#### 104TH CONGRESS 1ST SESSION

# H. R. 1234

To amend the Internal Revenue Code of 1986 to provide for reform of the health insurance market, to promote the availability and continuity of health coverage, to remove financial barriers to access, to enhance health care quality, to contain costs through market incentives and administrative reforms, and for other purposes.

#### IN THE HOUSE OF REPRESENTATIVES

MARCH 14, 1995

Mr. Thomas (for himself, Mrs. Johnson of Connecticut, Mr. McCrery, Mr. Ensign, Mr. Crane, Mr. Houghton, Mr. Castle, Mr. Hobson, Mr. Riggs, Mr. Horn, Mr. Clinger, Mr. Greenwood, Mr. Frelinghuysen, Mr. Lazio of New York, Mr. Blute, Mr. Longley, Mr. Ehlers, Ms. Pryce, Mr. Bass, Mr. Portman, Mr. Kolbe, Mrs. Fowler, Mr. Shays, Mr. Goss, Mr. English of Pennsylvania, Mr. Calvert, Mr. Gutknecht, and Mr. Packard) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committees on Commerce, Economic and Educational Opportunities, and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

### A BILL

To amend the Internal Revenue Code of 1986 to provide for reform of the health insurance market, to promote the availability and continuity of health coverage, to remove financial barriers to access, to enhance health care quality, to contain costs through market incentives and administrative reforms, and for other purposes.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.
- 4 (a) SHORT TITLE.—This Act may be cited as the
- 5 "Basic Health Care Reform Act of 1995".
- 6 (b) Table of Contents.—The table of contents of
- 7 this Act is as follows:
  - Sec. 1. Short title; table of contents.

## TITLE I—ASSURING AVAILABILITY AND CONTINUITY OF HEALTH COVERAGE

#### Subtitle A—Insurance Reform

#### PART 1—ACCESS TO HEALTH COVERAGE

- Sec. 1001. Guaranteed offer by carriers.
- Sec. 1002. Guaranteed issue by carriers.
- Sec. 1003. Guaranteed renewal.
- Sec. 1004. Restricting preexisting condition exclusions.
- Sec. 1005. Enrollment periods.

#### PART 2—PROVISION OF BENEFITS

- Sec. 1011. General coverage requirements.
- Sec. 1012. Standards for managed care arrangements.
- Sec. 1013. Utilization review.
- Sec. 1014. Medical savings accounts.

#### PART 3—FAIR RATING PRACTICES

- Sec. 1021. Use of fair rating practices.
- Sec. 1022. Establishment of risk adjustment mechanisms.

#### PART 4—CONSUMER PROTECTIONS

- Sec. 1031. Requirement for provision of information.
- Sec. 1032. Prohibition of improper incentives.
- Sec. 1033. Written policies and procedures respecting advance directives.

## PART 5—STANDARDS AND CERTIFICATION; ENFORCEMENT; PREEMPTION; GENERAL PROVISIONS

- Sec. 1041. Establishment of standards.
- Sec. 1042. Application of standards to carriers through States.
- Sec. 1043. Application to group health plans.
- Sec. 1044. Enforcement.
- Sec. 1045. Limitation on self insurance for certain employer plans.

#### PART 6—MARKETPLACE FOR INDIVIDUALS

Sec. 1051. Application of similar requirements.

## Subtitle B—Facilitating Establishment of Health Plan Choice Organizations (HPCOs)

- Sec. 1101. Establishment and organization.
- Sec. 1102. Agreements to offer qualified health coverage.
- Sec. 1103. Provision of information.
- Sec. 1104. Enrolling qualifying employees and qualifying individuals for qualified health coverage through a choice organization.
- Sec. 1105. Restriction on charges.

## Subtitle C—Preemption of State Benefit Mandates and Anti-Managed Care Laws

- Sec. 1201. Preemption from State benefit mandates.
- Sec. 1202. Preemption of State law restrictions on managed care arrangements.
- Sec. 1203. Preemption of State laws restricting utilization review programs.
- Sec. 1204. Preemption relating to different insurance standards.

#### Subtitle D—Definitions; General Provisions

- Sec. 1901. General definitions.
- Sec. 1902. Definitions relating to employment.
- Sec. 1903. Definitions relating to health coverage, plans, and carriers.
- Sec. 1904. Definitions relating to residence and immigration status.
- Sec. 1905. Effective dates.

#### TITLE II—ADMINISTRATIVE SIMPLIFICATION

- Sec. 2000. Purpose.
- Sec. 2001. Definitions.

#### Subtitle A—Standards for Data Elements and Transactions

- Sec. 2101. General requirements on Secretary.
- Sec. 2102. Standards for data elements of health information.
- Sec. 2103. Information transaction standards.
- Sec. 2104. Health information network privacy standards.
- Sec. 2105. Timetables for adoption of standards.

### Subtitle B—Requirements with Respect to Certain Transactions and Information

- Sec. 2201. Standard transactions and information.
- Sec. 2202. Accessing health information for authorized purposes.
- Sec. 2203. Ensuring availability of information.
- Sec. 2304. Timetables for compliance with requirements.

#### Subtitle C—Miscellaneous Provisions

- Sec. 2301. Standards and certification for health information network services.
- Sec. 2302. Imposition of additional requirements.
- Sec. 2303. Effect on State law.

#### TITLE III—FRAUD AND ABUSE REFORM: ADVISORY OPINIONS

Sec. 3001. Authorizing the Secretary of Health and Human Services to issue advisory opinions under title XI.

Sec. 3002. Authorizing the Secretary of Health and Human Services to issue advisory opinions relating to physician ownership and referral.

Sec. 3003. Effective date.

#### TITLE IV—MALPRACTICE REFORM AND ANTITRUST

#### Subtitle A—Malpractice Reform

#### PART 1—UNIFORM STANDARDS FOR MALPRACTICE CLAIMS

- Sec. 4001. Applicability.
- Sec. 4002. Requirement for initial resolution of action through alternative dispute resolution.
- Sec. 4003. Optional application of practice guidelines.
- Sec. 4004. Treatment of noneconomic and punitive damages.
- Sec. 4005. Periodic payments for future losses.
- Sec. 4006. Treatment of attorney's fees and other costs.
- Sec. 4007. Uniform statute of limitations.
- Sec. 4008. Special provision for certain obstetric services.
- Sec. 4009. Jurisdiction of Federal courts.
- Sec. 4010. Preemption.

## PART 2—REQUIREMENTS FOR STATE ALTERNATIVE DISPUTE RESOLUTION SYSTEMS (ADR)

- Sec. 4021. Basic requirements.
- Sec. 4022. Certification of State systems; applicability of alternative Federal system.
- Sec. 4023. Reports on implementation and effectiveness of alternative dispute resolution systems.

#### PART 3—DEFINITIONS

Sec. 4031. Definitions.

