuer in connection with the independent external review that is not contingent on the decision rendered by the reviewer; and

(v) not be held liable for decisions regarding medical determinations (but may be held liable for actions that are arbitrary and capricious).

(4) STANDARD OF REVIEW.—

(A) IN GENERAL.—An independent external reviewer shall—

(i) make an independent determination based on the valid, relevant, scientific and clinical evidence to determine the medical necessity, appropriateness, experimental or investigational nature of the proposed treatment; and

(ii) take into consideration appropriate and available information, including any evidence-based decision making or clinical practice guidelines used by the group health plan or health insurance issuer; timely evidence or information submitted by the plan, issuer, patient or patient's physician; the patient's medical record; expert consensus; and medical literature as defined in section 556(5) of the Federal Food, Drug, and Cosmetic Act.

(B) NOTICE.—The plan or issuer involved shall ensure that the participant or beneficiary receives notice, within 30 days after the determination of the independent medical expert, regarding the actions of the plan or issuer with respect to the determination of such expert under the independent external review.

(5) TIMEFRAME FOR REVIEW.—

(A) IN GENERAL.—The independent external reviewer shall complete a review of an adverse coverage determination in accordance with the medical exigencies of the case.

(B) LIMITATION.—Notwithstanding subparagraph (A), a review described in such subparagraph shall be completed not later than 30 working days after the later of—

(i) the date on which such reviewer is designated; or

(ii) the date on which all information necessary to completing such review is received.

(6) BINDING DETERMINATION.—The determination of an independent external reviewer under this subsection shall be binding upon the plan or issuer if the provisions of this subsection or the procedures implemented under such provisions were complied with by the independent external reviewer.

(7) STUDY.—Not later than 2 years after the date of enactment of this section, the General Accounting Office shall conduct a study of a statistically appropriate sample of completed independent external reviews. Such study shall include an assessment of the process involved during an independent external review and the basis of decisionmaking by the independent external reviewer. The results of such study shall be submitted to the appropriate committees of Congress.

(8) EFFECT ON CERTAIN PROVISIONS.—Nothing in this section shall be construed as affecting or modifying section 514 of this Act with respect to a group health plan.

(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a plan administrator or plan fiduciary or health plan medical director from requesting an independent external review by an independent external reviewer without first completing the internal review process.

(g) DEFINITIONS.—In this section:

(1) ADVERSE COVERAGE DETERMINATION.—The term "adverse coverage determination" means a coverage determination under the plan which results in a denial of coverage or reimbursement.

(2) COVERAGE DETERMINATION.—The term "coverage determination" means with respect to items and services for which coverage may be provided under a health plan, a determination of whether or not such items and services are covered or reimbursable under the coverage and terms of the contract.

(3) GRIEVANCE.—The term "grievance" means any complaint made by a participant or beneficiary that does not involve a coverage determination.

(4) GROUP HEALTH PLAN.—The term "group health plan" shall have the meaning given such term in section 733(a). In applying this paragraph, excepted benefits described in section 733(c) shall not be treated as benefits consisting of medical care.

(5) HEALTH INSURANCE COVERAGE.—The term "health insurance coverage" has the meaning given such term in section 733(b)(1). In applying this paragraph, excepted benefits described in section 733(c) shall not be treated as benefits consisting of medical care.

(6) HEALTH INSURANCE ISSUER.—The term "health insurance issuer" has the meaning given such term in section 733(b)(2).

(7) PRIOR AUTHORIZATION DETERMINATION.—The term "prior authorization determination" means a coverage determination prior to the provision of the items and services as a condition of coverage of the items and services under the coverage.

(8) TREATING HEALTH CARE PROFESSIONAL.—The term "treating health care professional" with respect to a group health plan, health insurance issuer or provider sponsored organization means a physician (medical doctor or doctor of osteopathy) or other health care practitioner who is acting within the scope of his or her State licensure or certification for the delivery of health care services and who is primarily responsible for delivering those services to the participant or beneficiary.

(9) UTILIZATION REVIEW.—The term "utilization review" with respect to a group health plan or health insurance coverage means a set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings. Techniques may include ambulatory review, prospective review, second opinion, certification, concurrent review, case management, discharge planning or retrospective review.

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PART 7—GROUP HEALTH PLAN REQUIREMENTS

Subpart A—Requirements Relating to Portability, Access, and Renewability

SEC. 701. * * *

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SEC. 702. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.

(a) IN ELIGIBILITY TO ENROLL.—

(1) IN GENERAL. * * *

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(F) Genetic information *(including information about a request for or receipt of genetic services).*

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(3) REFERENCE TO RELATED PROVISION.—For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group health plan on the basis of predictive genetic information (including information about a request for or receipt of genetic services), see section 715.

(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require predictive genetic information concerning any individual (including a dependent) or family member of the individual (including information about a request for or receipt of genetic services).

(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (d), of such predictive genetic information.

(d) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

(A) PREPARATION OF WRITTEN NOTICE.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall post or provide, in writing and in a clear and conspicuous manner, notice of the plan or issuer's confidentiality practices, that shall include—

(i) a description of an individual's rights with respect to predictive genetic information;

(ii) the procedures established by the plan or issuer for the exercise of the individual's rights; and

(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

(2) ESTABLISHMENT OF SAFEGUARDS.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such plan or issuer.

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SEC. 714. HEALTH PLAN COMPARATIVE INFORMATION.

(a) REQUIREMENT.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer that provides coverage in connection with group health insurance coverage, shall, not later than 12 months after the date of enactment of this section, and at least annually thereafter, provide for the disclosure, in a clear and accurate form to each participant and each beneficiary who does not reside at the same address as the participant, or upon request to an individual eligible for coverage under the plan, of the information described in subsection (b).

(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prevent a plan or issuer from entering into any agreement under which the issuer agrees to assume responsibility for compliance with the requirements of this section and the plan is released from liability for such compliance.

(3) PROVISION OF INFORMATION.—Information shall be provided to participants and beneficiaries under this section at the address maintained by the plan or issuer with respect to such participants or beneficiaries.

(b) REQUIRED INFORMATION.—The informational materials to be distributed under this section shall include for each package option available under a group health plan the following:

(1) A description of the covered items and services under each such plan and any in- and out-of-network features of each such plan, including a summary description of the specific exclusions from coverage under the plan.

(2) A description of any cost-sharing, including premiums, deductibles, coinsurance, and copayment amounts, for which the participant or beneficiary will be responsible, including any annual or lifetime limits on benefits, for each such plan.

(3) A description of any optional supplemental benefits offered by each such plan and the terms and conditions (including premiums or cost-sharing) for such supplemental coverage.

(4) A description of any restrictions on payments for services furnished to a participant or beneficiary by a health care professional that is not a participating professional and the liability of the participant or beneficiary for additional payments for these services.

(5) A description of the service area of each such plan, including the provision of any out-of-area coverage.

(6) A description of the extent to which participants and beneficiaries may select the primary care provider of their choice, including providers both within the network and outside the network of each such plan (if the plan permits out-of-network services).

(7) A description of the procedures for advance directives and organ donation decisions if the plan maintains such procedures.

(8) A description of the requirements and procedures to be used to obtain preauthorization for health services (including telephone numbers and mailing addresses), including referrals for specialty care.

(9) A description of the definition of medical necessity used in making coverage determinations by each such plan.

(10) A summary of the rules and methods for appealing coverage decisions and filing grievances (including telephone numbers and mailing addresses), as well as other available remedies.

(11) A summary description of any provisions for obtaining off-formulary medications if the plan utilizes a defined formulary for providing specific prescription medications.

(12) A summary of the rules for access to emergency room care. Also, any available educational material regarding proper use of emergency services.

(13) A description of whether or not coverage is provided for experimental treatments, investigational treatments, or clinical trials and the circumstances under which access to such treatments or trials is made available.

(14) A description of the specific preventative services covered under the plan if such services are covered.

(15) A statement regarding—

(A) the manner in which a participant or beneficiary may access an obstetrician, gynecologist, or pediatrician in accordance with section 723 or 724; and

(B) the manner in which a participant or beneficiary obtains continuity of care as provided for in section 726.

(16) A statement that the following information, and instructions on obtaining such information (including telephone numbers and, if available, Internet websites), shall be made available upon request:

(A) The names, addresses, telephone numbers, and State licensure status of the plan's participating health care professionals and participating health care facilities, and, if available, the education, training, speciality qualifications or certifications of such professionals.

(B) A summary description of the methods used for compensating participating health care professionals, such as capitation, fee-for-service, salary, or a combination thereof. The requirement of this subparagraph shall not be construed as requiring plans to provide information concerning proprietary payment methodology.

(C) A summary description of the methods used for compensating health care facilities, including per diem, fee-for-service, capitation, bundled payments, or a combination thereof. The requirement of this subparagraph shall not be construed as requiring plans to provide information concerning proprietary payment methodology.

(D) A summary description of the procedures used for utilization review.

(E) The list of the specific prescription medications included in the formulary of the plan, if the plan uses a defined formulary.

(F) A description of the specific exclusions from coverage under the plan.

(G) Any available information related to the availability of translation or interpretation services for non-English speakers and people with communication disabilities, including the availability of audio tapes or information in Braille.

(H) Any information that is made public by accrediting organizations in the process of accreditation if the plan is accredited, or any additional quality indicators that the plan makes available.

(c) MANNER OF DISTRIBUTION.—The information described in this section shall be distributed in an accessible format that is understandable to an average plan participant or beneficiary.

(d) RULE OF CONSTRUCTION.—Nothing in this section may be construed to prohibit a group health plan, or health insurance issuer in connection with group health insurance coverage, from distributing any other additional information determined by the plan or issuer to be important or necessary in assisting participants and beneficiaries or upon request potential participants and beneficiaries in the selection of a health plan or from providing information under subsection (b)(15) as part of the required information.

(e) CONFORMING REGULATIONS.—The Secretary shall issue regulations to coordinate the requirements on group health plans and health insurance issuers under this section with the requirements imposed under part 1, to reduce duplication with respect to any information that is required to be provided under any such requirements.

(f) HEALTH CARE PROFESSIONAL.—In this section, the term "health care professional" means a physician (as defined in section 1861(r) of the Social Security Act) or other health care professional if coverage for the professional's services is provided under the health plan involved for the services of the professional. Such term includes a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner,

clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

SEC. 715. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

A group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not adjust premium or contribution amounts for a group on the basis of predictive genetic information concerning any individual (including a dependent) or family member of the individual (including information about a request for or receipt of genetic services).

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Subpart C—Patient Right to Medical Advice and Care

SEC. 721. PATIENT ACCESS TO EMERGENCY MEDICAL CARE.

(a) IN GENERAL.—To the extent that the group health plan (other than a fully insured group health plan) provides coverage for benefits consisting of emergency medical care (as defined in subsection (c)), except for items or services specifically excluded—

(1) the plan shall provide coverage for benefits, without requiring preauthorization, for appropriate emergency medical screening examinations (within the capability of the emergency facility, including ancillary services routinely available to the emergency facility) to the extent that a prudent layperson, who possesses an average knowledge of health and medicine, would determine such examinations to be necessary to determine whether emergency medical care (as so defined) is necessary; and

(2) the plan shall provide coverage for benefits, without requiring preauthorization, for additional emergency medical care to stabilize an emergency medical condition following an emergency medical screening examination (if determined necessary under paragraph (1)), pursuant to the definition of stabilize under section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(b) UNIFORM COST-SHARING REQUIRED AND OUT-OF-NETWORK CARE.—

(1) UNIFORM COST-SHARING.—Nothing in this section shall be construed as preventing a group health plan (other than a fully insured group health plan) from imposing any form of cost-sharing applicable to any participant or beneficiary (including coinsurance, copayments, deductibles, and any other charges) in relation to coverage for benefits described in subsection (a), if such form of cost-sharing is uniformly applied under such plan, with respect to similarly situated participants and beneficiaries, to all benefits consisting of emergency medical care (as defined in subsection (c)) provided to such similarly situated participants and beneficiaries under the plan.

(2) OUT-OF-NETWORK CARE.—If a group health plan (other than a fully insured group health plan) provides any benefits

with respect to emergency medical care (as defined in subsection (c)), the plan shall cover emergency medical care under the plan in a manner so that, if such care is provided to a participant or beneficiary by a nonparticipating health care provider, the participant or beneficiary is not liable for amounts that exceed the amounts of liability that would be incurred if the services were provided by a participating provider.

(c) DEFINITION OF EMERGENCY MEDICAL CARE.—In this section:

(1) IN GENERAL.—The term "emergency medical care" means, with respect to a participant or beneficiary under a group health plan (other than a fully insured group health plan), covered inpatient and outpatient services that—

(A) are furnished by any provider, including a nonparticipating provider, that is qualified to furnish such services; and

(B) are needed to evaluate or stabilize (as such term is defined in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd)(e)(3)) an emergency medical condition (as defined in paragraph (2)).

(2) EMERGENCY MEDICAL CONDITION.—The term "emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

(A) placing the health of the participant or beneficiary (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

(B) serious impairment to bodily functions, or

(C) serious dysfunction of any bodily organ or part.

