

2. Laws, Acts, and Regulations Affecting Health Care

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2.1 Privacy Act (1974)

The Privacy Act of 1974 is a code of fair information practices which mandates how Government agencies, such as the Indian Health Service (IHS), shall maintain records about individuals. The Privacy Act requires that Government agencies:

- collect only information that is relevant, accurate, complete, and necessary to carry out an agency function;
- maintain no secret records on individuals;
- explain at the time the information is being collected, why it is needed and how it will be used;
- ensure that the records are used only for the reasons given, or seek the person's permission when another purpose for their use is considered necessary or desirable;
- provide adequate safeguards to protect the records from unauthorized access and disclosure;
- Allow individuals to see the records kept on them and provide them with the opportunity to correct inaccuracies in their records.

The Privacy Act only applies to Government records that contain information on individuals, are maintained by a Government agency or its contractors in an approved system of records, and are retrieved by a personal identifier, such as a person's name, Social Security Number, medical record number or other unique identifier.

2.2 Health Insurance Portability and Accountability Act (1996)

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 (P.L. 104-191) amends the Internal Revenue Code of 1986 and is designed to

- Improve portability and continuity of health insurance coverage in the group and individual markets.
- Combat waste, fraud, and abuse in health insurance and health care delivery.
- Promote the use of medical savings accounts.

- Improve access to long-term care services and coverage.
- Simplify the administration of health insurance, and for other purposes.

It is the purpose of this subtitle to improve the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of such Act, and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information.

Standards for Electronic Health Information Transactions

The Secretary of Health and Human Services (HHS) is required to adopt standards from among those already approved by private standards developing organizations for certain electronic health transactions, including claims, enrollment, eligibility, payment, and coordination of benefits. These standards also must address the security of electronic health information systems.

Mandate on Providers and Health Plans

Providers and health plans are required to use the standards for the specified electronic transactions. Plans and providers may comply directly, or may use a health care clearinghouse. Certain health plans, in particular workers compensation, are not covered.

Privacy

Privacy standards must be enacted.

Pre-Emption of State Law

The bill supersedes state laws, except where the Secretary determines that the State law is necessary to prevent fraud and abuse, to ensure appropriate state regulation of insurance or health plans, addresses controlled substances, or for other purposes. If the Secretary promulgates privacy regulations, those regulations do not pre-empt state laws that impose more stringent requirements. These provisions do not limit a State's ability to require health plan reporting or audits.

Penalties

The bill imposes civil money penalties and prison for certain violations.

2.3 Privacy Rule

Privacy regulations are designed to protect individually identifiable health care information during the transfer, storage, release, and destruction of that information. All medical records and other individual identifiable health information used or disclosed by a covered entity in any form, whether electronically, on paper, or orally, are covered by the final Privacy Rule.

Under the Privacy Rule, patients will have significant new rights to understand and control how their health information is used.

- **Patient education on privacy protections.** Providers and health plans will be required to give patients a clear written explanation of how the covered entity may use and disclose their health information.
- **Ensuring patient access to their medical records.** Patients will be able to see and get copies of their records and request amendments. In addition, a history of non-routine disclosures must be made accessible to patients.
- **Receiving patient consent information is released.** Health care providers who see patients will be required to obtain patient consent before sharing their information for treatment, payment, and health care operations. In addition, separate patient authorization must be obtained for non-routine disclosures and most non-health care purposes.

Patients will have the right to request restrictions on the uses and disclosures of their information. As part of this process, providers and facilities will need to create controls for staff, as well as their business partners (such as outsourced billing companies or clearing houses), and keep track of the various requests for information.

- **Providing recourse if privacy protections are violated.** People will have the right to file a formal complaint with a covered provider or health plan, or with the Department of Health and Human Services, about violations of the provisions of this rule or the policies and procedures of the covered entity.

With few exceptions, such as appropriate law enforcement needs, an individual's health information may only be used for health purposes.

- **Ensuring that health information is not used for non-health purposes.** Health information covered by the rule generally may not be used for purposes not related to health care – such as disclosures to employers to make personnel decisions or to financial institutions – without explicit authorization from the individual.

- **Providing the minimum amount of information necessary.** In general, disclosures of information will be limited to the minimum necessary for the purpose of the disclosure. However, this provision does not apply to the disclosure of medical records for treatment purposes because physicians and other providers need access to the full record to provide quality of care.