#### Subtitle B—Antitrust

- Sec. 4101. Publication of antitrust guidelines on activities of health plans.
- Sec. 4102. Issuance of health care certificates of public advantage.

### 1 TITLE I—ASSURING AVAILABIL-

### 2 ITY AND CONTINUITY OF

### 3 **HEALTH COVERAGE**

### 4 Subtitle A—Insurance Reform

#### 5 PART 1—ACCESS TO HEALTH COVERAGE

#### 6 SEC. 1001. GUARANTEED OFFER BY CARRIERS.

- 7 (a) IN GENERAL.—Each carrier that offers health in-
- 8 surance coverage in the small group market in a fair rat-

1	ing area (as defined in section 1903) shall make available,
2	to each small employer (covered in such market) in such
3	fair rating area—
4	(1) qualified standard coverage consistent with
5	section 1011(a), and
6	(2) subject to subsection (b), qualified high-de-
7	ductible coverage consistent with section 1011(b).
8	(b) High-Deductible Coverage.—
9	(1) Exception for health maintenance
10	ORGANIZATIONS.—The requirement of subsection
11	(a)(2) shall not apply with respect to health insur-
12	ance coverage that—
13	(A) is provided by a Federally qualified
14	health maintenance organization (as defined in
15	section 1301(a) of the Public Health Service
16	Act), or
17	(B) is not provided by such an organiza-
18	tion but is provided by an organization recog-
19	nized under State law as a health maintenance
20	organization or managed care organization or a
21	similar organization regulated under State law
22	for solvency.
23	(2) Limitation on offer of high-deduct-
24	IBLE COVERAGE.—Qualified high-deductible coverage
25	may not be made available by a carrier to a small

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employer with respect to an employee unless the carrier also makes available qualified standard coverage that has identical benefits (other than the amount of the deductible) and the employee demonstrates to the carrier that the employee has available assets (as defined by the Secretary) equal to at least the deductible amount established under section 1011(b)(2) applicable to the high-deductible coverage. A carrier may not make available to an employee health coverage (other than coverage for supplemental benefits) the actuarial value of which is less than the actuarial value of qualified high-deductible coverage, unless the employee has available assets (as defined by the Secretary) equal to at least the deductible amount of the coverage offered.

- (3) OPTION TO OFFER MEDISAVE COVERAGE.—
  The offer of high-deductible coverage under subsection (a)(2) may be accompanied by the contribution by an employer to a medical savings account (in accordance with section 7705 of the Internal Revenue Code of 1986).
- (c) Coverage of Entire Rating Area.—
  - (1) IN GENERAL.—With respect to each fair rating area for which a carrier offers health insurance coverage, the carrier shall provide for coverage

- of benefits for items and services furnished throughout the fair rating area.
  - (2) Special rule for carriers offering coverage in multi-state metropolitan statistical area, the carrier may not provide such coverage with respect to an employer in such metropolitan statistical area unless the carrier also offers such coverage in other portions of the area located in other States.
    - (3) Special rule for coverage through Managed care arrangement in a fair rating area, this subsection shall not be construed as requiring the establishment of facilities throughout the area, if the facilities are located consistent with section 1002(b)(1).
- 22 (d) Family Coverage Option.—The offer of cov-23 erage under this section with respect to an employee shall 24 include the option of coverage of family members of the 25 employee.

1	(e) Limitation on Carriers.—A carrier may not
2	require an employer under a group health plan to impose
3	through a waiting period for health coverage under a plan
4	or similarly require a limitation or condition on health cov-
5	erage or benefits based on—
6	(1) the health status of an individual,
7	(2) claims experience of an individual,
8	(3) receipt of health care by an individual,
9	(4) medical history of an individual, or
10	(5) receipt of public subsidies by an individual.
11	SEC. 1002. GUARANTEED ISSUE BY CARRIERS.
12	(a) In General.—Subject to subsections (b) and (c)
13	and section 1003, each carrier that offers health insurance
14	coverage in the small group market in a fair rating area—
15	(1) must accept every small employer in the
16	area that applies for such coverage during an enroll-
17	ment period provided under section 1005; and
18	(2) must accept for enrollment under such cov-
19	erage every qualifying individual (and family mem-
20	ber of such an individual) who applies for enrollment
21	during an enrollment period provided under section
22	1005 and may not place any restriction on the eligi-
23	bility of an individual to enroll so long as such indi-
24	vidual is a qualifying individual.

1	(b) Special Rules for Managed Care Arrange-
2	MENTS.—In the case of coverage offered by a carrier or
3	under a group health plan that provides benefits through
4	a managed care arrangement in a fair rating area, the
5	carrier or plan—
6	(1) need not establish facilities for the delivery
7	of health care services throughout the area so long
8	as such facilities are located in a manner that does
9	not discriminate on the basis of health status of in-
10	dividuals residing in proximity to such facilities, and
11	(2) may deny such coverage in a fair rating
12	area to employers if the organization demonstrates
13	to the applicable regulatory authority that—
14	(A) it will not have the capacity to deliver
15	services adequately to enrollees of any addi-
16	tional groups or additional enrollees because of
17	its obligations to existing group contract hold-
18	ers and enrollees, and
19	(B) it is applying this paragraph uniformly
20	to all employers without regard to the health
21	status, claims experience, or duration of cov-
22	erage of those employers and their employees.
23	Coverage may be denied under paragraph (2) only if the
24	denial is applied during a consecutive period of at least
25	180 days

1	(c) Special Rule for Financial Capacity Lim-
2	ITS.—In addition to the authority provided under sub-
3	section (b)(2), in the case of coverage offered by any car-
4	rier, the carrier may deny coverage to a small employer
5	if the carrier demonstrates to the applicable regulatory au-
6	thority that—
7	(1) it does not have the financial reserves nec-
8	essary to underwrite additional coverage, and
9	(2) it is applying this subsection uniformly to
10	all employers without regard to the health status,
11	claims experience, or duration of coverage of those
12	employers and their employees.
13	Coverage may be denied under this subsection only if the
14	denial is applied during a consecutive period of at least
15	180 days.
16	SEC. 1003. GUARANTEED RENEWAL.
17	(a) Limitation on Termination by Carriers.—
18	A carrier may not deny, cancel, or refuse to renew health
19	coverage of an eligible employer within a type of coverage
20	option described in section 1903(15) except—
21	(1) on the basis of nonpayment of premiums,
22	(2) on the basis of fraud or misrepresentation,
23	or
24	(3) subject to subsection (b), in a fair rating
25	area because the carrier is ceasing to provide any