SEC. 722. OFFERING OF CHOICE OF COVERAGE OPTIONS.

(a) REQUIREMENT.—

(1) OFFERING OF POINT-OF-SERVICE COVERAGE OPTION.—Except as provided in paragraph (2), if a group health plan (other than a fully insured group health plan) provides coverage for benefits only through a defined set of participating health care professionals, the plan shall offer the participant the option to purchase point-of-service coverage (as defined in subsection (b)) for all such benefits for which coverage is otherwise so limited. Such option shall be made available to the participant at the time of enrollment under the plan and at such other times as the plan offers the participant a choice of coverage options.

(2) EXCEPTION IN THE CASE OF MULTIPLE ISSUER OR COVERAGE OPTIONS.—Paragraph (1) shall not apply with respect to a participant in a group health plan (other than a fully insured group health plan) if the plan offers the participant 2 or more coverage options that differ significantly with respect to the use of participating health care professionals or the networks of such professionals that are used.

(b) POINT-OF-SERVICE COVERAGE DEFINED.—In this section, the term "point-of-service coverage" means, with respect to benefits covered under a group health plan (other than a fully insured group health plan), coverage of such benefits when provided by a nonparticipating health care professional.

(c) SMALL EMPLOYER EXEMPTION.—

(1) IN GENERAL.—This section shall not apply to any group health plan (other than a fully insured group health plan) of a small employer.

(2) SMALL EMPLOYER.—For purposes of paragraph (1), the term "small employer" means, in connection with a group health plan (other than a fully insured group health plan) with respect to a calendar year and a plan year, an employer who employed an average of at least 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year. For purposes of this paragraph, the provisions of subparagraph (C) of section 712(c)(1) shall apply in determining employer size.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) as requiring coverage for benefits for a particular type of health care professional;

(2) as requiring an employer to pay any costs as a result of this section or to make equal contributions with respect to different health coverage options;

(3) as preventing a group health plan (other than a fully insured group health plan) from imposing higher premiums or cost-sharing on a participant for the exercise of a point-of-service coverage option; or

(4) to require that a group health plan (other than a fully insured group health plan) include coverage of health care professionals that the plan excludes because of fraud, quality of care, or other similar reasons with respect to such professionals.

SEC. 723. PATIENT ACCESS TO OBSTETRIC AND GYNECOLOGICAL CARE.

(a) GENERAL RIGHTS.—

(1) WAIVER OF PLAN REFERRAL REQUIREMENT.—If a group health plan described in subsection (b) requires a referral to obtain coverage for speciality care, the plan shall waive the referral requirement in the case of a female participant or beneficiary who seeks coverage for routine obstetrical care or routine gynecological care.

(2) RELATED ROUTINE CARE.—With respect to a participant or beneficiary described in paragraph (1), a group health plan described in subsection (b) shall treat the ordering of other routine care that is related to routine obstetric or gynecologic care, by a physician who specializes in obstetrics and gynecology as the authorization of the primary care provider for such other routine care.

(b) APPLICATION OF SECTION.—A group health plan described in this subsection is a group health plan (other than a fully insured group health plan), that—

(1) provides coverage for routine obstetric care (such as pregnancy-related services) or routine gynecologic care (such as preventive women's health examinations); and

(2) requires the designation by a participant or beneficiary of a participating primary care provider who is not a physician who specializes in obstetrics or gynecology.

(c) RULES OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) as waiving any coverage requirement relating to medical necessity or appropriateness with respect to the coverage of obstetric or gynecologic care described in subsection (a);

(2) to preclude the plan from requiring that the physician who specializes in obstetrics or gynecology notify the designated primary care provider or the plan of treatment decisions; or

(3) to preclude a group health plan from allowing health care professionals other than physicians to provide routine obstetric or routine gynecologic care.

SEC. 724. PATIENT ACCESS TO PEDIATRIC CARE.

(a) IN GENERAL.—In the case of a group health plan (other than a fully insured group health plan) that provides coverage for routine pediatric care and that requires the designation by a participant or beneficiary of a participating primary care provider, if the designated primary care provider is not a physician who specializes in pediatrics—

(1) the plan may not require authorization or referral by the primary care provider in order for a participant or beneficiary to obtain coverage for routine pediatric care; and

(2) the plan shall treat the ordering of other routine care related to routine pediatric care by such a specialist as having been authorized by the designated primary care provider.

(b) RULES OF CONSTRUCTION.—Nothing in subsection (a) shall be construed—

(1) as waiving any coverage requirement relating to medical necessity or appropriateness with respect to the coverage of any pediatric care provided to, or ordered for, a participant or beneficiary;

(2) to preclude a group health plan from requiring that a specialist described in subsection (a) notify the designated primary care provider or the plan of treatment decisions; or

(3) to preclude a group health plan from allowing health care professionals other than physicians to provide routine pediatric care.

SEC. 725. ACCESS TO SPECIALISTS.

(a) IN GENERAL.—A group health plan (other than a fully insured group health plan) shall ensure that participants and beneficiaries have access to specialty care when such care is covered under the plan. Such access may be provided through contractual arrangements with specialized providers outside of the network of the plan.

(b) TREATMENT PLANS.—

(1) IN GENERAL.—Nothing in this section shall be construed to prohibit a group health plan (other than a fully insured group health plan) from requiring that speciality care be provided pursuant to a treatment plan so long as the treatment plan is—

(A) developed by the specialist, in consultation with the primary care provider, and the participant or beneficiary;

(B) approved by the plan; and

(C) in accordance with the applicable quality assurance and utilization review standards of the plan.

(2) NOTIFICATION.—Nothing in paragraph (1) shall be construed as prohibiting a plan from requiring the specialist to provide the primary care provider with regular updates on the specialty care provided, as well as all other necessary medical information.

(c) REFERRALS.—Nothing in this section shall be construed to prohibit a plan from requiring an authorization by the primary care provider of the participant or beneficiary in order to obtain coverage for speciality services so long as such authorization is for an adequate number of referrals under an approved treatment plan if such a treatment plan is required by the plan.

(d) SPECIALITY CARE DEFINED.—For purposes of this subsection, the term speciality care means, with respect to a condition, care and treatment provided by a health care practitioner, facility, or center (such as a center of excellence) that has adequate expertise (including age-appropriate expertise) through appropriate training and experience.

SEC. 726. CONTINUITY OF CARE.

(a) IN GENERAL.—

(1) TERMINATION OF PROVIDER.—If a contract between a group health plan (other than a fully insured group health plan) and a health care provider is terminated (as defined in paragraph (2)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in such group health plan, and an individual who is a participant or beneficiary in the plan is undergoing a course of treatment from the provider at the time of such termination, the plan shall—

(A) notify the individual on a timely basis of such termination;

(B) provide the individual with an opportunity to notify the plan of a need for transitional care; and

(C) in the case of termination described in paragraph (2), (3), or (4) of subsection (b), and subject to subsection (c), permit the individual to continue or be covered with respect to the course of treatment with the provider's consent during a transitional period (as provided under subsection (b)).

(2) TERMINATED.—In this section, the term "terminated" includes, with respect to a contract, the expiration or nonrenewal of the contract by the group health plan, but does not include a termination of the contract by the plan for failure to meet applicable quality standards or for fraud.

(3) CONTRACTS.—For purposes of this section, the term "contract between a group health plan (other than a fully insured group health plan) and a health care provider" shall include a contract between such a plan and an organized network of providers.

(b) TRANSITIONAL PERIOD.—

(1) GENERAL RULE.—Except as provided in paragraph (3), the transitional period under this subsection shall permit the participant or beneficiary to extend the coverage involved for up to 90 days from the date of the notice described in subsection (a)(1)(A) of the provider's termination.

(2) INSTITUTIONAL CARE.—Subject to paragraph (1), the transitional period under this subsection for institutional or inpatient care from a provider shall extend until the discharge or termination of the period of institutionalization and also shall include institutional care provided within a reasonable time of the date of termination of the provider status if the care was scheduled before the date of the announcement of the termination of the provider status under subsection (a)(1)(A) or if the individual on such date was on an established waiting list or otherwise scheduled to have such care.

(3) PREGNANCY.—Notwithstanding paragraph (1), if—

(A) a participant or beneficiary has entered the second trimester of pregnancy at the time of a provider's termination of participation; and

(B) the provider was treating the pregnancy before the date of the termination;

the transitional period under this subsection with respect to provider's treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

(4) TERMINAL ILLNESS.—Subject to paragraph (1), if—

(A) a participant or beneficiary was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) prior to a provider's termination of participation; and

(B) the provider was treating the terminal illness before the date of termination;

the transitional period under this subsection shall be for care directly related to the treatment of the terminal illness.

(c) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan (other than a fully insured group health plan) may condition coverage of continued treatment by a provider under subsection (a)(1)(C) upon the provider agreeing to the following terms and conditions:

(1) The provider agrees to accept reimbursement from the plan and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or at the rates applicable under the replacement plan after the date of the termination of the contract with the group health plan) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in subsection (a)(1) had not been terminated.

(2) The provider agrees to adhere to the quality assurance standards of the plan responsible for payment under paragraph (1) and to provide to such plan necessary medical information related to the care provided.

(3) The provider agrees otherwise to adhere to such plan's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require the coverage of benefits which would not have been covered if the provider involved remained a participating provider.

(e) DEFINITION.—In this section, the term "health care provider" or "provider" means—

(1) any individual who is engaged in the delivery of health care services in a State and who is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State; and

(2) any entity that is engaged in the delivery of health care services in a State and that, if it is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State, is so licensed.

SEC. 727. PROTECTION OF PATIENT-PROVIDER COMMUNICATIONS.

(a) IN GENERAL.—Subject to subsection (b), a group health plan (other than a fully insured group health plan and in relation to a participant or beneficiary) shall not prohibit or otherwise restrict a health care professional from advising such a participant or beneficiary who is a patient of the professional about the health status of the participant or beneficiary or medical care or treatment for the condition or disease of the participant or beneficiary, regardless of whether coverage for such care or treatment are provided under the contract, if the professional is acting within the lawful scope of practice.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as requiring a group health plan (other than a fully insured group health plan) to provide specific benefits under the terms of such plan.

SEC. 728. PATIENT'S RIGHT TO PRESCRIPTION DRUGS.

To the extent that a group health plan (other than a fully insured group health plan) provides coverage for benefits with respect to prescription drugs, and limits such coverage to drugs included in a formulary, the plan shall—

(1) ensure the participation of physicians and pharmacists in developing and reviewing such formulary; and

(2) in accordance with the applicable quality assurance and utilization review standards of the plan, provide for exceptions from the formulary limitation when a non-formulary alternative is medically necessary and appropriate.

SEC. 729. SELF-PAYMENT FOR BEHAVIORAL HEALTH CARE SERVICES.

(a) IN GENERAL.—A group health plan (other than a fully insured group health plan) may not—

(1) prohibit or otherwise discourage a participant or beneficiary from self-paying for behavioral health care services once the plan has denied coverage for such services; or

(2) terminate a health care provider because such provider permits participants or beneficiaries to self-pay for behavioral health care services—

(A) that are not otherwise covered under the plan; or

(B) for which the group health plan provides limited coverage, to the extent that the group health plan denies coverage of the services.

(b) RULE OF CONSTRUCTION.—Nothing in subsection (a)(2)(B) shall be construed as prohibiting a group health plan from terminating a contract with a health care provider for failure to meet applicable quality standards or for fraud.

SEC. 730. GENERALLY APPLICABLE PROVISION.

In the case of a group health plan that provides benefits under 2 or more coverage options, the requirements of this subpart, other than section 722, shall apply separately with respect to each coverage option.

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SEC. 732. SPECIAL RULES RELATING TO GROUP HEALTH PLANS.

(a) GENERAL EXCEPTION FOR CERTAIN SMALL GROUP HEALTH PLANS.—The requirements of this part (other than **[**section 711**]** *sections 711 and 714*) shall not apply to any group health plan (and group health insurance coverage offered in connection with a group health plan) for any plan year if, on the first day of such plan year, such plan has less than 2 participants who are current employees.

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[SUBPART C**]** *SUBPART D*—GENERAL PROVISIONS

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SEC. 733. DEFINITIONS.

(a) GROUP HEALTH PLAN. * * *

(1) IN GENERAL. * * *

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(3) FULLY INSURED GROUP HEALTH PLAN.—The term "fully insured group health plan" means a group health plan where benefits under the plan are provided pursuant to the terms of an arrangement between a group health plan and a health insurance issuer and are guaranteed by the health insurance issuer under a contract or policy of insurance.

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(d) OTHER DEFINITIONS.—For purposes of this part—

(1) COBRA CONTINUATION PROVISION. * * *

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(5) FAMILY MEMBER.—The term "family member" means with respect to an individual—

(A) the spouse of the individual;

(B) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and

(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

(6) GENETIC INFORMATION.—The term "genetic information" means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member (including information about a request for or receipt of genetic services).