The final rule establishes the privacy safeguard standards that covered facilities must meet, but it gives these same facilities the flexibility to design their own policies and procedures to meet those standards. Covered facilities will have to:

- **Adopt written privacy procedures.** These include who has access to protected information, how it will be used within the entity, and when the information may be disclosed. Covered entities will also need to take steps to ensure that their business associates protect the privacy of health information.
- **Train employees and designate a privacy officer.** Covered entities will need to train their employees in their privacy procedures and must designate an individual to be responsible for ensuring the procedures are followed.

With the passage of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Congress provided penalties for covered entities that misuse personal health information from the medical record. They include:

- **Civil penalties.** Health plans, providers, and clearing houses that violate these standards will be subject to civil liability. Civil money penalties are \$100 per violation, up to \$25,000 per person, per year for each requirement or prohibition violated.
- **Federal criminal penalties.** Under HIPAA, Congress also established criminal penalties for knowingly violating patient privacy. Criminal penalties are up to \$50,000 and one year in prison for obtaining or disclosing protected health information; up to \$100,000 and up to five years in prison for obtaining protected health information under “false pretenses”; and up to \$250,000 and up to 10 years in prison for obtaining or disclosing protected health information with the intent to sell, transfer, or use it for commercial advantage, personal gain, or malicious harm.

The final privacy rule permits, but does not require, covered entities to continue certain existing disclosures of health information without individual authorization for specific public responsibilities. These permitted disclosures include:

- Emergency circumstances
- Identification of the body of a deceased person or the cause of death
- Public health needs
- Research, generally limited to when a waiver of authorization is independently approved by a privacy board or Institutional Review Board
- Oversight of the health care system
- Judicial and administrative proceedings
- Limited law enforcement activities
- Activities related to national defense and security

Psychotherapy notes (used only by a psychotherapist) are held to a higher standard of protection because they are not part of the medical record and never intended to be shared with anyone else. All other personal health information is considered to be sensitive and protected consistently under this rule.

As required by HIPAA law itself, stronger state laws (like those covering mental health, HIV infection, and AIDS information) continue to apply. These confidentiality protections are cumulative; the final rule will set a national “floor” of privacy standards that protect everyone.

Many of the Indian facilities are reviewed by the Joint Commission standards which do include survey questions related to security. However, while compliance with the Joint Commission standards is a good start, facilities still have a lot of work to do to be in full compliance with the information security standards outlined in the HIPAA regulations.

HIPAA is a springboard for the health care industry to enter the world of e-commerce. With proper security measures (encryption, certificates of authority and private key infrastructure, to name a few, clinical and financial information may be exchanged safely via the Internet in real time.

For a discussion on the impact of the Privacy Rule on Business Office operations, see Part 1, Chapter 4, “Health Insurance Portability and Accountability Act Privacy Rule.”

2.4 Patient Self-Determination Act

The Patient Self-Determination Act has had a major impact on hospital and health care providers because it establishes guidelines that require the maintenance of written policies and procedures governing patients' rights to make health care decisions and the obligation of health care providers to communicate this information as well as other related information to their adult patients.

This includes the patient's right to accept or refuse medical or surgical treatment, as well as the patient's right to make advance directives. The law defines an advance directive as a written instruction, such as a Living Will or a Durable Power of Attorney for health care, related to the provision of health care when the patient is incapacitated. Providers will also be required to provide adult patients with written policies respecting their patient rights.

2.5 False Claims Act

The False Claims Act imposes liability on those who:

- Knowingly present or cause to be presented a false or fraudulent claim for payment to the U.S. government
- Knowingly use a false record or statement to obtain payment on a false or fraudulent claim paid by the U.S. government
- Engage in a conspiracy to defraud the U.S. government to obtain allowance for or payment of a false or fraudulent claim

The False Claim Act defines "knowing" or "knowingly" as having actual knowledge of the falsity of the claim, acting in deliberate ignorance of the truth or the falsity of the claim, or acting in reckless disregard of the truth or falsity of the claim.

The Act prescribes civil monetary penalties for violation from \$5,000 to \$10,000 per claim or higher. The statute of limitations for a False Claims Act action is six years; however, there is a "discovery rule" that may be tallied three years from the point at which the government or realtor knew or should have known of the alleged fraud.