1	health insurance coverage in the small group market
2	within such type of coverage option in the area.
3	(b) Limitations on Market Exit by Carriers.—
4	(1) NOTICE, ETC.—Subsection (a)(3) shall not
5	apply to a carrier ceasing to provide health insur-
6	ance coverage unless—
7	(A) such termination of coverage takes ef-
8	fect at the end of a contract year, and
9	(B) the carrier provides notice of such ter-
10	mination to employers and individuals covered
11	at least 30 days before the date of an annual
12	open enrollment period established with respect
13	to the employer or individual under section
14	1005.
15	(2) Limitation on reentry in small group
16	MARKET.—If a carrier ceases to offer or provide
17	health insurance coverage in an area with respect to
18	the small group market for a type of coverage op-
19	tion, the insurer may not offer health insurance cov-
20	erage in the area in such market within such type
21	of coverage option until 5 years after the date of the
22	termination.
23	(c) Rule for Multiemployer Plans.—A multi-
24	employer plan may not cancel coverage or deny renewal

1	of coverage under such a plan or arrangement with respect
2	to an employer other than—
3	(1) for nonpayment of contributions,
4	(2) for fraud or other misrepresentation by the
5	employer, or
6	(3) because the plan is ceasing to provide any
7	coverage in a geographic area.
8	SEC. 1004. RESTRICTING PREEXISTING CONDITION EXCLU-
9	SIONS.
10	(a) In General.—Except as provided in this section,
11	a carrier or group health plan providing health coverage
12	may not exclude health coverage with respect to services
13	related to treatment of a condition based on the fact that
14	the condition of an individual existed before the effective
15	date of coverage of the individual.
16	(b) Limited 12-month Exclusion Permitted.—
17	(1) In general.—Subject to paragraph (2)
18	and subsections (c) through (e), a carrier or group
19	health plan providing health coverage may exclude
20	health coverage with respect to services related to
21	treatment of a condition of an individual based on
22	the fact that the condition existed before the effec-
23	tive date of coverage of the individual only if the pe-
24	riod of the exclusion does not exceed 12 months be-
25	ginning on the date of coverage.

(2)	Cred	ITIN	G OF	PRE	VIOUS	COVERA	GE	—
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(A) IN GENERAL.—A carrier or group health plan providing health coverage shall provide that if a covered individual is in a period of continuous coverage (as defined in subparagraph (C)) as of a date upon which coverage is initiated or reinitiated, any period of exclusion of coverage with respect to a preexisting condition (as defined in subparagraph (B)) for such services or type of services shall be reduced by 1 month for each month in the period of continuous coverage.

(B) PREEXISTING CONDITION DEFINED.—
In this paragraph, the term "preexisting condition" means, with respect to health coverage, a condition which has been diagnosed or treated during the 6-month period ending on the day before the first date of such coverage (without regard to any waiting period).

(C) Period of continuous coverage.—
In this part, the term "period of continuous coverage" means the period beginning on the date an individual has health coverage (or coverage under a public plan providing medical benefits) and ends on the date the individual

1	does not have such coverage for a continuous
2	period of more than 3 months (or 6 months in
3	the case of an individual who loses coverage due
4	to involuntary termination of employment, other
5	than by reason of an employee's gross mis-
6	conduct).
7	(c) Exclusion Not Applicable to Pregnancy.—
8	Any exclusion of coverage under subsection (b)(1) shall
9	not apply if the exclusion relates to pregnancy.
10	(d) Exclusion Not Applicable to Newborns
11	and Adopted Children.—
12	(1) NEWBORNS.—Any exclusion of coverage
13	under subsection (b)(1) shall not apply to a child
14	who is covered at the time of birth and remains in
15	a period of continuous coverage after such time.
16	(2) Adopted Children.—Any exclusion of
17	coverage under subsection (b)(1) shall not apply (be-
18	ginning on the date of adoption) to an adopted child
19	who is covered at the time of adoption and remains
20	in a period of continuous coverage after such time.
21	(e) Exclusion Not Applicable to Individuals
22	Enrolled or Enrolling During Certain Open En-
23	ROLLMENT PERIODS.—
24	(1) Individuals enrolling during pe-
25	RIOD —In the case of an individual who enrolls and

- obtains coverage during an open enrollment period described in section 1005(b), any exclusion of coverage under subsection (b)(1) shall not apply so long as the individual remains in a period of continuous coverage.
  - (2) INDIVIDUALS ENROLLED AT BEGINNING OF PERIOD.—In the case of an individual who has health coverage as of the first day of the initial open enrollment period described in section 1005(b)(1), any exclusion of coverage under subsection (b)(1) shall not apply as of such date and so long as the individual is in a period of continuous coverage.
- 13 (f) APPLICATION OF RULES BY CERTAIN HEALTH
  14 MAINTENANCE ORGANIZATIONS.—A health maintenance
  15 organization that provides health insurance coverage shall
  16 not be considered as failing to meet the requirements of
  17 section 1301 of the Public Health Service Act notwith18 standing that it provides for an exclusion of the coverage
  19 based on a preexisting condition consistent with the provi20 sions of this part so long as such exclusion is applied con21 sistent with the provisions of this part.
- 22 SEC. 1005. ENROLLMENT PERIODS.
- 23 (a) IN GENERAL.—Each carrier and each group 24 health plan providing health coverage (and each health 25 plan choice organization under subtitle B) in the small

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- group market shall permit qualifying individuals and eligi-
- ble employers to obtain health coverage from the carrier
- 3 or group health plan during each enrollment period pro-
- 4 vided under this section.

- 5 (b) Open Enrollment Periods for Which Pre-
- EXISTING CONDITION EXCLUSIONS WAIVED.— 6
- 7 (1) Initial Period.—There shall be an initial 8 open enrollment period, with respect to individuals 9 and employees who are residents of a State, during 10 the 60-day period beginning on January 1, 1997.
- (2) Enrollment of Newborns and Newly 12 ADOPTED CHILDREN.—There shall be an open en-13 rollment period with respect to a newborn child and 14 a newly adopted child during the 30-day period be-15 ginning on the date of the birth or adoption of a 16 child, if family coverage is available as of such date.
- 17 Annual Open Enrollment Periods for Which Preexisting Condition Exclusions May 19 APPLY.—
- 20 (1) IN GENERAL.—Each carrier and each group health plan providing health coverage (and each 21 22 health plan choice organization under subtitle B) in 23 the small group market shall provide for at least one 24 annual open enrollment period (of not less than 30 25 days) each year. Such period shall be in addition to

1	the open enrollment periods described in subsection
2	(b).
3	(2) COORDINATION.—Such annual open enroll-
4	ment periods with respect to carriers in the small
5	group market are subject to coordination by States.
6	(d) Other Open Enrollment Periods for
7	Which Preexisting Condition Exclusions May
8	Apply.—
9	(1) TERMINATION OF RESIDENCE AREA.—For
10	each qualifying individual, at the time the individual
11	terminates residence in the service area of coverage
12	provided by a carrier to the individual, there shall be
13	an open enrollment period (of not less than 30 days)
14	during which the individual may enroll in health cov-
15	erage.
16	(2) Family or employment changes.—In
17	the case of a qualifying individual who—
18	(A) through divorce or death of a family
19	member experiences a change in family com-
20	position, or
21	(B) experiences a change in employment
22	status (including a significant change in the
23	terms and conditions of employment or the
24	terms and conditions of employment of a
25	spouse),