(7) GENETIC SERVICES.—The term "genetic services" means health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

(8) PREDICTIVE GENETIC INFORMATION.—

(A) IN GENERAL.—The term "predictive genetic information" means, in the absence of symptoms, clinical signs, or a diagnosis of the condition related to such information—

(i) information about an individual's genetic tests;

(ii) information about genetic tests of family members of the individual; or

(iii) information about the occurrence of a disease or disorder in family members.

(B) EXCEPTIONS.—The term "predictive genetic information" shall not include—

(i) information about the sex or age of the individual;

(ii) information derived from physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests; and

(iii) information about physical exams of the individual.

(9) GENETIC TEST.—The term "genetic test" means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals. Such term does not include physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests, and physical exams of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease.

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[TITLE IX—AGENCY FOR HEALTH CARE POLICY AND RESEARCH

[PART A—ESTABLISHMENT AND GENERAL DUTIES

[SEC. 901. ESTABLISHMENT.

[(a) IN GENERAL.—There is established within the Service an agency to be known as the Agency for Health Care Policy and Research.

[(b) PURPOSE.—The purpose of the Agency is to enhance the quality, appropriateness, and effectiveness of health care services, and access to such services, through the establishment of a board base of scientific research and through the promotion of improvements in clinical practice (including the prevention of diseases and other health conditions) and in the organization, financing, and delivery of health care services.

[(c) APPOINTMENT OF ADMINISTRATOR.—There shall be at the head of the Agency an official to be known as the Administrator for Health Care Policy and Research. The Administrator shall be appointed by the Secretary. The Secretary, acting through the Administrator, shall carry out the authorities and duties established in this title.

[SEC. 902. GENERAL AUTHORITIES AND DUTIES.

[(a) IN GENERAL.—In carrying out section 901(b), the Administrator shall conduct and support research, demonstration projects, evaluations, training, guideline development, and the dissemina-

tion of information, on health care services and on systems for the delivery of such services, including activities with respect to—

[(1) the effectiveness, efficiency, and quality of health care services;

[(2) subject to subsection (d), the outcomes of health care services and procedures;

[(3) clinical practice, including primary care and practice-oriented research;

[(4) health care technologies, facilities, and equipment;

[(5) health care costs, productivity, and market forces;

[(6) health promotion and disease prevention;

[(7) health statistics and epidemiology; and

[(8) medical liability.

[(b) REQUIREMENTS WITH RESPECT TO RURAL AREAS AND UNDERSERVED POPULATIONS.—In carrying out subsection (a), the Administrator shall undertake and support research, demonstration projects, and evaluations with respect to—

[(1) the delivery of health care services in rural areas (including frontier areas); and

[(2) the health of low-income groups, minority groups, and the elderly.

PUBLIC HEALTH SERVICE ACT

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Section 1. * * *

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TITLE IX—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

PART A—ESTABLISHMENT AND GENERAL DUTIES

Sec. 901. Mission and duties.
Sec. 902. General authorities.

PART B—HEALTHCARE IMPROVEMENT RESEARCH

Sec. 911. Healthcare outcome improvement research.
Sec. 912. Private-public partnerships to improve organization and delivery.
Sec. 913. Information on quality and cost of care.
Sec. 914. Information systems for healthcare improvement.
Sec. 915. Research supporting primary care and access in underserved areas.
Sec. 916. Clinical practice and technology innovation.
Sec. 917. Coordination of Federal Government quality improvement efforts.

PART C—GENERAL PROVISIONS

Sec. 921. Advisory Council for Healthcare Research and Quality.
Sec. 922. Peer review with respect to grants and contracts.
Sec. 923. Certain provisions with respect to development, collection, and dissemination of data.
Sec. 924. Dissemination of information.
Sec. 925. Additional provisions with respect to grants and contracts.
Sec. 926. Certain administrative authorities.
Sec. 927. Funding.
Sec. 928. Definitions.

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[(c) HEALTH SERVICES TRAINING GRANTS.—The Administrator may provide training grants in the field of health services research related to activities authorized under subsection (a), to include pre-

and post-doctoral fellowships and training programs, young investigator awards, and other programs and activities as appropriate.

[(d) MULTIDISCIPLINARY CENTERS.—The Administrator may provide financial assistance to public or nonprofit private entities for meeting the costs of planning and establishing new centers, and operating existing and new centers, for multidisciplinary health services research, demonstration projects, evaluations, training, policy analysis, and demonstrations respecting the matters referred to in subsection (a).

[(e) RELATION TO CERTAIN AUTHORITIES REGARDING SOCIAL SECURITY.—Activities authorized in this section may include, and shall be appropriately coordinated with, experiments, demonstration projects, and other related activities authorized by the Social Security Act and the Social Security Amendments of 1967. Activities under subsection (a)(2) of this section that affect the programs under titles XVIII and XIX of the Social Security Act shall be carried out consistent with section 1142 of such Act.

[SEC. 903. DISSEMINATION.

[(a) IN GENERAL.—The Administrator shall—

[(1) promptly publish, make available, and otherwise disseminate, in a form understandable and on as broad a basis as practicable so as to maximize its use, the results of research, demonstration projects, and evaluation conducted or supported under this title and the guidelines, standards, and review criteria developed under this title;

[(2) promptly make available to the public data developed in such research, demonstration projects, and evaluations;

[(3) provide indexing, abstracting, translating, publishing and other services leading to a more effective and timely dissemination of information on research, demonstration projects, and evaluations with respect to health care to public and private entities and individuals engaged in the improvement of health care delivery and the general public, and undertake programs to develop new or improved methods for making such information available; and

[(4) as appropriate, provide technical assistance to State and local government and health agencies and conduct liaison activities to such agencies to foster dissemination.

[(b) PROHIBITION AGAINST RESTRICTIONS.—Except as provided in subsection (c), the Administrator may not restrict the publication or dissemination of date from, or the results of, projects conducted or supported under this title.

[(c) LIMITATION ON USE OF CERTAIN INFORMATION.—No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under this title may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such purpose. Such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

[(d) CERTAIN INTERAGENCY AGREEMENT.—The Administrator and the Director of the National Library of Medicine shall enter into an agreement providing for the implementation of subsection (a)(3).

[(e) REQUIRED INTERAGENCY AGREEMENT.—The Administrator and the Director of the National Library of Medicine shall enter into an agreement providing for the implementation of section 478A.

[SEC. 904. HEALTH CARE TECHNOLOGY AND TECHNOLOGY ASSESSMENT.

[(a) IN GENERAL.—In carrying out section 901(b), the Administrator shall promote the development and application of appropriate health care technology assessments—

[(1) by identifying needs in, and establishing priorities for, the assessment of specific health care technologies;

[(2) by developing and evaluating criteria and methodologies for health care technology assessment;

[(3) by conducting and supporting research on the development and diffusion of health care technology;

[(4) by conducting and supporting research on assessment methodologies;

[(5) by promoting education, training, and technical assistance in the use of health care technology assessment methodologies and results; and

[(6) by conducting assessments and reassessments of existing and new health care technologies.

(b) SPECIFIC ASSESSMENTS.—

[(1) IN GENERAL.—In carrying out section 901(b), the Administrator shall conduct and support specific assessments of health care technologies.

[(2) CONSIDERATION OF CERTAIN FACTORS.—In carrying out paragraph (1), the Administrator shall consider the safety, efficacy, and effectiveness, and, as appropriate, the legal, social, and ethical implications, and appropriate uses of such technologies, including consideration of geographic factors. In carrying out such paragraph, the Administrator shall also consider the cost effectiveness of such technologies where cost information is available and reliable.

[(c) AGENDA AND PRIORITIES.—

[(1) ESTABLISHMENT OF PRIORITIES.—In accordance with paragraph (2), the Administrator, in consultation with the Advisory Council established under section 921, shall establish an annual list of technology assessments under consideration by the Agency, including those assessments performed at the request of the Health Care Financing Administration and the Department of Defense and those assessments performed under subsections (d) and (f).

[(2) PUBLIC NOTICE.—The Administrator, in consultation with the Advisory Council shall publish the list established in paragraph (1) annually in the Federal Register.

[(d) CONDUCT OF ASSESSMENTS.—

[(1) RECOMMENDATIONS WITH RESPECT TO HEALTH CARE TECHNOLOGY.—The Administrator shall make recommendations to the Secretary with respect to whether specific health care technologies should be reimbursable under federally fi-

nanced health programs, including recommendations with respect to any conditions and requirements under which any such reimbursement should be made.

[(2) CONSIDERATIONS OF CERTAIN FACTORS.—In making recommendations respecting health care technologies, the Administrator shall consider the safety, efficacy, and effectiveness, and, as appropriate, the appropriate uses of such technologies. The Administrator shall consider the cost effectiveness of such technologies where cost information is available and reliable.

[(3) ADDITIONAL ASSESSMENTS.—The Administrator may conduct technology assessments in addition to those assessments performed at the request of the Administrator of the Health Care Financing Administration or of the Secretary of Defense.

[(4) .—The Administrator shall develop criteria for determining the priority of assessments performed under this subsection. Such criteria shall include—

[(A) the prevalence of the health condition for which the technology aims to prevent, diagnose, treat and clinically manage;

[(B) variations in current practice;

[(C) the economic burden posed by the prevention, diagnosis, treatment, and clinical management of the health condition, including the impact on publicly-funded programs;

[(D) aggregate cost of the use of technology;

[(E) the morbidity and mortality associated with health condition; and

[(F) the potential of an assessment to improve health outcomes or affect costs associated with the prevention, diagnosis, or treatment of the condition.

[(5) CONSULTATIONS.—In carrying out this subsection, the Administrator shall cooperate and consult with the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the heads of any other interested Federal department or agency.

[(e) DESCRIPTION OF PROCESS.—Not later than January 1, 1994, the Administrator shall develop and publish a description of the methodology used to establish priorities for technology assessment and the process used to conduct its technology assessments under this section.

[(f) Program of Innovative Assessments.—

[(1) IN GENERAL.—The Administrator may make grants to, or enter cooperative agreements or contracts with, entities described in paragraph (2) for the establishment of collaborative arrangements for the purpose of conducting assessments of experimental, emerging, existing, or potentially outmoded health care technologies, and for related activities. Such assessments may include controlled clinical trials, large simple trials, and other methodologies that can be conducted in partnership between the public and private sectors or among multiple government agencies.

[(2) ELIBIGLE ENTITIES.—The entities referred to in paragraph (1) are entities determined to be appropriate by the Administrator, which entities may include academic medical cen-

ters, research institutions, nonprofit professional organizations, public or private third party payers, other governmental agencies, and consortia of appropriate research entities established for the purpose of conducting technology assessments.

[(3) USE OF AWARD.—A grant, cooperative agreement, or contract under paragraph (1) may be expended for data collection, data analysis, protocol development, report development, dissemination and evaluation, and other activities determined to be appropriate by the Administrator. Such funds shall not be used for direct services.

[(4) APPLICATION FOR AWARD.—To be eligible to receive a grant, cooperative agreement, or contract under paragraph (1), an entity shall prepare and submit to the Administrator an application, at such time, in such form, and containing such information as the Administrator may require.

[(5) INTERAGENCY MEMORANDA OF UNDERSTANDING.—In carrying out paragraph (1), the Administrator may enter into memoranda of understanding with the heads of other Federal agencies.

[PART B—FORUM FOR QUALITY AND EFFECTIVENESS IN HEALTH CARE

[SEC. 911. ESTABLISHMENT OF OFFICE.

[There is established within the Agency an office to known as the Office of the Forum for Quality and Effectiveness in Health Care. The office shall be headed by a director, who shall be appointed by the Administrator. The Administrator shall carry out this part acting through the Director.

[SEC. 912. DUTIES.

[(a) ESTABLISHMENT OF FORUM PROGRAM.—The Administrator shall establish a program to be known as the Forum for Quality and Effectiveness in Health Care. For the purpose of promoting the quality, appropriateness, and effectiveness of health care, the Administrator, using the process set forth in section 913, shall arrange for the development and periodic review and updating of—

[(1) clinically relevant guidelines that may be used by physicians, educators, and health care practitioners to assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated and managed clinically; and

[(2) standards of quality, performance measures, and medical review criteria through which health care providers and other appropriate entities may assess or review the provision of health care and assure the quality of such care.

[(b) CERTAIN REQUIREMENTS.—Guidelines, standards, performance measures, and review criteria under subsection (a) shall—

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

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

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

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

[(5) 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.

[(c) AUTHORITY FOR CONTRACTS.—In carrying out this part, the Administrator may enter into contracts with public or nonprofit private entities.

[(d) DATE CERTAIN FOR INITIAL GUIDELINES AND STANDARDS.—The Administrator, by not later than January 1, 1991, shall assure the development of an initial set of guidelines, standards, performance measures, and review criteria under subsection (a) that includes not less than 3 clinical treatments or conditions described in section 1142(a)(3) of the Social Security Act.

[(e) RELATIONSHIP WITH MEDICARE PROGRAM.—To assure an appropriate reflection of the needs and priorities of the program under title XVIII of the Social Security Act, activities under this part that affect such programs shall be conducted consistent with section 1142 of such Act.