2.6 Emergency Medical Treatment and Active Labor Act (EMTALA)

Originally enacted in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act (COBRA), the Emergency Medical Treatment and Active Labor Act (EMTALA) specifically prohibits hospitals and emergency medical departments from refusing to treat individuals with unstable emergency medical conditions, and prohibits inappropriate transfer of those individuals.

COBRA was amended in both 1988 and 1989 to include more stringent provisions regarding on-call physicians in general and more specifically, the practice of obstetrics.

For IHS compliance requirements related to this Act, see Section see Part 1, Chapter 3, Section 3.4.2, “Emergency Medical Treatment and Active Labor Act (EMTALA),”

2.7 Balanced Budget Act (1997)

The Balanced Budget Act of 1997 (BBA) focuses on reducing payments to hospitals and providers over the forthcoming years. Some of the reductions are:

- Reduced rates of increase for health care facility payments
- Reductions to PPS capital payments
- Elimination of medical education and disproportionate share factors in computing health care facility outlier payments
- Reductions in the indirect medical education payment factor
- Decreased payment for certain health care facility discharges that will now be deemed to be transfers
- A reduction in the amount paid by Medicare for beneficiary-incurred bad debts.
- Increased Medicare Part B payment

Highlights of changes that have occurred:

- Patient selection of choosing either a fee-for-service program or a Medicare-Choice Plan that include coordinated care plans from Health Maintenance Organizations (HMOs), Preferred Provider Organizations (PPOs), and insurance plans operated in conjunction with Medical Savings Accounts (MSAs)
- Co-payment changes from 20% of charges to 20% of payment

- A hospital outpatient Prospective Payment System (PPS)
- Having home health plans submit claims based on the location of where the service was performed versus where the plan is located.
- Fraud and abuse regulations, controls, and penalties

2.8 Federal Medical Care Recovery Act (FMCRA)

Sec. 2651. Recovery by United States

- (a) Conditions; exceptions; persons liable; amount of recovery; subrogation; assignment

In any case in which the United States is authorized or required by law to furnish or pay for hospital, medical, surgical, or dental care and treatment (including prostheses and medical appliances) to a person who is injured or suffers a disease, after the effective date of this Act, under circumstances creating a tort liability upon some third person to pay damages, therefore, the United States shall have a right to recover (independent of the rights of the injured or diseased person) from said third person, or that person's insurer, the reasonable value of the care and treatment so furnished, to be furnished, paid for, or to be paid for and shall as to this right be subrogated to any right or claim that the injured or diseased person, his guardian, personal representative, estate, dependents, or survivors has against such third person to the extent of the reasonable value of the care and treatment so furnished, to be furnished, paid for, or to be paid for. The head of the department or agency of the United States furnishing such care or treatment may also require the injured or diseased person, his guardian, personal representative, estate, dependents, or survivors, as appropriate, to assign his claim or cause of action against the third person to the extent of that right or claim.

- (b) Recovery of cost of pay for member of uniformed services unable to perform duties

If a member of the uniformed services is injured, or contracts a disease, under circumstances creating a tort liability upon a third person for damages for such injury or disease and the member is unable to perform the member's regular military duties as a result of the injury or disease, the United States shall have a right (independent of the rights of the member) to recover from the third person or an insurer of the third person, or both, the amount equal to the total amount of the pay that accrues and is to accrue to the member for the period for which the member is unable to perform such duties as a result of the injury or disease and is not assigned to perform other military duties.

- (c) United States deemed third party beneficiary under alternative system of compensation

(1) If, pursuant to the laws of a State that are applicable in a case of a member of the uniformed services who is injured or contracts a disease as a result of tortious conduct of a third person, there is in effect for such a case (as a substitute or alternative for compensation for damages through tort liability) a system of compensation or reimbursement for expenses of hospital, medical, surgical, or dental care and treatment or for lost pay pursuant to a policy of insurance, contract, medical or hospital service agreement, or similar arrangement, the United States shall be deemed to be a third-party beneficiary of such a policy, contract, agreement or arrangement.

- (2) For the purposes of paragraph (1) -

(A) The expenses incurred or to be incurred by the United States for care and treatment for an injured or diseased member shall be deemed to have been incurred by the member.