1	there shall be an open enrollment period (of at least
2	30 days) in which the individual is permitted to
3	change the individual or family basis of coverage or
4	the health coverage in which the individual is en-
5	rolled. The circumstances under which such enroll-
6	ment periods are required and the duration of such
7	periods shall be specified by the Secretary.
8	(3) Enrollment due to loss of previous
9	COVERAGE.—In the case of a qualifying individual
10	who—
11	(A) had health coverage at the time of an
12	individual's enrollment period,
13	(B) stated at the time of such period that
14	having other health coverage was the reason for
15	declining enrollment, and
16	(C) lost the other health coverage as a re-
17	sult of the termination of the coverage, termi-
18	nation or reduction of employment, or other
19	reason, except termination at the option of the
20	individual,
21	there shall be an open enrollment period during the
22	30-day period beginning on the date of termination
23	of the other coverage.
24	(4) Enrollment at time of marriage.—
25	There shall be an open enrollment period with re-

- spect to the spouse of an individual (including children of the spouse) during the 30-day period beginning on the date of the marriage, if family coverage is available as of such date.
  - (5) No effect on cobra continuation ben-Efits.—Nothing in this subsection shall be construed as affecting rights of individuals to continuation coverage under section 4980B of the Internal Revenue Code of 1986 or under similar provisions of law.

#### (e) Period of Coverage.—

- (1) IN GENERAL.—In the case of a qualifying individual who enrolls under health coverage during an open enrollment period under this section, coverage shall begin on such date (not later than the first day of the first month that begins at least 15 days after the date of enrollment) as the Secretary shall specify, consistent with this subsection.
- (2) Coverage of family members.—In the case of an open enrollment period described in subsection (b)(2), (b)(3), or (d)(4), the Secretary shall provide for coverage of family members to begin as soon as possible on or after the date of the event that gives rise to the special enrollment period (or,

1	in the case of birth or adoption, as of the date of
2	birth or adoption).
3	PART 2—PROVISION OF BENEFITS
4	SEC. 1011. GENERAL COVERAGE REQUIREMENTS.
5	(a) Standard Coverage.—For purposes of this
6	title, health insurance coverage is considered to provide
7	standard coverage consistent with this subsection if bene-
8	fits under such coverage meet standards promulgated
9	under section 1041 to carry out this subsection. In pro-
10	mulgating such standards to carry out this section, the
11	NAIC and the Secretary shall take into account the follow-
12	ing:
13	(1) Classes of Benefits.—The classes of
14	benefits (such as inpatient and outpatient hospital
15	services and physicians services) typically included in
16	health plans under the Federal Employees Health
17	Benefits Program.
18	(2) ACTUARIAL VALUE.—The actuarial value of
19	benefits included in benchmark coverage for the
20	areas involved (adjusted to take into account a
21	standardized population and standardized utilization
22	and cost factors).
23	(3) Preventive Benefits.—The need to cover
24	cost-effective preventive benefits (such as well-baby

1	and well-child care and childhood immunizations)
2	without inappropriate cost sharing.
3	(b) High-Deductible Coverage.—For purposes
4	of this title, health insurance coverage is considered to
5	provide high-deductible coverage consistent with this sub-
6	section if—
7	(1) benefits include the same type of benefits as
8	provided for under standard coverage under sub-
9	section (a);
10	(2) the deductible amount is within a range of
11	amounts established under such standards so that
12	the actuarial value of high-deductible coverage is at
13	least 20 percent (but not more than 40 percent) less
14	than the actuarial value of standard coverage;
15	(3) benefits under the coverage in any year
16	(other than preventive benefits as provided under
17	the standards) are covered only to the extent ex-
18	penses incurred for items and services included in
19	the coverage for the year exceed the deductible
20	amount specified in paragraph (2); and
21	(4) the actuarial value of the coverage (as de-
22	termined under rules established under such stand-
23	ards) is equivalent to a percentage (specified in such

standards and not less than 60 percent and not

- 1 more than 80 percent) of an actuarial value for 2 standard coverage.
- 3 (c) Rules Regarding Offering of Supple-
- 4 MENTAL BENEFITS.—A carrier or group health plan offer-
- 5 ing qualified health coverage may offer coverage of items
- 6 and services only in addition to the qualified standard cov-
- 7 erage offered (whether in the form of coverage of addi-
- 8 tional items and services or a reduction in cost sharing)
- 9 and only if—

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- 10 (1) such supplemental coverage is offered and 11 priced separately from the standard coverage offered 12 and is only made available to individuals who obtain 13 qualified standard coverage through the carrier or 14 plan;
  - (2) the purchase of the qualified health coverage is not conditioned upon the purchase of such supplemental coverage; and
  - (3) in the case of supplemental coverage that consists of a reduction in the cost-sharing otherwise applicable, the premium for the supplemental coverage takes into account any expected increase in utilization of items and services included in the qualified health coverage resulting from obtaining the supplemental coverage.

(d) Model Benefit Packages.—The standards es-

2	tablished to carry out this section may provide for mode
3	benefit packages that will be considered to meet applicable
4	requirements for standard coverage or high-deductible cov-
5	erage, and which shall include model cost sharing arrange-
6	ments for fee-for-service options, managed care options,
7	and point-of-service options.
8	(e) FLEXIBILITY IN BENEFITS.—Nothing in this sec-
9	tion (or section 1103) may be construed—
10	(1) to require the coverage of any specific pro-
11	cedure or treatment or class of service in health cov-
12	erage under this Act or through regulation;
13	(2) as requiring coverage to include benefits for
14	items and services that are not medically necessary
15	or appropriate;
16	(3) as limiting the benefits that may be offered
17	as part of a group health plan or health insurance
18	coverage; and
19	(4) to require or prohibit the use of a particular
20	class of provider, among the providers that are le-
21	gally authorized to provide such treatment.
22	SEC. 1012. STANDARDS FOR MANAGED CARE ARRANGE
23	MENTS.
24	(a) Application of Requirements.—Each group
25	health plan, and each carrier providing health insurance

- 1 coverage, that provides for health care through a managed
- 2 care arrangement (as defined in section 1903(12)(A))
- 3 shall comply with the applicable requirements of this sec-
- 4 tion.

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- (b) Scope of Arrangements With Providers.—
- 6 (1) Access to care.—The entity providing for 7 a managed care arrangement with respect to health 8 coverage shall enter into such agreements with 9 health care providers (including primary and spe-10 cialty providers) or have such other arrangements as 11 may be necessary to assure that covered individuals 12 have reasonably prompt access through the entity's 13 provider network to all items and services contained 14 in the package of benefits for which coverage is pro-15 vided (including access to emergency services on a 16 24-hour basis where medically necessary), in a man-17 ner that assures the continuity of the provision of 18 such items and services.
  - (2) ACCESS TO SPECIALIZED TREATMENT.—
    The entity providing for a managed care arrangement under health coverage shall demonstrate that covered individuals (including individuals with chronic diseases) have access through the entity's provider network to specialized treatment expertise.