[(f) DEVELOPMENT OF CERTAIN GUIDELINES AND STANDARDS.—Not later than January 1, 1996, the Administrator shall ensure that a set of guidelines, standards, performance measures, and review criteria, are developed under subsection (a)(1) that address the prevention of not fewer than three conditions that account for significant national health expenditures. In carrying out this subsection the Administrator shall consult with the United States Preventive Services Task Force and other recognized experts in the field of disease prevention.

[SEC. 913. PROCESS FOR DEVELOPMENT OF GUIDELINES AND STANDARDS.

[(a) DEVELOPMENT THROUGH CONTRACTS AND PANELS.—The Administrator shall—

[(1) enter into contracts with public and nonprofit private entities for the purpose of developing and periodically reviewing and updating the guidelines, standards, performance measures, and review criteria described in section 912(a); and

[(2) convene panels of appropriately qualified experts (including practicing physicians with appropriate expertise) and health care consumers for the purpose of—

[(A) developing and periodically reviewing and updating the guidelines, standards, performance measures, and review criteria described in section 912(a); and

[(B) reviewing the guidelines, standards, performance measures, and review criteria developed under contracts under paragraph (1).

[(b) AUTHORITY FOR ADDITIONAL PANELS.—The Administrator may convene panels of appropriately qualified experts (including

practicing physicians with appropriate expertise) and health care consumers for the purpose of—

[(1) developing the standards and criteria described in section 914(b); and

[(2) providing advice to the Administrator and the Director with respect to any other activities carried out under this part or under section 902(a)(2).

[(c) SELECTION OF PANEL MEMBERS.—The Administrator shall select the chairpersons and the members of the panels convened as well as other participants in the guideline process under this section. In selecting individuals to serve on panels convened under this section, the Administrator shall consult with a broad range of interested individuals and organizations, including organizations representing physicians in the general practice of medicine and organizations representing physicians in specialties and subspecialties pertinent to the purposes of the panel involved. The Administrator shall seek to appoint physicians reflecting a variety of practice settings. In making such selecting, the Administrator shall ensure that a balance is maintained between individuals selected from academic settings and individuals selected without full-time academic appointments. At least two other members of such panels shall be individuals who do not derive their primary source of revenue directly from the performance of procedures discussed in the guideline. The Administrator shall ensure that at least one participant in the guideline process shall have expertise in epidemiology as well as familiarity with the clinical condition or treatment in question. The Administrator shall also ensure that at least one participant in the guideline process shall have expertise in health services research or health economics as well as familiarity with the clinical condition or treatment in question.

[SEC. 914. ADDITIONAL REQUIREMENTS.

[(a) PROGRAM AGENDA.—

[(1) IN GENERAL.—The Administrator shall provide for an agenda for the development of the guidelines, standards, performance measures, and review criteria described in section 912(a), including—

[(A) with respect to the guidelines, identifying specific diseases, disorders, and other health conditions for which the guidelines are to be developed and those that are to be given priority in the development of the guidelines; and

[(B) with respect to the standards, performance measures, and review criteria, identifying specific aspects of health care for which the standards, performance measures, and review criteria, are to be developed and those that are to be given priority in the development of the standards, performance measures, and review criteria.

[(2) CONSIDERATION OF CERTAIN FACTORS IN ESTABLISHING PRIORITIES.—

[(A) Factors considered by the Administrator in establishing priorities for purposes of paragraph (1) shall include consideration of the extent to which the guidelines, standards, performance measures, and review criteria involved can be expected—

[(i) to improve methods for disease prevention;

[(ii) to improve methods of diagnosis, treatment, and clinical management for the benefit of a significant number of individuals;

[(iii) to reduce clinically significant variations among physicians in the particular services and procedures utilized in making diagnoses and providing treatments; and

[(iv) to reduce clinically significant variations in the outcomes of health care services and procedures.

[(B) In providing for the agenda required in paragraph (1), including the priorities, the Administrator shall consult with the Administrator of the Health Care Financing Administration and otherwise act consistent with section 1142(b)(3) of the Social Security Act.

[(C) The Administrator shall develop and publish a methodology for establishing priorities for guideline topics. Such methodology may include the considerations described in section 904(d)(2) or 914(a)(2), and other considerations determined by the Administrator to be appropriate. Using such methodology, the Administrator shall establish and publish annually in the Federal Register a list of guideline topics under consideration.

[(b) STANDARDS AND CRITERIA.—

[(1) PROCESS FOR DEVELOPMENT, REVIEW, AND UPDATING.—The Administrator shall establish standards and criteria to be utilized by the recipients of contracts under section 913, and by the expert panels convened under such section, with respect to the development and periodic review and updating of the guidelines, standards, performance measures, and review criteria described in section 912(a).

[(2) AWARD OF CONTRACTS.—The Administrator shall establish standards and criteria to be utilized for the purpose of ensuring that contracts entered into for the development or periodic review or updating of the guidelines, standards, performance measures, and review criteria described in section 912(a) will be entered into only with appropriately qualified entities.

[(3) CERTAIN REQUIREMENTS FOR STANDARDS AND CRITERIA.—The Administrator shall ensure that the standards and criteria established under paragraphs (1) and (2) specify that—

[(A) appropriate consultations with interested individuals and organizations are to be conducted in the development of the guidelines, standards, performance measures, and review criteria described in section 912(a); and

[(B) such development may be accomplished through the adoption, with or without modification, of guidelines, standards, performance measures, and review criteria that—

[(i) meet the requirements of this part; and

[(ii) are developed by entities independently of the program established in this part.

[(4)IMPROVEMENTS OF STANDARDS AND CRITERIA.—The Administrator shall conduct and support research with respect to improving the standards and criteria developed under this subsection.

[(c) DISSEMINATION.—The Administrator shall promote and support the dissemination of the guidelines, standards, performance measures, and review criteria described in section 912(a). Such dissemination shall be carried out through organizations representing health care providers, organizations representing health care consumers, peer review organizations, accrediting bodies, and other appropriate entities.

[(d) PILOT TESTING.—The Administrator may conduct or support pilot testing of the guidelines, standards, performance measures, and review criteria developed under section 912(a). Any such pilot testing may be conducted prior to, or concurrently with, their dissemination under subsection (c).

[(e) EVALUATIONS.—The Administrator shall conduct and support evaluations of the extent to which the guidelines, standards, performance standards, and review criteria developed under section 912 have had an effect on the clinical practice of medicine. Evaluations shall be developed prior to the completion and release of the guideline, so that baseline data concerning practice patterns and health care costs may be obtained as part of the evaluation.

[(f) RECOMMENDATIONS TO ADMINISTRATOR.—The Director shall make recommendations to the Administrator on activities that should be carried out under section 902(a)(2) and under section 1142 of the Social Security Act, including recommendations of particular research projects that should be carried out with respect to—

[(1) evaluating the outcomes of health care services and procedures;

[(2) developing the standards and criteria required in subsection (b); and

[(3) promoting the utilization of the guidelines, standards, performance standards, and review criteria developed under section 912(a).

[PART C—GENERAL PROVISIONS

[SEC 921. ADVISORY COUNCIL FOR HEALTH CARE POLICY, RESEARCH, AND EVALUATION.

[(a) ESTABLISHMENT.—There is established an advisory council to be known as the National Advisory Council for Health Care Policy, Research, and Evaluation.

[(b) DUTIES.—

[(1) IN GENERAL.—The Council shall advise the Secretary and the Administrator with respect to activities to carry out the purpose of the Agency under section 901(b).

[(2) CERTAIN RECOMMENDATIONS.—Activiites of the Council under paragraph (1) shall include making recommendations to the Administrator regarding priorities for a national agenda and strategy for—

[(A) the conduct of research, demonstration projects, and evaluations with respect to health care, including clinical practice and primary care;

[(B) the development and application of appropriate health care technology assessments;

[(C) the development and periodic review and updating of guidelines for clinical practice, standards of quality, per-

formance measures, and medical review criteria with respect to health care; and

[(D) the conduct of research on outcomes of health care services and procedures.

[(c) MEMBERSHIP.—

[(1) IN GENERAL.—The council shall, in accordance with this subsection, be composed of appointed members and ex officio members. All members of the Council shall be voting members, other than officials designated under paragraph (3)(B) as ex officio members of the Council.

[(2) APPOINTED MEMBERS.—The Secretary shall appoint to the Council 17 appropriately qualified representatives of the public who are not officers or employees of the United States. The Secretary shall ensure that the appointed members of the Council, as a group, are representative of professions and entities concerned with, or affected by, activities under this title and under section 1142 of the Social Security Act. Of such members—

[(A) 8 shall be individuals distinguished in the conduct of research, demonstration projects, and evaluations with respect to health care;

[(B) 3 shall be individuals distinguished in the practice of medicine;

[(C) 2 shall be individuals distinguished in the health professions;

[(D) 2 shall be individuals distinguished in the fields of business, law, ethics, economics, and pubic policy; and

[(E) 2 shall be individuals representing the interests of consumers of health care.

[(3) EX OFFICIO MEMBERS.—The Secretary shall designate as ex officio members of the Council—

[(A) the Director of the National Institutes of Health, the Director of the Centers for Disease Control, the Administrator of the Health Care Financing Administration, the Assistant Secretary of Defense (Health Affairs), the Chief Medical Officer of the Department of Veterans Affairs; and

[(B) such other Federal officials as the Secretary may consider appropriate.

[(d) TERMS.—

[(1) IN GENERAL.—Except as provided in paragraph (2), members of the Council appointed under subsection (c)(2) shall serve for a term of 3 years.

[(2) STAGGERED ROTATION.—Of the members first appointed to the Council under subsection (c)(2), the Secretary shall appoint 6 members to serve for a term of 3 years, 6 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 appointed under subsection (c)(2) 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 appointed under subsection (c)(2) 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 Administrator shall, from among the members of the Council appointed under subsection (c)(2), designate an individual to serve as the chair of the Council.

[(g) MEETINGS.—The Council shall meet not less than once during each discrete 4-month period and shall otherwise meet at the call of the Administrator or the chair.

[(h) Compensation and Reimbursement of Expenses.—

[(1) APPOINTED MEMBERS.—Members of the Council appointed under subsection (c)(2) shall receive compensation for each day (including traveltime) 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 GS–18 of the General Schedule.

[(2) EX OFFICIO MEMBERS.—Officials designated under subsection (c)(3) as ex officio members of the Council may not receive compensation for service on the Council in addition to the compensation otherwise received for duties carried out as officers of the United States.

[(i) STAFF.—The Administrator 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.

[SEC. 922. PEER REVIEW WITH RESPECT TO GRANTS AND CONTRACTS.

[(a) REQUIREMENT OF REVIEW.—

[(1) IN GENERAL.—Appropriate technical and scientific peer review shall be conducted with respect to each application for a grant, cooperative agreement, or contract under this title.

[(2) REPORTS TO ADMINISTRATOR.—Each peer review group to which an application is submitted pursuant to paragraph (1) shall report its finding and recommendations respecting the application to the Administrator in such form and in such manner as the Administrator shall require.

[(b) APPROVAL AS PRECONDITION OF AWARDS.—The Administrator may not approve an application described in subsection (a)(1) unless the application is recommended for approval by a peer review group established under subsection (c).

[(c) ESTABLISHMENT OF PEER REVIEW GROUPS.—

[(1) IN GENERAL.—The Administrator shall establish such technical and scientific peer review groups as may be necessary to carry out this section. Such groups shall be established without regard to the provisions of title 5, United States Code, that govern appointments in the competitive service, and without regard to the provisions of chapter 51, and subchapter III of chapter 53, of such title that relate to classification and pay rates under the General Schedule.

[(2) MEMBERSHIP.—The members of any peer review group established under this section shall be appointed from among individuals who by virtue of their training or experience are eminently qualified to carry out the duties of such peer review group. Officers and employees of the United States may not

constitute more than 25 percent of the membership of any such group. Such officers and employees may not receive compensation for service on such groups in addition to the compensation otherwise received for duties carried out as such officers and employees.

[(3) DURATION.—Notwithstanding section 14(a) of the Federal Advisory Committee Act, peer review groups established under this section shall continue in existence until otherwise provided by law.

[(d) CATEGORIES OF REVIEW.—

[(1) IN GENERAL.—With respect to technical and scientific peer review under this section, there shall be two categories of peer review groups as follows:

[(A) One category of such groups shall, subject to subparagraph (B), review applications with respect to research, demonstration projects, or evaluations.

[(B) The other category of such groups shall review applications with respect to dissemination activities or the development of research agendas (including conferences, workshops, and meetings). If the purpose of a proposal presented in an application is a matter described in the preceding sentence, the application shall be reviewed by the groups referred to in such sentence, notwithstanding that the proposal involves research, demonstration projects, or evaluations.

[(2) AUTHORITY FOR PROCEDURAL ADJUSTMENTS IN CERTAIN CASES.—In the case of application described in subsection (a)(1) for financial assistance whose direct costs will not exceed $50,000, the Administrator may make appropriate adjustments in the procedures otherwise established by the Administrator for the conduct of peer review under this section. Such adjustments may be made for the purpose of encouraging the entry of individuals into the field of research, for the purpose of encouraging clinical practice-oriented research, and for such other purposes as the Administrator may determine to be appropriate.