(B) The cost to the United States of the pay of the member shall be deemed to have been pay lost by the member as a result of the injury or disease, and

(C) The United States shall be subrogated to any right or claim that the injured or diseased member or the member's guardian, personal representative, estate, dependents, or survivors have under a policy, contract, agreement, or arrangement

- (d) Enforcement procedure; intervention; joinder of parties; State or Federal court proceedings

The United States may intervene or join in any action or proceeding brought by the injured or diseased person, his guardian, personal representative, estate, dependents, or survivors, against the third person who is liable for the injury or disease or the insurance carrier or other entity responsible for the payment of reimbursement of the medical expenses or lost pay. If such action or proceeding is not commenced within six months after the first day in which care and treatment is furnished or paid for by the United States in connection with the injury or disease involved, institute and prosecute legal proceedings against the third person who is liable for the injury or disease or the insurance carrier or other entity responsible for the payment or reimbursement of medical expenses or lost pay, in a State or Federal court, either alone or in conjunction with the injured or diseased person, his guardian, personal representative, estate, dependents, or survivors.

- (e) Veterans' exception

The provisions of this section shall not apply with respect to hospital, medical, surgical, or dental care and treatment furnished by the Department of Veterans Affairs to an eligible veteran for a service-connected disability.

- (f) Crediting of amounts recovered

- (1) Any amount recovered under this section for medical care and related services furnished by a military medical treatment facility or similar military activity shall be credited to the appropriation or appropriations supporting the operation of that facility or activity, as determined under regulations prescribed by the Secretary of Defense
- (2) Any amount recovered under this section for the cost to the United States of pay of an injured or diseased member of the uniformed services shall be credited to the appropriation that supports the operation of the command, activity, or other unit to which the member was assigned at the time of the injury or illness, as determined under regulations prescribed by the Secretary concerned.

2.9 Administrative Simplification Compliance Act

Signed into law on December 27, 2001 as Public Law 107-105, the Administrative Simplification Compliance Act provides a one-year extension to HIPAA “covered entities” to meet HIPAA electronic and code set transaction requirements. Also, this Act allows the Secretary of HHS to exclude providers from Medicare if they are not compliant with the HIPAA electronic and code set transaction requirements and to prohibit Medicare payment of paper claims received after October 16, 2003, except under certain situations.

2.10 Indian Health Care Improvement Act Reauthorization (2001)

Congress makes the following findings:

- (1) Federal delivery of health services and funding of tribal and urban Indian health programs to maintain and improve the health of the Indians are consonant with and required by the Federal Government's historical and unique legal relationship with the American Indian people, as reflected in the Constitution, treaties, Federal laws, and the course of dealings of the United States with Indian Tribes, and the United States' resulting government to government and trust responsibility and obligations to the American Indian people.
- (2) From the time of European occupation and colonization through the 20th century, the policies and practices of the United States caused or contributed to the severe health conditions of Indians.
- (3) Indian Tribes have, through the cession of over 400,000,000 acres of land to the United States in exchange for promises, often reflected in treaties, of health care secured a de facto contract that entitles Indians to health care in perpetuity, based on the moral, legal, and historic obligation of the United States.
- (4) The population growth of the Indian people that began in the later part of the 20th century increases the need for Federal health care services.
- (5) A major national goal of the United States is to provide the quantity and quality of health services which will permit the health status of Indians, regardless of where they live, to be raised to the highest possible level, a level that is not less than that of the general population, and to provide for the maximum participation of Indian Tribes, tribal organizations, and urban Indian organizations in the planning, delivery, and management of those services.

- (6) Federal health services to Indians have resulted in a reduction in the prevalence and incidence of illnesses among, and unnecessary and premature deaths of, Indians.
- (7) Despite such services, the unmet health needs of the American Indian people remain alarmingly severe, and even continue to increase, and the health status of the Indians is far below the health status of the general population of the United States.
- (8) The disparity in health status that is to be addressed is formidable. In death rates for example, Indian people suffer a death rate for diabetes mellitus that is 249 percent higher than the death rate for all races in the United States, a pneumonia and influenza death rate that is 71 percent higher, a tuberculosis death rate that is 533 percent higher, and a death rate from alcoholism that is 627 percent higher.