1	(3) Choice of Personal Physician.—The en-
2	tity providing for a managed care arrangement
3	under health coverage shall permit each enrollee to
4	choose a personal physician from among available
5	participating physicians and change that selection as
6	appropriate.
7	(c) Provision of Emergency Care Services.—
8	The entity providing for a managed care arrangement
9	under health coverage must cover medically necessary
10	emergency care services provided to covered individuals
11	without regard to whether or not the provider furnishing
12	such services has a contractual (or other) arrangement
13	with the entity to provide items or services to covered indi-
14	viduals and, in the case of services furnished for the treat-
15	ment of an emergency medical condition (as defined in sec-
16	tion 1867(e)(1) of the Social Security Act), without regard
17	to prior authorization.
18	(d) Due Process Standards Relating to Pro-
19	vider Networks.—
20	(1) Standards for selection of providers
21	FOR NETWORK.—The entity providing for a man-
22	aged care arrangement under health coverage shall
23	establish standards (including criteria for quality, ef-
24	ficiency, credentialing, and services) to be used by
25	the entity for contracting with health care providers

- with respect to the entity's provider network. Such standards shall be established in consultation with providers who are members of the network.
  - (2) TERMINATION PROCESS.—The entity may not terminate or refuse to renew a participation agreement with a provider in the entity's provider network unless the entity provides written notification to the provider of the entity's decision to terminate or refuse to renew the agreement. The notification shall include a statement of the reasons for the entity's decision, consistent with the standards established under paragraph (1).
  - (3) REVIEW PROCESS.—The entity shall provide a process under which the provider may request a review of the entity's decision to terminate or refuse to renew the provider's participation agreement.
  - (4) Construction.—Nothing in this subsection shall be construed to affect any other provision of law that provides an appeals process or other form of relief to a provider of health care services or an entity providing for a managed care arrangement.

#### 23 SEC. 1013. UTILIZATION REVIEW.

24 (a) ESTABLISHMENT OF STANDARDS BY SEC-25 RETARY.—The Secretary shall establish standards for uti-

- 1 lization review programs, consistent with subsection (c),
- 2 and shall periodically review and update such standards
- 3 to reflect changes in the delivery of health care services.
- 4 The Secretary shall establish such standards in consulta-
- 5 tion with appropriate parties.
- 6 (b) REQUIRING REVIEW TO MEET STANDARDS.—A
- 7 group health plan or carrier providing health insurance
- 8 coverage may not deny coverage of or payment for items
- 9 and services on the basis of a utilization review program
- 10 unless the program meets the standards established by the
- 11 Secretary under this section.
- 12 (c) REQUIREMENTS FOR STANDARDS.—Under the
- 13 standards established under subsection (a)—
- 14 (1) individuals performing utilization review
- may not receive financial compensation based upon
- the number of denials of coverage;
- 17 (2) negative determinations of the medical ne-
- cessity or appropriateness of services or the site at
- which services are furnished may be made only by
- clinically qualified personnel;
- 21 (3) the utilization review program shall provide
- for a process under which an enrollee or provider
- may obtain timely review of a denial of coverage, in-
- cluding upon request a review conducted by the med-

1	ical director of the carrier or plan or a physician
2	designated by the carrier or plan;
3	(4) utilization review shall be conducted in ac-
4	cordance with uniformly applied standards that are
5	based on currently available medical evidence; and
6	(5) providers shall participate in the develop-
7	ment of the utilization review program.
8	(d) Preemption.—For provision preempting State
9	laws relating to utilization review, see section 1103.
10	SEC. 1014. MEDICAL SAVINGS ACCOUNTS.
11	(a) IN GENERAL.—Chapter 79 of the Internal Reve-
12	nue Code of 1986 is amended by adding at the end the
13	following new section:
14	"SEC. 7705. MEDICAL SAVINGS ACCOUNTS.
15	"(a) GENERAL RULE.—For purposes of this title, the
16	term 'medical savings account' means a trust created or
17	organized in the United States for the exclusive benefit
18	of an individual or his beneficiaries, but only if the written
19	instrument creating the trust meets the following require-
20	ments:
21	"(1) Except in the case of a rollover contribu-
22	tion described in subsection $(d)(3)$ , no contribution
23	will be accepted unless—
24	"(A) it is in cash, and

1	"(B) such individual is a qualifying em-
2	ployee for the period for which such contribu-
3	tion is made.
4	"(2) The trustee is a bank (as defined in sec-
5	tion 408(n)), insurance company (as defined in sec-
6	tion 816), or such other person who demonstrates to
7	the satisfaction of the Secretary that the manner in
8	which such other person will administer the trust
9	will be consistent with the requirements of this sec-
10	tion.
11	"(3) No part of the trust funds will be invested
12	in life insurance contracts.
13	"(4) The interest of an individual in the bal-
14	ance of the account is nonforfeitable.
15	"(5) The assets of the trust will not be commin-
16	gled with other property except in a common trust
17	fund or common investment fund.
18	"(b) Eligible Employee.—For purposes of this
19	section—
20	"(1) IN GENERAL.—The term 'eligible em-
21	ployee' means any employee who has high-deductible
22	coverage (as defined in section 1011(b) of the Basic
23	Health Care Reform Act of 1995) offered by the em-
24	ployer.

1	"(2) Exception.—An employee shall be treat-
2	ed as not being an eligible employee for any calendar
3	year if, for any month during such year, it is reason-
4	ably expected that such employee—
5	"(A) will have adjusted gross income that
6	is less than 100 percent of the income official
7	poverty line (as determined by the Director of
8	the Office of Management and Budget) for a
9	family of the size involved; or
10	"(B) is an AFDC recipient or SSI recipi-
11	ent.
12	"(3) Definitions.—For purposes of paragraph
13	(2)—
14	"(A) AFDC RECIPIENT.—The term
15	'AFDC recipient' means, for a month, an indi-
16	vidual who is receiving aid or assistance under
17	any plan of the State approved under title I, X,
18	XIV, or XVI, or part A or part E of title IV,
19	of the Social Security Act for the month.
20	"(B) SSI RECIPIENT.—The term 'SSI re-
21	cipient' means, for a month, an individual—
22	"(i) with respect to whom supple-
23	mental security income benefits are being
24	paid under title XVI of the Social Security
25	Act for the month,

1	"(ii) who is receiving a supplementary
2	payment under section 1616 of such Act or
3	under section 212 of Public Law 93-66 for
4	the month,
5	"(iii) who is receiving monthly bene-
6	fits under section 1619(a) of the Social Se-
7	curity Act (whether or not pursuant to sec-
8	tion 1616(c)(3) of such Act) for the
9	month, or
10	"(iv) who is treated under section
11	1619(b) of the Social Security Act as re-
12	ceiving supplemental security income bene-
13	fits in a month for purposes of title XIX
14	of such Act.
15	"(c) Tax Treatment of Accounts.—
16	"(1) ACCOUNT TAXED AS GRANTOR TRUST.—
17	"(A) IN GENERAL.—Except as provided in
18	subparagraph (B), the account beneficiary of a
19	medical savings account shall be treated for
20	purposes of this title as the owner of such ac-
21	count and shall be subject to tax thereon in ac-
22	cordance with subpart E of part I of subchapter
23	J of this chapter (relating to grantors and oth-
24	ers treated as substantial owners).