[(e) REGULATIONS.—The Secretary shall issue regulations for the conduct of peer review under this section.

[SEC. 923. CERTAIN PROVISIONS WITH RESPECT TO DEVELOPMENT, COLLECTION, AND DISSEMINATION OF DATA.

[(a) STANDARDS WITH RESPECT TO UTILITY OF DATA.—

[(1) IN GENERAL.—With respect to data developed or collected by any entity for the purpose described in section 901(b), the administrator shall, in order to assure the utility, accuracy, and sufficiency of such data for all interested entities, establish guidelines for uniform methods of developing and collecting such data. Such guidelines shall include specifications for the development and collection of data on the outcomes of health care services and procedures.

[(2) RELATIONSHIP WITH MEDICARE PROGRAM.—In any case where guidelines under paragraph (1) may affect the administration of the program under title XVIII of the Social Security Act, the guidelines shall be in the form of recommendations to the Secretary for such program.

[(b) STATISTICS.—The Administrator shall—

[(1) take such action as may be necessary to assure that statistics developed under this title are of high quality, timely, and comprehensive, as well as specific, standardized, and adequately analyzed and indexed; and

[(2) publish, make available, and disseminate such statistics on as well a basis as is practicable.

[(c) AUTHORITY REGARDING CERTAIN REQUESTS.—Upon the request of a public or nonprofit private entity, the Administrator may tabulate and analyze statistics under arrangements under which such entity will pay the cost of the service provided. Amounts appropriated to the Administrator from payments made under such arrangements shall be available to the Administrator for obligation until expended.

[SEC. 924. ADDITIONAL PROVISIONS WITH RESPECT TO GRANTS AND CONTRACTS.

[(a) FINANCIAL CONFLICTS OF INTEREST.—With respect to projects for which awards of grants, cooperative agreement, or contracts are authorized to be made under this title, the Administrator shall by regulation define——

[(1) the specific circumstances that constitute financial interests in such projects that will, or may be reasonably expected to, create a bias in favor of obtaining results in the projects that are consistent with such interests; and

[(2) the actions that will be taken by the Administrator in response to any such interests identified by the Administrator.

[(b) REQUIREMENT OF APPLICATION.—The Administrator may not, with respect to any program under this title authorizing the provision of grants, cooperative agreements, or contracts, provide any such financial assistance unless an application for the assistance is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Administrator determines to be necessary to carry out the program involved.

[(c) PROVISION OF SUPPLIES AND SERVICES IN LIEU OF FUNDS.—

[(1) IN GENERAL.—Upon the request of an entity receiving a grant, cooperative agreement, or contract under this title, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the entity in carrying out the project involved and, for such purpose, may detail to the entity any officer or employee of the Department of Health and Human Services.

[(2) CORRESPONDING REDUCTION IN FUNDS.—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of the financial assistance involved by an amount equal to the costs of detailing assistance involved by amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Administrator. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

[(d) APPLICABILITY OF CERTAIN PROVISIONS WITH RESPECT TO CONTRACTS.—Contracts may be entered into under this part with

out regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

[SEC. 925. CERTAIN ADMINISTRATIVE AUTHORITIES.

[(a) DEPUTY ADMINISTRATOR AND OTHER OFFICERS AND EMPLOYEES.—

[(1) DEPUTY ADMINISTRATOR.—The Administrator may appoint a deupty administrator for the Agency.

[(2) OTHER OFFICERS AND EMPLOYEES.—The Administrator may appoint and fix the compensation of such officers and employees as may be necessary to carry out this title. Except as otherwise provided by law, such officers and employees shall be appointed in accordance with the civil service laws and their compensation fixed in accordance with title 5, United States Code.

[(b) FACILITIES.—The Secretary, in carrying out this title—

[(1) may acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or portions of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed 10 years; and

[(2) may acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other real or personal property (including patents) as the Secretary deems necessary.

[(c) PROVISION OF FINANCIAL ASSISTANCE.—The Administrator, in carrying out this title, may make grants to, and enter into cooperative agreements with, public and nonprofit private entities and individuals, and when appropriate, may enter into contracts with public and private entities and individuals.

[(d) UTILIZATION OF CERTAIN PERSONNEL AND RESOURCES.—

[(1) DEPARTMENT OF HEALTH AND HUMAN SERVICES.—The Administrator, in carrying out this title, may utilize personnel and equipment, facilities, and other physical resources of the Department of Health and Human Services, permit appropriate (as determined by the Secretary) entities and individuals to utilize the physical resources of such Department, and provide technical assistance and advice.

[(2) OTHER AGENCIES.—The Administrator, in carrying out this title, may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, or of any foreign government, with or without reimbursement of such agencies.

[(e) CONSULTANTS.—The Secretary, in carrying out this title, may secure, from time to time and for such periods as the Administrator deems advisable but in accordance with section 3109 of title 5, United States Code, the assistance and advice of consultants from the United States or abroad.

[(f) EXPERTS.—

[(1) IN GENERAL.—The Secretary may, in carrying out this title, obtain the services of not more than 50 experts or consultants who have appropriate scientific or professional qualifications. Such experts or consultants shall be obtained in accordance with section 3109 of title 5, United States Code, ex-

cept that the limitation in such section on the duration of service shall not apply.

[(2) TRAVEL EXPENSES.—

[(A) Experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed for their expenses associated with traveling to and from their assignment location in accordance with sections 5724, 5724a(a), 5724a(c), and 5726(c) of title 5, United States Code.

[(B) Expenses specified in subparagraph (A) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless and until the expert agrees in writing to complete the entire period of assignment, or one year, whichever is shorter, unless separated or reassigned for reasons that are beyond the control of the expert or consultant and that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (a) is recoverable from the expert or consultant as a debt of the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

[(g) VOLUNTARY AND UNCOMPENSATED SERVICES.—The Administrator, in carrying out this title, may accept voluntary and uncompensated services.

SEC. 926. FUNDING.

[(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this title, there are authorized to be appropriated $115,000,000 for fiscal year 1993, $145,000,000 for fiscal year 1994, and $175,000,000 for fiscal year 1995.

[(b) EVALUATIONS.—In addition to amounts available pursuant to subsection (a) for carrying out this title, there shall be made available for such purpose, from the amounts made available pursuant to section 241 of this Act (relating to evaluations), an amount equal to 40 percent of the maximum amount authorized in such section 241 to be made available.

[(c) INFORMATION CENTER.—For purposes of carrying out the activities under section 903(e), there are authorized to be appropriate $3,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 and 1995.

[(d) HEALTH CARE TECHNOLOGY ASSESSMENT.—For the purpose of carrying out technology assessment activities under section 904(d), there are authorized to be appropriate $2,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 and 1995.

[(e) PROGRAM OF INNOVATIVE ASSESSMENTS.—For purposes of establishing the program of innovative assessments under section 904(f), there are authorized to be appropriated $2,000,000 for fiscal year 1993, and such sums as may be necessary in each of the fiscal years 1994 and 1995.

[SEC. 927. DEFINITIONS.

[For purposes of this title:

[(1) The term "Administrator" means the Administrator for Health Care Policy and Research.

[(2) The term "Agency" means the Agency for Health Care Policy and Research.

[(3) The term "Council" means the National Advisory Council on Health Care Policy, Research, and Evaluation.

[(4) The term "Director" means the Director of the Office of the Forum for Quality and Effectiveness in Health Care.]

TITLE IX—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

PART A—ESTABLISHMENT AND GENERAL DUTIES

SEC. 901. MISSION AND DUTIES.

(a) IN GENERAL.—There is established within the Public Health Service an agency to be known as the Agency for Healthcare Research and Quality. In carrying out this subsection, the Secretary shall redesignate the Agency for Health Care Policy and Research as the Agency for Healthcare Research and Quality.

(b) MISSION.—The purpose of the Agency is to enhance the quality, appropriateness, and effectiveness of healthcare services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health system practices, including the prevention of diseases and other health conditions. The Agency shall promote healthcare quality improvement by—

(1) conducting and supporting research that develops and presents scientific evidence regarding all aspects of healthcare, including—

(A) the development and assessment of methods for enhancing patient participation in their own care and for facilitating shared patient-physician decision-making;

(B) the outcomes, effectiveness, and cost-effectiveness of healthcare practices, including preventive measures and long-term care;

(C) existing and innovative technologies;

(D) the costs and utilization of, and access to healthcare;

(E) the ways in which healthcare services are organized, delivered, and financed and the interaction and impact of these factors on the quality of patient care;

(F) methods for measuring quality and strategies for improving quality; and

(G) ways in which patients, consumers, purchasers, and practitioners acquire new information about best practices and health benefits, the determinants and impact of their use of this information;

(2) synthesizing and disseminating available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

(3) advancing private and public efforts to improve healthcare quality.

(c) REQUIREMENTS WITH RESPECT TO RURAL AREAS AND PRIORITY POPULATIONS.—In carrying out subsection (b), the Director shall un-

dertake and support research, demonstration projects, and evaluations with respect to the delivery of health services—

(1) the delivery of health services in rural areas (including frontier areas);

(2) health services for low-income groups, and minority groups;

(3) the health of children;

(4) for elderly; and

(5) for people with special healthcare needs, including disabilities, chronic care and end-of-life healthcare.

(d) APPOINTMENT OF DIRECTOR.—There shall be at the head of the Agency an official to be known as the Director for Healthcare Research and Quality. The Director shall be appointed by the Secretary. The Secretary, acting through the Director, shall carry out the authorities and duties established in this title.

SEC. 902. GENERAL AUTHORITIES.

(a) IN GENERAL.—In carrying out section 901(b), the Director shall support demonstration projects, conduct and support research, evaluations, training, research networks, multi-disciplinary centers, technical assistance, and the dissemination of information, on healthcare, and on systems for the delivery of such care, including activities with respect to—

(1) the quality, effectiveness, efficiency, appropriateness and value of healthcare services;

(2) quality measurement and improvement;

(3) the outcomes, cost, cost-effectiveness, and use of healthcare services and access to such services;

(4) clinical practice, including primary care and practice-oriented research;

(5) healthcare technologies, facilities, and equipment;

(6) healthcare costs, productivity, organization, and market forces;

(7) health promotion and disease prevention, including clinical preventive services;

(8) health statistics, surveys, database development, and epidemiology; and

(9) medical liability.

(b) HEALTH SERVICES TRAINING GRANTS.—

(1) IN GENERAL.—The Director may provide training grants in the field of health services research related to activities authorized under subsection (a), to include pre- and post-doctoral fellowships and training programs, young investigator awards, and other programs and activities as appropriate. In carrying out this subsection, the Director shall make use of funds made available under section 487 as well as other appropriated funds.

(2) REQUIREMENTS.—In developing priorities for the allocation of training funds under this subsection, the Director shall take into consideration shortages in the number of trained researchers addressing the priority populations.

(c) MULTIDISCIPLINARY CENTERS.—The Director may provide financial assistance to assist in meeting the costs of planning and establishing new centers, and operating existing and new centers, for multidisciplinary health services research, demonstration projects,

evaluations, training, and policy analysis with respect to the matters referred to in subsection (a).

(d) RELATION TO CERTAIN AUTHORITIES REGARDING SOCIAL SECURITY.—Activities authorized in this section shall be appropriately coordinated with experiments, demonstration projects, and other related activities authorized by the Social Security Act and the Social Security Amendments of 1967. Activities under subsection (a)(2) of this section that affect the programs under titles XVIII, XIX and XXI of the Social Security Act shall be carried out consistent with section 1142 of such Act.

(e) DISCLAIMER.—The Agency shall not mandate national standards of clinical practice or quality healthcare standards. Recommendations resulting from projects funded and published by the Agency shall include a corresponding disclaimer.

(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to imply that the Agency's role is to mandate a national standard or specific approach to quality measurement and reporting. In research and quality improvement activities, the Agency shall consider a wide range of choices, providers, healthcare delivery systems, and individual preferences.

PART B—HEALTHCARE IMPROVEMENT RESEARCH

SEC. 911. HEALTHCARE OUTCOME IMPROVEMENT RESEARCH.

(a) EVIDENCE RATING SYSTEMS.—In collaboration with experts from the public and private sector, the Agency shall identify and disseminate methods or systems that it uses to assess healthcare research results, particularly methods or systems that it uses to rate the strength of the scientific evidence behind healthcare practice, recommendations in the research literature, and technology assessments. The Agency shall make methods and systems for evidence rating widely available. Agency publications containing healthcare recommendations shall indicate the level of substantiating evidence using such methods or systems.

(b) HEALTHCARE IMPROVEMENT RESEARCH CENTERS AND PROVIDER-BASED RESEARCH NETWORKS.—

(1) IN GENERAL.—In order to address the full continuum of care and outcomes research, to link research to practice improvement, and to speed the dissemination of research findings to community practice settings, the Agency shall employ research strategies and mechanisms that will link research directly with clinical practice in geographically diverse locations throughout the United States, including—

(A) Healthcare Improvement Research Centers that combine demonstrated multidisciplinary expertise in outcomes or quality improvement research with linkages to relevant sites of care;

(B) Provider-based Research Networks, including plan, facility, or delivery system sites of care (especially primary care), that can evaluate and promote quality improvement; and

(C) other innovative mechanisms or strategies to link research with clinical practice.