2.10.1 Declaration of Health Objectives

Congress hereby declares that it is the policy of the United States, in fulfillment of its special trust responsibilities and legal obligations to the American Indian people, to

- (1) Assure the highest possible health status for Indians and to provide all resources necessary to effect that policy;
- (2) Raise the health status of Indians by the year 2010 to at least the levels set forth in the goals contained within the Healthy People 2010, or any successor standards thereto;
- (3) Raise the health status of Indian people to at least the levels set forth in the goals contained within the Healthy People 2010, or any successor standards thereto, to permit Indian Tribes and tribal organizations to set their own health care priorities and establish goals that reflect their unmet needs;
- (4) Increase the proportion of all degrees in the health professions and allied and associated health professions awarded to Indians so that the proportion of Indian health professionals in each geographic service area is raised to at least the level of that of the general population;
- (5) Require meaningful, active consultation with Indian Tribes, Indian organizations, and urban Indian organizations to implement this Act and the national policy of Indian self-determination, and
- (6) Provide funds for health care programs and facilities operated by Tribes and tribal organizations in amounts that are not less than the funds that are provided to programs and facilities operated directly by the Service.

2.11 Access to Medical Treatment Act (2001)

The Access to Medical Treatment Act of 2001 states that a patient may receive and a health care practitioner may provide or administer any unapproved drug or medical device that the patient desires or the legal representative of the patient authorizes if:

- Such practitioner has personally examined such patient and agrees to treat such patient.
- The unapproved drug or medical device is recommended by a health care practitioner within that practitioner's scope of practice under State law.
- The provision or administration of the unapproved drug or medical device is not a violation of the laws of the State or State in which the activity is carried out.
- The health care practitioner abides by all of the requirements set forth in the following section.

2.11.1 Requirements

A health care practitioner may recommend, provide, or administer any unapproved drug or medical device for a patient, if the practitioner:

- Does not violate Federal or State law by providing or administering the unapproved drug or medical device.
- Does not violate the Controlled Substances Act by recommending, providing or administering the unapproved drug.
- Has concluded based on generally accepted principles and current information that the unapproved drug or medical device, when used as directed, will not cause a danger to the patient.
- Provides the recommendation under circumstances that give the patient sufficient opportunity to consider whether or not to use such a drug or medical device and that minimize the possibility of coercion or undue influence by the health care practitioner.
- Discloses to the patient any financial interest that such a practitioner may have in the drug or medical device.

- Has informed the patient in writing, prior to recommending, providing, or administering the unapproved drug or medical device
 - That the unapproved drug or medical device is not approved by the Secretary as safe and effective for the condition of the patient and is considered experimental.
 - Of the foreseeable risks and benefits of the unapproved drug or medical device, including any risk to an embryo or fetus, and expected possible side effects of discomforts that the patient may experience and any medical treatment available if side effects occur.
 - Of any appropriate alternative procedures or courses of treatment (including procedures or courses of treatment that may involve the use of a drug or medical device that has been approved by the Food and Drug Administration), if any, that may be advantageous for the patient's condition.
 - Of any interactions the unapproved drug or medical device may have with other drugs, if any.
 - Of the active and inactive ingredients of the unapproved drug and the mechanism of action of the medical device, if known.
 - Of the health condition for which the unapproved drug or medical device is provided, the method of administration that will be used and the unit does.
 - Of the procedures that will be employed by the health care practitioner in using such a drug or medical device.
 - Of the extent, if any, to which confidentiality of records identifying the patient will be maintained.
 - For use of such a drug or medical device involving more than minimal risk, of the treatments available if injury occurs, what such treatments involve, and where additional information regarding such treatments may be obtained.
 - Of any anticipated circumstances under which the patient's use of such a drug or medical device may be terminated by the health care practitioner without regard to the patient's consent.
 - That the use of such a drug or medical device is voluntary and that the patient may suspend or terminate treatment at any time.
 - Of the consequences of patient's decision to withdraw from the use of such a drug or medical device.
 - Of any information that cannot be provided by the health care practitioner because such information is not known at the time the practitioner provides or administers such drug or medical device.
 - Of any other information or disclosures required by applicable State law for the administration of experimental drugs or medical devices to human subjects.

- Has not made any advertising claims for the unapproved drug or medical device.
- Does not impose a charge for the unapproved drug or medical device in excess of costs.
- Complies with requirements for reporting a danger.
- Has received a signed affidavit from the patient or the patient's legal representative confirming that the patient or legal representative has received the written information and understands it, and desires treatment with the unapproved drug or medical device.

If a health care practitioner discovers that an unapproved drug or medical device causes a danger to a patient, the practitioner shall immediately cease use and recommendation of the unapproved drug or medical device, and provide to the manufacturer of the unapproved drug or medical device and the Director of the Centers for Disease Control and Prevention, a written evaluation of the adverse reaction.