1	"(B) Treatment of capital losses.—
2	With respect to assets held in a medical savings
3	account, any capital loss for a taxable year
4	from the sale or exchange of such an asset shall
5	be allowed only to the extent of capital gains
6	from such assets for such taxable year. Any
7	capital loss which is disallowed under the pre-
8	ceding sentence shall be treated as a capital
9	loss from the sale or exchange of such an asset
10	in the next taxable year. For purposes of this
11	subparagraph, all medical savings accounts of
12	the account beneficiary shall be treated as 1 ac-
13	count.
14	"(2) Account terminates if individual en-
15	GAGES IN PROHIBITED TRANSACTION.—
16	"(A) IN GENERAL.—If, during any taxable
17	year of the account beneficiary, such beneficiary
18	engages in any transaction prohibited by section
19	4975 with respect to the account, the account
20	shall cease to be a medical savings account as
21	of the first day of such taxable year.
22	"(B) ACCOUNT TREATED AS DISTRIBUTING
23	ALL ITS ASSETS.—In any case in which any ac-
24	count ceases to be a medical savings account by
25	reason of subparagraph (A) on the first day of

1	any taxable year, subsection (d) shall be applied
2	as if—
3	"(i) there were a distribution on such
4	first day in an amount equal to the fair
5	market value (on such first day) of all as-
6	sets in the account (on such first day), and
7	"(ii) no portion of such distribution
8	were used to pay qualified medical ex-
9	penses.
10	"(3) Effect of pledging account as secu-
11	RITY.—If, during any taxable year, the account ben-
12	eficiary uses the account or any portion thereof as
13	security for a loan, the portion so used is treated as
14	distributed and not used to pay qualified medical ex-
15	penses.
16	"(d) Tax Treatment of Distributions.—
17	"(1) INCLUSION OF AMOUNTS NOT USED FOR
18	QUALIFIED MEDICAL EXPENSES.—
19	"(A) IN GENERAL.—Any amount paid or
20	distributed out of a medical savings account
21	which is not used exclusively to pay the quali-
22	fied medical expenses of the account beneficiary
23	or of the spouse or dependents (as defined in
24	section 152) of such beneficiary shall be in-
25	cluded in the gross income of such beneficiary

1	to the extent such amount does not exceed the
2	excess of—
3	"(i) the aggregate contributions to
4	such account which were not includible in
5	gross income by reason of section 106(2),
6	over
7	"(ii) the aggregate prior payments or
8	distributions from such account which were
9	includible in gross income under this para-
10	graph.
11	"(B) Special rules.—For purposes of
12	subparagraph (A)—
13	"(i) all medical savings accounts of
14	the account beneficiary shall be treated as
15	1 account,
16	"(ii) all payments and distributions
17	during any taxable year shall be treated as
18	1 distribution, and
19	"(iii) any distribution of property
20	shall be taken into account at its fair mar-
21	ket value on the date of the distribution.
22	"(2) Penalty for distributions not used
23	FOR QUALIFIED MEDICAL EXPENSES.—
24	"(A) In general.—The tax imposed by
25	chapter 1 on the account beneficiary for any

1	taxable year in which there is a payment or dis-
2	tribution from a medical savings account of
3	such beneficiary which is includible in gross in-
4	come under paragraph (1) shall be increased by
5	100 percent of the amount which is so includ-
6	ible.
7	"(B) Exception for distributions
8	AFTER AGE 65.—Subparagraph (A) shall not
9	apply to any payment or distribution after the
10	date on which the account beneficiary attains
11	age 65.
12	"(C) Exception for disability or
13	DEATH.—Subparagraph (A) shall not apply if
14	the payment or distribution is made after the
15	account beneficiary becomes disabled within the
16	meaning of section $72(m)(7)$ or dies.
17	"(3) ROLLOVER CONTRIBUTION.—An amount is
18	described in this paragraph as a rollover contribu-
19	tion if it meets the requirements of subparagraphs
20	(A) and (B).
21	"(A) In General.—Paragraph (1) shall
22	not apply to any amount paid or distributed
23	from a medical savings account to the account
24	beneficiary to the extent the amount received is
25	paid into a medical savings account for the ben-

1	efit of such beneficiary not later than the 60th
2	day after the day on which he receives the pay-
3	ment or distribution.
4	"(B) Limitation.—This paragraph shall
5	not apply to any amount described in subpara-
6	graph (A) received by an individual from a
7	medical savings account if, at any time during
8	the 1-year period ending on the day of such re-
9	ceipt, such individual received any other amount
10	described in subparagraph (A) from a medical
11	savings account which was not includible in his
12	gross income because of the application of this
13	paragraph.
14	"(4) Coordination with medical expense
15	DEDUCTION.—For purposes of section 213, any pay-
16	ment or distribution out of a medical savings ac-
17	count for qualified medical expenses shall not be
18	treated as an expense paid for medical care to the
19	extent of the amount of such payment or distribu-
20	tion which is excludable from gross income solely by
21	reason of paragraph (1)(A).
22	"(e) Definitions.—For purposes of this section—
23	"(1) Qualified medical expenses.—
24	"(A) In general.—The term 'qualified
25	medical expenses' means any amounts paid dur-

1	ing the taxable year, not compensated for by in-
2	surance or otherwise, for medical care (as de-
3	fined in section 213(d)) of the taxpayer, his
4	spouse, or a dependent (as defined in section
5	152).
6	"(B) Long-term care insurance.—
7	Such term includes premiums paid during the
8	taxable year for any long-term care insurance
9	contract for the benefit of the individual or
10	such individual's spouse.
11	"(C) Long-term care insurance con-
12	TRACT.—For purposes of subparagraph (B),
13	the term 'long-term care insurance contract'
14	means any insurance contract issued if—
15	"(i) the only insurance protection pro-
16	vided under such contract is coverage of
17	qualified long-term care services and bene-
18	fits incidental to such coverage (as defined
19	under regulations prescribed by the Sec-
20	retary),
21	"(ii) the maximum benefit under the
22	policy for expenses incurred for any day
23	does not exceed \$200,
24	"(iii) such contract does not cover ex-
25	penses incurred for services or items to the