(2) REQUIREMENTS.—The Director is authorized to establish the requirements for entities applying for grants under this subsection.

SEC. 912. PRIVATE-PUBLIC PARTNERSHIPS TO IMPROVE ORGANIZATION AND DELIVERY.

(a) SUPPORT FOR EFFORTS TO DEVELOP INFORMATION ON QUALITY.—

(1) SCIENTIFIC AND TECHNICAL SUPPORT.—In its role as the principal agency for healthcare research and quality, the Agency may provide scientific and technical support for private and public efforts to improve healthcare quality, including the activities of accrediting organizations.

(2) ROLE OF THE AGENCY.—With respect to paragraph (1), the role of the Agency shall include—

(A) the identification and assessment of methods for the evaluation of the health of—

(i) enrollees in health plans by type of plan, provider, and provider arrangements; and

(ii) other populations, including those receiving long-term care services;

(B) the ongoing development, testing, and dissemination of quality measures, including measures of health and functional outcomes;

(C) the compilation and dissemination of healthcare quality measures developed in the private and public sector;

(D) assistance in the development of improved healthcare information systems;

(E) the development of survey tools for the purpose of measuring participant and beneficiary assessments of their healthcare; and

(F) identifying and disseminating information on mechanisms for the integration of information on quality into purchaser and consumer decision-making processes.

(b) CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS.—

(1) IN GENERAL.—The Secretary, acting through the Director and in consultation with the Commissioner of Food and Drugs, shall establish a program for the purpose of making one or more grants for the establishment and operation of one or more centers to carry out the activities specified in paragraph (2).

(2) REQUIRED ACTIVITIES.—The activities referred to in this paragraph are the following:

(A) The conduct of state-of-the-art clinical research for the following purposes:

(i) To increase awareness of—

(I) new uses of drugs, biological products, and devices;

(II) ways to improve the effective use of drugs, biological products, and devices; and

(III) risks of new uses and risks of combinations of drugs and biological products.

(ii) To provide objective clinical information to the following individuals and entities:

(I) Healthcare practitioners and other providers of healthcare goods or services.

(II) Pharmacists, pharmacy benefit managers and purchasers.

(III) Health maintenance organizations and other managed healthcare organizations.

(IV) Healthcare insurers and governmental agencies.

(V) Patients and consumers.

(iii) To improve the quality of healthcare while reducing the cost of Healthcare through—

(I) an increase in the appropriate use of drugs, biological products, or devices; and

(II) the prevention of adverse effects of drugs, biological products, and devices and the consequences of such effects, such as unnecessary hospitalizations.

(B) The conduct of research on the comparative effectiveness, cost-effectiveness, and safety of drugs, biological products, and devices.

(C) Such other activities as the Secretary determines to be appropriate, except that grant funds may not be used by the Secretary in conducting regulatory review of new drugs.

(c) REDUCING ERRORS IN MEDICINE.—The Director shall conduct and support research and build private-public partnerships to—

(1) identify the causes of preventable healthcare errors and patient injury in healthcare delivery;

(2) develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and

(3) promote the implementation of effective strategies throughout the healthcare industry.

SEC. 913. INFORMATION ON QUALITY AND COST OF CARE.

(a) IN GENERAL.—In carrying out 902(a), the Director shall—

(1) conduct a survey to collect data on a nationally representative sample of the population on the cost, use and, for fiscal year 2001 and subsequent fiscal years, quality of healthcare, including the types of healthcare services Americans use, their access to healthcare services, frequency of use, how much is paid for the services used, the source of those payments, the types and costs of private health insurance, access, satisfaction, and quality of care for the general population including rural residents and for the populations identified in section 901(c); and

(2) develop databases and tools that provide information to States on the quality, access, and use of healthcare services provided to their residents.

(b) QUALITY AND OUTCOMES INFORMATION.—

(1) IN GENERAL.—Beginning in fiscal year 2001, the Director shall ensure that the survey conducted under subsection (a)(1) will—

(A) identify determinants of health outcomes and functional status, and their relationships to healthcare access and use, determine the ways and extent to which the priority populations enumerated in section 901(c) differ from the general population with respect to such variables, measure changes over time with respect to such variable, and

monitor the overall national impact of changes in Federal and State policy on healthcare;

(B) provide information on the quality of care and patient outcomes for frequently occurring clinical conditions for a nationally representative sample of the population including rural residents; and

(C) provide reliable national estimates for children and persons with special healthcare needs through the use of supplements or periodic expansions of the survey.

In expanding the Medical Expenditure Panel Survey, as in existence on the date of enactment of this title, in fiscal year 2001 to collect information on the quality of care, the Director shall take into account any outcomes measurements generally collected by private sector accreditation organizations.

(2) ANNUAL REPORT.—Beginning in fiscal year 2003, the Secretary, acting through the Director, shall submit to Congress an annual report on national trends in the quality of healthcare provided to the American people.

SEC. 914. INFORMATION SYSTEMS FOR HEALTHCARE IMPROVEMENT.

(a) IN GENERAL.—In order to foster a range of innovative approaches to the management and communication of health information, the Agency shall support research, evaluations and initiatives to advance—

(1) the use of information systems for the study of healthcare quality, including the generation of both individual provider and plan-level comparative performance data;

(2) training for healthcare practitioners and researchers in the use of information systems;

(3) the creation of effective linkages between various sources of health information, including the development of information networks;

(4) the delivery and coordination of evidence-based healthcare services, including the use of real-time healthcare decision-support programs;

(5) the utility and comparability of health information data and medical vocabularies by addressing issues related to the content, structure, definitions and coding of such information and data in consultation with appropriate Federal, State and private entities;

(6) the use of computer-based health records in all settings for the development of personal health records for individual health assessment and maintenance, and for monitoring public health and outcomes of care within populations; and

(7) the protection of individually identifiable information in health services research and healthcare quality improvement.

(b) DEMONSTRATION.—The Agency shall support demonstrations into the use of new information tools aimed at improving shared decision-making between patients and their care-givers.

SEC. 915. RESEARCH SUPPORTING PRIMARY CARE AND ACCESS IN UNDERSERVED AREAS.

(a) PREVENTIVE SERVICES TASK FORCE.—

(1) ESTABLISHMENT AND PURPOSE.—The Director may periodically convene a Preventive Services Task Force to be com-

posed of individuals with appropriate expertise. Such a task force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the healthcare community, and updating previous clinical preventive recommendations.

(2) ROLE OF AGENCY.—The Agency shall provide ongoing administrative, research, and technical support for the operations of the Preventive Services Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force.

(3) OPERATION.—In carrying out its responsibilities under paragraph (1), the Task Force is not subject to the provisions of Appendix 2 of title 5, United States Code.

(b) PRIMARY CARE RESEARCH.—

(1) IN GENERAL.—There is established within the Agency a Center for Primary Care Research (referred to in this subsection as the 'Center') that shall serve as the principal source of funding for primary care practice research in the Department of Health and Human Services. For purposes of this paragraph, primary care research focuses on the first contact when illness or health concerns arise, the diagnosis, treatment or referral to specialty care, preventive care, and the relationship between the clinician and the patient in the context of the family and community.

(2) RESEARCH.—In carrying out this section, the Center shall conduct and support research concerning—

(A) the nature and characteristics of primary care practice;

(B) the management of commonly occurring clinical problems;

(C) the management of undifferentiated clinical problems; and

(D) the continuity and coordination of health services.

SEC. 916. CLINICAL PRACTICE AND TECHNOLOGY INNOVATION.

(a) IN GENERAL.—The Director shall promote innovation in evidence-based clinical practice and healthcare technologies by—

(1) conducting and supporting research on the development, diffusion, and use of healthcare technology;

(2) developing, evaluating, and disseminating methodologies for assessments of healthcare practices and healthcare technologies;

(3) conducting intramural and supporting extramural assessments of existing and new healthcare practices and technologies;

(4) promoting education, training, and providing technical assistance in the use of healthcare practice and healthcare technology assessment methodologies and results; and

(5) working with the National Library of Medicine and the public and private sector to develop an electronic clearinghouse of currently available assessments and those in progress.

(b) SPECIFICATION OF PROCESS.—

(1) IN GENERAL.—Not later than December 31, 2000, the Director shall develop and publish a description of the method-

ology used by the Agency and its contractors in conducting practice and technology assessment.

(2) CONSULTATIONS.—In carrying out this subsection, the Director shall cooperate and consult with the Assistant Secretary for Health, the Administrator of the Health Care Financing Administration, the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the heads of any other interested Federal department or agency, and shall seek input, where appropriate, from professional societies and other private and public entities.

(3) METHODOLOGY.—The Director shall, in developing assessment methodology, consider—

(A) safety, efficacy, and effectiveness;

(B) legal, social, and ethical implications;

(C) costs, benefits, and cost-effectiveness;

(D) comparisons to alternate technologies and practices; and

(E) requirements of Food and Drug Administration approval to avoid duplication.

(c) SPECIFIC ASSESSMENTS.—

(1) IN GENERAL.—The Director shall conduct or support specific assessments of healthcare technologies and practices.

(2) REQUESTS FOR ASSESSMENTS.—The Director is authorized to conduct or support assessments, on a reimbursable basis, for the Health Care Financing Administration, the Department of Defense, the Department of Veterans Affairs, the Office of Personnel Management, and other public or private entities.

(3) GRANTS AND CONTRACTS.—In addition to conducting assessments, the Director may make grants to, or enter into cooperative agreements or contracts with, entities described in paragraph (4) for the purpose of conducting assessments of experimental, emerging, existing, or potentially outmoded healthcare technologies, and for related activities.

(4) ELIGIBLE ENTITIES.—An entity described in this paragraph is an entity that is determined to be appropriate by the Director, including academic medical centers, research institutions and organizations, professional organizations, third party payers, governmental agencies, and consortia of appropriate research entities established for the purpose of conducting technology assessments.

SEC. 917. COORDINATION OF FEDERAL GOVERNMENT QUALITY IMPROVEMENT EFFORTS.

(a) REQUIREMENT.—

(1) IN GENERAL.—To avoid duplication and ensure that Federal resources are used efficiently and effectively, the Secretary, acting through the Director, shall coordinate all research, evaluations, and demonstrations related to health services research, quality measurement and quality improvement activities undertaken and supported by the Federal Government.

(2) SPECIFIC ACTIVITIES.—The Director, in collaboration with the appropriate Federal officials representing all concerned executive agencies and departments, shall develop and manage a process to—

(A) improve interagency coordination, priority setting, and the use and sharing of research findings and data pertaining to Federal quality improvement programs, technology assessment, and health services research;

(B) strengthen the research information infrastructure, including databases, pertaining to Federal health services research and healthcare quality improvement initiatives;

(C) set specific goals for participating agencies and departments to further health services research and healthcare quality improvement; and

(D) strengthen the management of Federal healthcare quality improvement programs.

(b) STUDY BY THE INSTITUTE OF MEDICINE.—

(1) IN GENERAL.—To provide Congress, the Department of Health and Human Services, and other relevant departments with an independent, external review of their quality oversight, quality improvement and quality research programs, the Secretary shall enter into a contract with the Institute of Medicine—

(A) to describe and evaluate current quality improvement, quality research and quality monitoring processes through—

(i) an overview of pertinent health services research activities and quality improvement efforts conducted by all Federal programs, with particular attention paid to those under titles XVIII, XIX, and XXI of the Social Security Act; and

(ii) a summary of the partnerships that the Department of Health and Human Services has pursued with private accreditation, quality measurement and improvement organizations; and

(B) to identify options and make recommendations to improve the efficiency and effectiveness of quality improvement programs through—

(i) the improved coordination of activities across the medicare, medicaid and child health insurance programs under titles XVIII, XIX and XXI of the Social Security Act and health services research programs;

(ii) the strengthening of patient choice and participation by incorporating state-of-the-art quality monitoring tools and making information on quality available; and

(iii) the enhancement of the most effective programs, consolidation as appropriate, and elimination of duplicative activities within various federal agencies.

(2) REQUIREMENTS.—

(A) IN GENERAL.—The Secretary shall enter into a contract with the Institute of Medicine for the preparation—

(i) not later than 12 months after the date of enactment of this title, of a report providing an overview of the quality improvement programs of the Department of Health and Human Services for the medicare, medicaid, and CHIP programs under titles XVIII, XIX, and XXI of the Social Security Act; and

(ii) not later than 24 months after the date of enactment of this title, of a final report containing recommendations.

(B) REPORTS.—The Secretary shall submit the reports described in subparagraph (A) to the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Commerce of the House of Representatives.

PART C—GENERAL PROVISIONS

SEC. 921. ADVISORY COUNCIL FOR HEALTHCARE RESEARCH AND QUALITY.

(a) ESTABLISHMENT.—There is established an advisory council to be known as the Advisory Council for Healthcare Research and Quality.