2.12 Medically Underserved Access to Care Act (2001)

Several of the findings noted under the Medically Underserved Access to Care Act of 2001 include:

- Minority individuals living in medically underserved areas are generally socio-economically less well off and are often sicker than the population traditionally served by managed care organizations.
- Many managed care organizations are not equipped to deal effectively with minorities in underserved areas and consequently may offer lower quality health care in such areas.
- Often managed care organizations do not contract with physicians and other community-based service providers who traditionally serve medically underserved areas.
- There is a concern among minority physicians that selective marketing practices and referral processes may keep minority and community-based physicians out of some managed care organizations.
- Managed care organization sometimes exclude physicians and other community-based health care providers who traditionally provide service to the underserved areas; this is particularly the case among minority physicians who may be well established in their community based practices but are not board certified.

A managed care organization offering a managed care plan shall establish and maintain adequate arrangements, as defined under regulations of the Secretary, with a sufficient number, mix, and distribution of health care professionals and providers to assure that covered items and services are available and accessible to each enrollee under the plan –

- in the service area of the organization,
- in a variety of sites of service,
- with reasonable promptness (including reasonable hours of operation and after-hours services),
- with reasonable proximity to the residences and workplaces of enrollees, and
- takes into account the diverse needs of the enrollees and reasonably assures continuity of care.

2.13 Drug Availability and Health Care Access Improvement Act (2001)

The Drug Availability and Health Care Access Improvement Act of 2001 provides the availability of prescribed drugs (in the same amount, duration, and scope as for all other patients) to medical assistance patients, and to individuals who would be qualified Medicare beneficiaries but for the fact that their income exceeds the income level established by the State but is less than 175% of the official poverty line for a family of the same size.

With respect to an individual whose income exceeds 135% of the official poverty line, the State plan shall provide for charging of a premium according to a sliding scale under which such percentage increases from 0 percent to 100 percent, in reasonable increments, as the individual's income increases from 135% of such poverty line to 175% of such poverty line.

A State shall not require prepayment of a premium imposed and shall not terminate eligibility of an individual for medical assistance under this title on the basis of failure to pay any such premium until such failure continues for a period of not less than 60 days. The State may waive payment of any such premium in any case where the State determines that requiring such payment would create an undue hardship.

2.14 Health Care Antitrust Improvements Acts (2002)

Several of the findings related to the Health Care Antitrust Improvements Acts of 2002 are:

- The market power of insurance companies increased tremendously since the early 1990's. This unprecedented consolidation has provided health plans with significant leverage over health care professionals and patients in determining the scope, coverage, and quality of health care in this country.
- Due to the concentration and exertion of market and economic power, health plans systematically and improperly manipulate the practice of medicine through such mechanisms as inappropriately making medical necessity determinations, down-coding and bundling, knowingly denying and delaying payment, and engaging in a variety of practices that may affect the continuity and quality of patient care.
- The intent of the antitrust laws is to encourage competition and protect the consumer and the current per se standard for enforcing the antitrust laws in the health care field frequently does not achieve these objectives.
- An application of the rule of reason to health care professionals' business activities and interactions with health care plans will tend to promote both competition and high-quality patient care.

In any action under the antitrust laws challenging the efforts of two or more physicians or other health care professionals to negotiate with a health plan, the conduct of such physicians or health care professionals shall not be deemed illegal per se, but shall be judged on the basis of its reasonableness, taking into account all relevant factors affecting competition, including patient access to health care, the quality of health care received by patients, and contract terms or proposed contract terms.

Any party to a health care cooperative venture that intends, or has begun to negotiate with a health plan may file with the Attorney General of the United States a written notification disclosing:

- The identities of the parties to such venture, and the name and address of each agent representing such venture
- The identity of each health plan with which such venture is or may be negotiating
- The general nature and objectives of the negotiations

The Attorney General, in accordance with the recommendations of the advisory committee, under which health care professionals in the States designated as demonstration project sites may act together to jointly negotiate contracts and agreements with health plans to provide health care items and services for which benefits are provided under such health plans. The Demonstration Projects shall be established for the purpose of testing various options in the health care market to allow negotiations and agreements by health care professionals that will enhance efficiency, quality, and availability of health care, while promoting competition in the health care market.