1	extent that such expenses are reimbursable
2	under title XVIII of the Social Security
3	Act or would be so reimbursable but for
4	the application of a deductible or coinsur-
5	ance amount,
6	"(iv) such contract is guaranteed re-
7	newable,
8	"(v) such contract does not have any
9	cash surrender value, and
10	"(vi) all refunds of premiums, and all
11	policyholder dividends or similar amounts,
12	under such contract are to be applied as a
13	reduction in future premiums or to in-
14	crease future benefits.
15	"(2) Account beneficiary.—The term 'ac-
16	count beneficiary' means the individual for whose
17	benefit the medical savings account is maintained.
18	"(f) Custodial Accounts.—For purposes of this
19	section, a custodial account shall be treated as a trust if—
20	"(1) the assets of such account are held by a
21	bank (as defined in section 408(n)), insurance com-
22	pany (as defined in section 816), or another person
23	who demonstrates to the satisfaction of the Sec-
24	retary that the manner in which he will administer

1	the account will be consistent with the requirements
2	of this section, and
3	"(2) the custodial account would, except for the
4	fact that it is not a trust, constitute a medical sav-
5	ings account described in subsection (a).
6	For purposes of this title, in the case of a custodial ac-
7	count treated as a trust by reason of the preceding sen-
8	tence, the custodian of such account shall be treated as
9	the trustee thereof.
10	"(g) Reports.—The trustee of a medical savings ac-
11	count shall keep such records and make such reports re-
12	garding such account to the Secretary and to the account
13	beneficiary with respect to contributions, distributions,
14	and such other matters as the Secretary may require
15	under regulations. The reports required by this subsection
16	shall be filed at such time and in such manner and fur-
17	nished to such individuals at such time and in such man-
18	ner as may be required by such regulations."
19	(b) Income and Employment Tax Treatment of
20	Employer Contributions.—
21	(1) Employer payments excluded from
22	GROSS INCOME.—The text of section 106 of such
23	Code is amended to read as follows:
24	"Gross income of an employee does not include—

1	"(1) employer-provided coverage under an acci-
2	dent or health plan, and
3	"(2) employer contributions to any medical sav-
4	ings account (as defined in section 7705) of an eligi-
5	ble employee, but only to the extent that the amount
6	contributed does not exceed the excess of premium
7	for standard coverage over the premium for high-de-
8	ductible coverage (as such terms are defined in sec-
9	tion 1903 of the Basic Health Care Reform Act of
10	1995).''
11	(2) Employer payments excluded from
12	EMPLOYMENT TAX BASE.—
13	(A) Social security taxes.—
14	(i) Subsection (a) of section 3121 of
15	such Code is amended by striking "or" at
16	the end of paragraph (20), by striking the
17	period at the end of paragraph (21) and
18	inserting "; or", and by inserting after
19	paragraph (21) the following new para-
20	graph:
21	"(22) any payment made to or for the benefit
22	of an employee if at the time of such payment it is
23	reasonable to believe that the employee will be able
24	to exclude such payment from income under section
25	106(2)."

1	(ii) Subsection (a) of section 209 of
2	the Social Security Act is amended by
3	striking "or" at the end of paragraph (18),
4	by striking the period at the end of para-
5	graph (19) and inserting "; or", and by in-
6	serting after paragraph (19) the following
7	new paragraph:
8	"(20) any payment made to or for the benefit
9	of an employee if at the time of such payment it is
10	reasonable to believe that the employee will be able
11	to exclude such payment from income under section
12	106(2) of the Internal Revenue Code of 1986."
13	(B) RAILROAD RETIREMENT TAX.—Sub-
14	section (e) of section 3231 of such Code is
15	amended by adding at the end the following
16	new paragraph:
17	"(10) Medical savings account contribu-
18	TIONS.—The term 'compensation' shall not include
19	any payment made to or for the benefit of an em-
20	ployee if at the time of such payment it is reason-
21	able to believe that the employee will be able to ex-
22	clude such payment from income under section
23	106(2).''
24	(C) Unemployment Tax.—Subsection (b)
25	of section 3306 of such Code is amended by

1	striking "or" at the end of paragraph (15), by
2	striking the period at the end of paragraph (16)
3	and inserting "; or", and by inserting after
4	paragraph (16) the following new paragraph:
5	"(17) any payment made to or for the benefit
6	of an employee if at the time of such payment it is
7	reasonable to believe that the employee will be able
8	to exclude such payment from income under section
9	106(2).''
10	(D) WITHHOLDING TAX.—Subsection (a)
11	of section 3401 of such Code is amended by
12	striking "or" at the end of paragraph (19), by
13	striking the period at the end of paragraph (20)
14	and inserting "; or", and by inserting after
15	paragraph (20) the following new paragraph:
16	"(21) any payment made to or for the benefit
17	of an employee if at the time of such payment it is
18	reasonable to believe that the employee will be able
19	to exclude such payment from income under section
20	106(2).''
21	(c) TECHNICAL AMENDMENTS.—
22	(1) Tax on prohibited transactions.—Sec-
23	tion 4975 of such Code (relating to prohibited trans-
24	actions) is amended—

1	(A) by adding at the end of subsection (c)
2	the following new paragraph:
3	"(4) Special rule for medical savings ac-
4	COUNTS.—An individual for whose benefit a medical
5	savings account (within the meaning of section
6	7705) is established shall be exempt from the tax
7	imposed by this section with respect to any trans-
8	action concerning such account (which would other-
9	wise be taxable under this section) if, with respect
10	to such transaction, the account ceases to be a medi-
11	cal savings account by reason of the application of
12	section 7705(c)(2)(A) to such account.", and
13	(B) by inserting "or a medical savings ac-
14	count described in section 7705" in subsection
15	(e)(1) after "described in section 408(a)".
16	(2) Failure to provide reports on medi-
17	CAL SAVINGS ACCOUNTS.—Section 6693 of such
18	Code (relating to failure to provide reports on indi-
19	vidual retirement account or annuities) is amend-
20	ed—
21	(A) by inserting " <b>OR ON MEDICAL SAV</b> -
22	INGS ACCOUNTS" after "ANNUITIES" in the
23	heading of such section, and
24	(B) by adding at the end of subsection (a)
25	the following: "The person required by section