(b) DUTIES.—

(1) IN GENERAL.—The Advisory Council shall advise the Secretary and the Director with respect to activities proposed or undertaken to carry out the purpose of the Agency under section 901(b).

(2) CERTAIN RECOMMENDATIONS.—Activities of the Advisory Council under paragraph (1) shall include making recommendations to the Director regarding—

(A) priorities regarding healthcare research, especially studies related to quality, outcomes, cost and the utilization of, and access to, healthcare services;

(B) the field of healthcare research and related disciplines, especially issues related to training needs, and dissemination of information pertaining to healthcare quality; and

(C) the appropriate role of the Agency in each of these areas in light of private sector activity and identification of opportunities for public-private sector partnerships.

(c) MEMBERSHIP.—

(1) IN GENERAL.—The Advisory Council shall, in accordance with this subsection, be composed of appointed members and ex officio members. All members of the Advisory Council shall be voting members other than the individuals designated under paragraph (3)(B) as ex officio members.

(2) APPOINTED MEMBERS.—The Secretary shall appoint to the Advisory Council 21 appropriately qualified individuals. At least 17 members of the Advisory Council shall be representatives of the public who are not officers or employees of the United States. The Secretary shall ensure that the appointed members of the Council, as a group, are representative of professions and entities concerned with, or affected by, activities under this title and under section 1142 of the Social Security Act. Of such members—

(A) 4 shall be individuals distinguished in the conduct of research, demonstration projects, and evaluations with respect to healthcare;

(B) 4 shall be individuals distinguished in the practice of medicine of which at least 1 shall be a primary care practitioner;

(C) 3 shall be individuals distinguished in the other health professions;

(D) 4 shall be individuals either representing the private healthcare sector, including health plans, providers, and purchasers or individuals distinguished as administrators of healthcare delivery systems;

(E) 4 shall be individuals distinguished in the fields of healthcare quality improvement, economics, information systems, law, ethics, business, or public policy, including at least 1 individual specializing in rural aspects in 1 or more of these fields; and

(F) 2 shall be individuals representing the interests of patients and consumers of healthcare.

(3) EX OFFICIO MEMBERS.—The Secretary shall designate as ex officio members of the Advisory Council—

(A) the Assistant Secretary for Health, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, the Administrator of the Health Care Financing Administration, the Assistant Secretary of Defense (Health Affairs), and the Under Secretary for Health of the Department of Veterans Affairs; and

(B) such other Federal officials as the Secretary may consider appropriate.

(d) TERMS.—Members of the Advisory Council appointed under subsection (c)(2) shall serve for a term of 3 years. A member of the Council appointed under such subsection may continue to serve after the expiration of the term of the members until a successor is appointed.

(e) VACANCIES.—If a member of the Advisory Council appointed under subsection (c)(2) 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 Director shall, from among the members of the Advisory Council appointed under subsection (c)(2), designate an individual to serve as the chair of the Advisory Council.

(g) MEETINGS.—The Advisory Council shall meet not less than once during each discrete 4-month period and shall otherwise meet at the call of the Director or the chair.

(h) COMPENSATION AND REIMBURSEMENT OF EXPENSES.—

(1) APPOINTED MEMBERS.—Members of the Advisory Council appointed under subsection (c)(2) shall receive compensation for each day (including travel time) engaged in carrying out the duties of the Advisory Council unless declined by the member. Such compensation may not be in an amount in excess of the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day during which such member is engaged in the performance of the duties of the Advisory Council.

(2) EX OFFICIO MEMBERS.—Officials designated under subsection (c)(3) as ex officio members of the Advisory Council may not receive compensation for service on the Advisory Council in addition to the compensation otherwise received for duties carried out as officers of the United States.

(i) STAFF.—The Director shall provide to the Advisory Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.

SEC. 922. PEER REVIEW WITH RESPECT TO GRANTS AND CONTRACTS.

(a) REQUIREMENT OF REVIEW.—

(1) IN GENERAL.—Appropriate technical and scientific peer review shall be conducted with respect to each application for a grant, cooperative agreement, or contract under this title.

(2) REPORTS TO DIRECTOR.—Each peer review group to which an application is submitted pursuant to paragraph (1) shall report its finding and recommendations respecting the application to the Director in such form and in such manner as the Director shall require.

(b) APPROVAL AS PRECONDITION OF AWARDS.—The Director may not approve an application described in subsection (a)(1) unless the application is recommended for approval by a peer review group established under subsection (c).

(c) ESTABLISHMENT OF PEER REVIEW GROUPS.—

(1) IN GENERAL.—The Director shall establish such technical and scientific peer review groups as may be necessary to carry out this section. Such groups shall be established without regard to the provisions of title 5, United States Code, that govern appointments in the competitive service, and without regard to the provisions of chapter 51, and subchapter III of chapter 53, of such title that relate to classification and pay rates under the General Schedule.

(2) MEMBERSHIP.—The members of any peer review group established under this section shall be appointed from among individuals who by virtue of their training or experience are eminently qualified to carry out the duties of such peer review group. Officers and employees of the United States may not constitute more than 25 percent of the membership of any such group. Such officers and employees may not receive compensation for service on such groups in addition to the compensation otherwise received for these duties carried out as such officers and employees.

(3) DURATION.—Notwithstanding section 14(a) of the Federal Advisory Committee Act, peer review groups established under this section may continue in existence until otherwise provided by law.

(4) QUALIFICATIONS.—Members of any peer-review group shall, at a minimum, meet the following requirements:

(A) Such members shall agree in writing to treat information received, pursuant to their work for the group, as confidential information, except that this subparagraph shall not apply to public records and public information.

(B) Such members shall agree in writing to recuse themselves from participation in the peer-review of specific applications which present a potential personal conflict of in-

terest or appearance of such conflict, including employment in a directly affected organization, stock ownership, or any financial or other arrangement that might introduce bias in the process of peer-review.

(d) AUTHORITY FOR PROCEDURAL ADJUSTMENTS IN CERTAIN CASES.—In the case of applications for financial assistance whose direct costs will not exceed $100,000, the Director may make appropriate adjustments in the procedures otherwise established by the Director for the conduct of peer review under this section. Such adjustments may be made for the purpose of encouraging the entry of individuals into the field of research, for the purpose of encouraging clinical practice-oriented or provider-based research, and for such other purposes as the Director may determine to be appropriate.

(e) REGULATIONS.—The Director shall issue regulations for the conduct of peer review under this section.

SEC. 923. CERTAIN PROVISIONS WITH RESPECT TO DEVELOPMENT, COLLECTION, AND DISSEMINATION OF DATA.

(a) STANDARDS WITH RESPECT TO UTILITY OF DATA.—

(1) IN GENERAL.—To ensure the utility, accuracy, and sufficiency of data collected by or for the Agency for the purpose described in section 901(b), the Director shall establish standard methods for developing and collecting such data, taking into consideration—

(A) other Federal health data collection standards; and

(B) the differences between types of healthcare plans, delivery systems, healthcare providers, and provider arrangements.

(2) RELATIONSHIP WITH OTHER DEPARTMENT PROGRAMS.—In any case where standards under paragraph (1) may affect the administration of other programs carried out by the Department of Health and Human Services, including the programs under title XVIII, XIX or XXI of the Social Security Act, or may affect health information that is subject to a standard developed under part C of title XI of the Social Security Act, they shall be in the form of recommendations to the Secretary for such program.

(b) STATISTICS AND ANALYSES.—The Director shall—

(1) take appropriate action to ensure that statistics and analyses developed under this title are of high quality, timely, and duly comprehensive, and that the statistics are specific, standardized, and adequately analyzed and indexed; and

(2) publish, make available, and disseminate such statistics and analyses on as wide a basis as is practicable.

(c) AUTHORITY REGARDING CERTAIN REQUESTS.—Upon request of a public or private entity, the Director may conduct or support research or analyses otherwise authorized by this title pursuant to arrangements under which such entity will pay the cost of the services provided. Amounts received by the Director under such arrangements shall be available to the Director for obligation until expended.

SEC. 924. DISSEMINATION OF INFORMATION.

(a) IN GENERAL.—The Director shall—

(1) without regard to section 501 of title 44, United States Code, promptly publish, make available, and otherwise disseminate, in a form understandable and on as broad a basis as practicable so as to maximize its use, the results of research, demonstration projects, and evaluations conducted or supported under this title;

(2) ensure that information disseminated by the Agency is science-based and objective and undertakes consultation as necessary to assess the appropriateness and usefulness of the presentation of information that is targeted to specific audiences;

(3) promptly make available to the public data developed in such research, demonstration projects, and evaluations;

(4) provide, in collaboration with the National Library of Medicine where appropriate, indexing, abstracting, translating, publishing, and other services leading to a more effective and timely dissemination of information on research, demonstration projects, and evaluations with respect to healthcare to public and private entities and individuals engaged in the improvement of healthcare delivery and the general public, and undertake programs to develop new or improved methods for making such information available; and

(5) as appropriate, provide technical assistance to State and local government and health agencies and conduct liaison activities to such agencies to foster dissemination.

(b) PROHIBITION AGAINST RESTRICTIONS.—Except as provided in subsection (c), the Director may not restrict the publication or dissemination of data from, or the results of, projects conducted or supported under this title.

(c) LIMITATION ON USE OF CERTAIN INFORMATION.—No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under this title may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Director) to its use for such other purpose. Such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Director) to its publication or release in other form.

(d) PENALTY.—Any person who violates subsection (c) shall be subject to a civil monetary penalty of not more than $10,000 for each such violation involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A of the Social Security Act are imposed and collected.

SEC. 925. ADDITIONAL PROVISIONS WITH RESPECT TO GRANTS AND CONTRACTS.

(a) FINANCIAL CONFLICTS OF INTEREST.—With respect to projects for which awards of grants, cooperative agreements, or contracts are authorized to be made under this title, the Director shall by regulation define—

(1) the specific circumstances that constitute financial interests in such projects that will, or may be reasonably expected

to, create a bias in favor of obtaining results in the projects that are consistent with such interests; and

(2) the actions that will be taken by the Director in response to any such interests identified by the Director.

(b) REQUIREMENT OF APPLICATION.—The Director may not, with respect to any program under this title authorizing the provision of grants, cooperative agreements, or contracts, provide any such financial assistance unless an application for the assistance is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out the program involved.

(c) PROVISION OF SUPPLIES AND SERVICES IN LIEU OF FUNDS.—

(1) IN GENERAL.—Upon the request of an entity receiving a grant, cooperative agreement, or contract under this title, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the entity in carrying out the project involved and, for such purpose, may detail to the entity any officer or employee of the Department of Health and Human Services.

(2) CORRESPONDING REDUCTION IN FUNDS.—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of the financial assistance involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Director. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(d) APPLICABILITY OF CERTAIN PROVISIONS WITH RESPECT TO CONTRACTS.—Contracts may be entered into under this part without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

SEC. 926. CERTAIN ADMINISTRATIVE AUTHORITIES.

(a) DEPUTY DIRECTOR AND OTHER OFFICERS AND EMPLOYEES.—

(1) DEPUTY DIRECTOR.—The Director may appoint a deputy director for the Agency.

(2) OTHER OFFICERS AND EMPLOYEES.—The Director may appoint and fix the compensation of such officers and employees as may be necessary to carry out this title. Except as otherwise provided by law, such officers and employees shall be appointed in accordance with the civil service laws and their compensation fixed in accordance with title 5, United States Code.

(b) FACILITIES.—The Secretary, in carrying out this title—

(1) may acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Director of General Services, buildings or portions of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed 10 years; and

(2) may acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other real or personal property (including patents) as the Secretary deems necessary.

(c) PROVISION OF FINANCIAL ASSISTANCE.—The Director, in carrying out this title, may make grants to public and nonprofit entities and individuals, and may enter into cooperative agreements or contracts with public and private entities and individuals.

(d) UTILIZATION OF CERTAIN PERSONNEL AND RESOURCES.—

(1) DEPARTMENT OF HEALTH AND HUMAN SERVICES.—The Director, in carrying out this title, may utilize personnel and equipment, facilities, and other physical resources of the Department of Health and Human Services, permit appropriate (as determined by the Secretary) entities and individuals to utilize the physical resources of such Department, and provide technical assistance and advice.

(2) OTHER AGENCIES.—The Director, in carrying out this title, may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, or of any foreign government, with or without reimbursement of such agencies.

(e) CONSULTANTS.—The Secretary, in carrying out this title, may secure, from time to time and for such periods as the Director deems advisable but in accordance with section 3109 of title 5, United States Code, the assistance and advice of consultants from the United States or abroad.

(f) EXPERTS.—

(1) IN GENERAL.—The Secretary may, in carrying out this title, obtain the services of not more than 50 experts or consultants who have appropriate scientific or professional qualifications. Such experts or consultants shall be obtained in accordance with section 3109 of title 5, United States Code, except that the limitation in such section on the duration of service shall not apply.

(2) TRAVEL EXPENSES.—

(A) IN GENERAL.—Experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed for their expenses associated with traveling to and from their assignment location in accordance with sections 5724, 5724a(a), 5724a(c), and 5726(C) of title 5, United States Code.

(B) LIMITATION.—Expenses specified in subparagraph (A) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless and until the expert agrees in writing to complete the entire period of assignment, or 1 year, whichever is shorter, unless separated or reassigned for reasons that are beyond the control of the expert or consultant and that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable from the expert or consultant as a statutory obligation owed to the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

(g) VOLUNTARY AND UNCOMPENSATED SERVICES.—The Director, in carrying out this title, may accept voluntary and uncompensated services.

SEC. 927. FUNDING.

(a) INTENT.—To ensure that the United States's investment in biomedical research is rapidly translated into improvements in the quality of patient care, there must be a corresponding investment in research on the most effective clinical and organizational strategies for use of these findings in daily practice. The authorization levels in subsection (b) and (c) provide for a proportionate increase in healthcare research as the United States investment in biomedical research increases.

(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this title, there are authorized to be appropriated $250,000,000 for fiscal year 2000, and such sums as may be necessary for each of the fiscal years 2001 through 2006.

(c) EVALUATIONS.—In addition to amounts available pursuant to subsection (b) for carrying out this title, there shall be made available for such purpose, from the amounts made available pursuant to section 241 (relating to evaluations), an amount equal to 40 percent of the maximum amount authorized in such section 241 to be made available for a fiscal year.

SEC. 928. DEFINITIONS.

In this title:

(1) ADVISORY COUNCIL.—The term "Advisory Council" means the Advisory Council on Healthcare Research and Quality established under section 921.

(2) AGENCY.—The term "Agency" means the Agency for Healthcare Research and Quality.

(3) DIRECTOR.—The term "Director" means the Director for the Agency for Healthcare Research and Quality.

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TITLE XXVII—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

PART A—GROUP MARKET REFORMS

Subpart 1—Portability, Access, and Renewability Requirements

SEC. 2701. INCREASED PORTABILITY THROUGH LIMITATION ON PREEXISTING CONDITION EXCLUSIONS.

(a) LIMITATION ON PREEXISTING CONDITION EXCLUSION PERIOD; CREDITING FOR PERIODS OF PREVIOUS COVERAGE. * * *

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SEC. 2702. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.

(a) IN ELIGIBILITY TO ENROLL.—

(1) IN GENERAL. * * *

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(F) Genetic information *(including information about a request for or receipt of genetic services).*

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(3) REFERENCE TO RELATED PROVISION.—For a provision prohibiting the adjustment of premium or contribution amounts for

a group under a group health plan on the basis of predictive genetic information (including information about a request for or receipt of genetic services), see section 2707.

(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (d), of such predictive genetic information.

(d) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

(A) PREPARATION OF WRITTEN NOTICE.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall post or provide, in writing and in a clear and conspicuous manner, notice of the plan or issuer's confidentiality practices, that shall include—

(i) a description of an individual's rights with respect to predictive genetic information;

(ii) the procedures established by the plan or issuer for the exercise of the individual's rights; and

(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

(2) ESTABLISHMENT OF SAFEGUARDS.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such plan or issuer.

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SEC. 2707. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION IN THE GROUP MARKET.

A group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan shall not adjust premium or contribution amounts for a group on the basis of predictive genetic information concerning any individual (including a dependent) or family member of the individual (including information about a request for or receipt of genetic services).

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Subpart [3]2—Other Requirements

SEC. 2751. STANDARDS RELATING TO BENEFITS FOR MOTHERS AND NEWBORNS.

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SEC. 2753. PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

(a) PROHIBITION ON PREDICTIVE GENETIC INFORMATION AS A CONDITION OF ELIGIBILITY.—A health insurance issuer offering health insurance coverage in the individual market may not use predictive genetic information as a condition of eligibility of an individual to enroll in individual health insurance coverage (including information about a request for or receipt of genetic services).

(b) PROHIBITION ON PREDICTIVE GENETIC INFORMATION IN SETTING PREMIUM RATES.—A health insurance issuer offering health insurance coverage in the individual market shall not adjust premium rates for individuals on the basis of predictive genetic information concerning such an individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a health insurance issuer offering health insurance coverage in the individual market shall not request or require predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

(A) IN GENERAL.—Notwithstanding paragraph (1), a health insurance issuer offering health insurance coverage

in the individual market that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the health insurance issuer offering health insurance coverage in the individual market shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (d), of such predictive genetic information.

(d) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

(A) PREPARATION OF WRITTEN NOTICE.—A health insurance issuer offering health insurance coverage in the individual market shall post or provide, in writing and in a clear and conspicuous manner, notice of the issuer's confidentiality practices, that shall include—

(i) a description of an individual's rights with respect to predictive genetic information;

(ii) the procedures established by the issuer for the exercise of the individual's rights; and

(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

(2) ESTABLISHMENT OF SAFEGUARDS.—A health insurance issuer offering health insurance coverage in the individual market shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such issuer.

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PART C—DEFINITIONS; MISCELLANEOUS PROVISIONS

SEC. 2791. DEFINITIONS.

(a) GROUP HEALTH PLAN.—

(1) DEFINITION. * * *

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(d) OTHER DEFINITIONS.—

(1) APPLICABLE STATE AUTHORITY. * * *

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(15) FAMILY MEMBER.—The term "family member" means, with respect to an individual—

(A) the spouse of the individual;

(B) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and

(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

(16) GENETIC INFORMATION.—The term "genetic information" means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member (including information about a request for or receipt of genetic services).

(17) GENETIC SERVICES.—The term "genetic services" means health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

(18) PREDICTIVE GENETIC INFORMATION.—

(A) IN GENERAL.—The term "predictive genetic information" means, in the absence of symptoms, clinical signs, or a diagnosis of the condition related to such information—

(i) information about an individual's genetic tests;

(ii) information about genetic tests of family members of the individual; or

(iii) information about the occurrence of a disease or disorder in family members.

(B) EXCEPTIONS.—The term "predictive genetic information" shall not include—

(i) information about the sex or age of the individual;

(ii) information derived from physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests; and

(iii) information about physical exams of the individual.

(19) GENETIC TEST.—The term "genetic test" means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals. Such term does not include physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests, and physical exams of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease.

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INTERNAL REVENUE ACT OF 1986

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Section 1. * * *

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Sec. 9813. Health plan comparative information.

Sec. 9814. Prohibiting premium discrimination against groups on the basis of predictive genetic information.

SEC. 9802. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.

(a) IN ELIGIBILITY TO ENROLL.—

(1) IN GENERAL. * * *

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(F) Genetic information (including information about a request for or receipt of genetic services).

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(b) IN PREMIUM CONTRIBUTIONS.—

(1) IN GENERAL. * * *

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(3) REFERENCE TO RELATED PROVISION.—For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group health plan on the basis of predictive genetic information (including information about a request for or the receipt of genetic services), see section 9814.

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(d) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a group health plan shall not request or require predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

(B) NOTICE OF CONFIDENTIALITY PRACTICES; DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (e), of such predictive genetic information.

(e) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

(A) PREPARATION OF WRITTEN NOTICE.—A group health plan shall post or provide, in writing and in a clear and conspicuous manner, notice of the plan's confidentiality practices, that shall include—

(i) a description of an individual's rights with respect to predictive genetic information;

(ii) the procedures established by the plan for the exercise of the individual's rights; and

(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

(2) ESTABLISHMENT OF SAFEGUARDS.—A group health plan shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such plan.

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SEC. 9813. HEALTH PLAN COMPARATIVE INFORMATION.

(a) REQUIREMENT.—

(1) IN GENERAL.—A group health plan shall, not later than 12 months after the date of enactment of this section, and at least annually thereafter, provide for the disclosure, in a clear and accurate form to each participant and beneficiary, or upon request to a potential participant or beneficiary eligible to receive benefits under the plan, of the information described in subsection (b).

(2) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to prevent a plan from entering into any agreement under which a health insurance issuer agrees to assume responsibility for compliance with the requirements of this section and the plan is released from liability for such compliance.

(3) PROVISION OF INFORMATION.—Information shall be provided to participants and beneficiaries under this section at the address maintained by the plan with respect to such participants or beneficiaries.

(b) REQUIRED INFORMATION.—The informational materials to be distributed under this section shall include for each package option available under a group health plan the following:

(1) A description of the covered items and services under each such plan and any in- and out-of-network features of each such plan, including a summary description of the specific exclusions from coverage under the plan.

(2) A description of any cost-sharing, including premiums, deductibles, coinsurance, and copayment amounts, for which the participant or beneficiary will be responsible, including any annual or lifetime limits on benefits, for each such plan.

(3) A description of any optional supplemental benefits offered by each such plan and the terms and conditions (including premiums or cost-sharing) for such supplemental coverage.

(4) A description of any restrictions on payments for services furnished to a participant or beneficiary by a health care professional that is not a participating professional and the liabil-

ity of the participant or beneficiary for additional payments for these services.

(5) A description of the service area of each such plan, including the provision of any out-of-area coverage.

(6) A description of the extent to which participants and beneficiaries may select the primary care provider of their choice, including providers both within the network and outside the network of each such plan (if the plan permits out-of-network services).

(7) A description of the procedures for advance directives and organ donation decisions if the plan maintains such procedures.

(8) A description of the requirements and procedures to be used to obtain preauthorization for health services (including telephone numbers and mailing addresses), including referrals for specialty care.

(9) A description of the definition of medical necessity used in making coverage determinations by each such plan.

(10) A summary of the rules and methods for appealing coverage decisions and filing grievances (including telephone numbers and mailing addresses), as well as other available remedies.

(11) A summary description of any provisions for obtaining off-formulary medications if the plan utilizes a defined formulary for providing specific prescription medications.

(12) A summary of the rules for access to emergency room care. Also, any available educational material regarding proper use of emergency services.

(13) A description of whether or not coverage is provided for experimental treatments, investigational treatments, or clinical trials and the circumstances under which access to such treatments or trials is made available.

(14) A description of the specific preventative services covered under the plan if such services are covered.

(15) A statement regarding—

(A) the manner in which a participant or beneficiary may access an obstetrician, gynecologist, or pediatrician in accordance with section 723 or 724; and

(B) the manner in which a participant or beneficiary obtains continuity of care as provided for in section 726.

(16) A statement that the following information, and instructions on obtaining such information (including telephone numbers and, if available, Internet websites), shall be made available upon request:

(A) The names, addresses, telephone numbers, and State licensure status of the plan's participating health care professionals and participating health care facilities, and, if available, the education, training, speciality qualifications or certifications of such professionals.

(B) A summary description of the methods used for compensating participating health care professionals, such as capitation, fee-for-service, salary, or a combination thereof. The requirement of this subparagraph shall not be construed as requiring plans to provide information concerning proprietary payment methodology.

(C) A summary description of the methods used for compensating health care facilities, including per diem, fee-for-service, capitation, bundled payments, or a combination thereof. The requirement of this subparagraph shall not be construed as requiring plans to provide information concerning proprietary payment methodology.

(D) A summary description of the procedures used for utilization review.

(E) The list of the specific prescription medications included in the formulary of the plan, if the plan uses a defined formulary.

(F) A description of the specific exclusions from coverage under the plan.

(G) Any available information related to the availability of translation or interpretation services for non-English speakers and people with communication disabilities, including the availability of audio tapes or information in Braille.

(H) Any information that is made public by accrediting organizations in the process of accreditation if the plan is accredited, or any additional quality indicators that the plan makes available.

(c) MANNER OF DISTRIBUTION.—The information described in this section shall be distributed in an accessible format that is understandable to an average plan participant or beneficiary.

(d) RULE OF CONSTRUCTION.—Nothing in this section may be construed to prohibit a group health plan from distributing any other additional information determined by the plan to be important or necessary in assisting participants and beneficiaries or upon request potential participants and beneficiaries in the selection of a health plan or from providing information under subsection (b)(15) as part of the required information.

SEC. 9814. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

A group health plan shall not adjust premium or contribution amounts for a group on the basis of predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

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SEC. 9832. DEFINITIONS.

(a) GROUP HEALTH PLAN.

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(d) OTHER DEFINITIONS.—For purposes of this chapter—

(1) COBRA CONTINUATION PROVISIONS. * * *

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(6) FAMILY MEMBER.—The term "family member" means, with respect to an individual—

(A) the spouse of the individual;

(B) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and

(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

(7) GENETIC INFORMATION.—The term "genetic information" means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member (including information about a request for or receipt of genetic services).

(8) GENETIC SERVICES.—The term "genetic services" means health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

(9) PREDICTIVE GENETIC INFORMATION.—

(A) IN GENERAL.—The term "predictive genetic information" means, in the absence of symptoms, clinical signs, or a diagnosis of the condition related to such information—

(i) information about an individual's genetic tests;

(ii) information about genetic tests of family members of the individual; or

(iii) information about the occurrence of a disease or disorder in family members.

(B) EXCEPTIONS.—The term "predictive genetic information" shall not include—

(i) information about the sex or age of the individual;

(ii) information derived from physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests; and

(iii) information about physical exams of the individual.

(10) GENETIC TEST.—The term "genetic test" means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals. Such term does not include physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests, and physical exams of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease.

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