1	7705(g) to file a report regarding a medical
2	savings account at the time and in the manner
3	required by such section shall pay a penalty of
4	\$50 for each failure unless it is shown that
5	such failure is due to reasonable cause."
6	(3) CLERICAL AMENDMENTS.—
7	(A) The table of sections for chapter 79 of
8	such Code is amended by adding at the end the
9	following:
	"Sec. 7705. Medical savings accounts."
10	(B) The table of sections for subchapter B
11	of chapter 68 of such Code is amended by in-
12	serting "or on medical savings accounts" after
13	"annuities" in the item relating to section
14	6693.
15	(d) Effective Date.—The amendments made by
16	this section shall apply to taxable years beginning after
17	December 31, 1996.
18	PART 3—FAIR RATING PRACTICES
19	SEC. 1021. USE OF FAIR RATING PRACTICES.
20	(a) Use of Fair Rating Practices.—The pre-
21	mium rate established by a carrier for health insurance
22	coverage in the small group market may not vary except
23	by the following:

- 45 1 (1) AGE.—By age, based on classes of age es-2 tablished by the Secretary, in consultation with the NAIC, consistent with subsection (b). 3 4 (2) GEOGRAPHIC AREA.—By geographic area, 5 as identified by a State consistent with subsection 6 (c). (3) Family class.—By family class, based on 7 the following 4 classes of family coverage: individual, 8 9 individual with one or more children, married couple without a child, and married couple with one or 10 11 more children. 12 (4) Benefit design of coverage, including by type of coverage, such as 13 14 standard coverage and high-deductible coverage, and 15 by type of coverage option (described in section 16 1903(15)) with respect to standard coverage. 17 (5) Administrative categories.—By per-18 mitted expense category, based on differences in ex-19 penses among such categories, consistent with sub-20 section (d). 21 The premiums shall be established for the different benefit designs (including standard coverage and high-deductible
- 23 coverage) based on the actuarial value of the coverage for
- the population of the small group market in the fair rating

1	area, without regard to the distribution of such population
2	among the types of coverage or type of coverage options.
3	(b) Limitation on Variation by Age.—
4	(1) IN GENERAL.—Any variation in premium
5	rates by age under subsection (a)(1) for age classes
6	of individuals under 65 years of age may not result
7	in the ratio of the highest age rate to the lowest age
8	rate exceeding the limiting ratio described in para-
9	graph (2).
10	(2) LIMITING RATIO.—For purposes of para-
11	graph (1), the limiting ratio described in this para-
12	graph is—
13	(A) 4-to-1, for premiums for months in
14	1997,
15	(B) 3.67-to-1, for premiums for months in
16	1998,
17	(C) 3.33-to-1, for premiums for months in
18	1999, and
19	(D) 3-to-1, for premiums for months in
20	2000 and any succeeding year.
21	(3) Separate age classes for individuals
22	65 YEARS OF AGE OR OLDER.—The Secretary shall
23	establish one or more separate age classes for indi-
24	viduals 65 years of age or older.

1	(4) Preemption.—For preemption of State
2	laws relating to establishment of premium rates, see
3	section 1204.
4	(c) Geographic Area Variations.—For purposes
5	of subsection (a)(2), a State—
6	(1) may not identify an area that divides a 3-
7	digit zip code, a county, or all portions of a metro-
8	politan statistical area,
9	(2) shall not permit premium rates for coverage
10	offered in a portion of an interstate metropolitan
11	statistical area to vary based on the State in which
12	the coverage is offered, and
13	(3) may, upon agreement with one or more ad-
14	jacent States, identify multi-state geographic areas
15	consistent with paragraphs (1) and (2).
16	(d) Administrative Variations.—
17	(1) Expense categories.—Expense cat-
18	egories shall be established under subsection (a)(5)
19	by a carrier in a manner that only reflects dif-
20	ferences based on marketing, commissions, and simi-
21	lar expenses. Such categories shall take into account
22	health plan choice organizations.
23	(2) Limitation on variations.—The vari-
24	ation provided among expense categories under sub-
25	section (a)(5) may not result in a premium for the

- 1 highest expense category exceeding 120 percent of
- 2 the premium for the lowest expense category.
- 3 (e) Premium Rating in Group Health Plans.—
- 4 The premium rate established under a group health plan
- 5 for health insurance coverage may not vary within a bene-
- 6 fit design except by the factors described in subsection (a)
- 7 and subject to the limitation specified in subsection (b).
- 8 (f) ACTUARIAL CERTIFICATION.—Each carrier that
- 9 offers health insurance coverage in a State shall file annu-
- 10 ally with the State commissioner of insurance a written
- 11 statement by a member of the American Academy of Actu-
- 12 aries (or other individual acceptable to the commissioner)
- 13 that, based upon an examination by the individual which
- 14 includes a review of the appropriate records and of the
- 15 actuarial assumptions of the carrier and methods used by
- 16 the carrier in establishing premium rates for applicable
- 17 health insurance coverage—
- 18 (1) the carrier is in compliance with the appli-
- cable provisions of this section, and
- 20 (2) the rating methods are actuarially sound.
- 21 Each such carrier shall retain a copy of such statement
- 22 for examination at its principal place of business.
- 23 (g) Construction.—The provisions of this section
- 24 shall apply to premium rates based on the fair rating area

- 1 in which the covered individual or employee resides to re-
- 2 flect the population in the small group market.
- 3 SEC. 1022. ESTABLISHMENT OF RISK ADJUSTMENT MECHA-
- 4 NISMS.

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- (a) Establishment of Standards.—
  - (1) DEVELOPMENT OF MODELS.—

(A) IN GENERAL.—The Secretary shall request the NAIC to develop, within 9 months after the date of the enactment of this Act and in consultation with the American Academy of Actuaries, a model risk adjustment system composed of one or more risk adjustment mechanisms under which premiums applicable to health insurance coverage in the small group market would be adjusted to take into account such factors as may be appropriate to predict the future need and the efficient use of services by covered individuals in the market. Such factors may include the age, gender, geographic residence, health status, or other demographic characteristics of individuals enrolled in such plans and shall include consideration of enrollment of a disproportionate share of individuals who enroll during the initial open enrollment period under section 1005(b)(1).

1	(B) Promulgation as proposed
2	RULE.—If the NAIC develops such model with-
3	in such period, the Secretary shall publish the
4	model as a proposed rule under section 553 of
5	title 5, United States Code. If the NAIC has
6	not developed such model within such period,
7	the Secretary shall publish (not later than 60
8	days after the end of such period) a proposed
9	rule that specifies a proposed model that pro-
10	vides for effective risk adjustment mechanisms.
11	(2) Rule making process.—The Secretary
12	shall provide for a period (described in section
13	553(c) of title 5, United States Code) of not less
14	than 30 days for public comment on a proposed rule
15	published under paragraph (1)(B). The Secretary
16	shall publish a final rule, by not later than July 1,
17	1996, that specifies risk adjustment mechanisms
18	that the Secretary finds are effective for purposes of
19	carrying out this section. Such rule shall include
20	models developed by the NAIC if the Secretary finds
21	that such models provide for effective risk adjust-
22	ment mechanisms.
23	(3) Modification.—The Secretary, at the re-
24	quest of the NAIC or otherwise, may by regulation

- 1 modify the model risk adjustment system established
- 2 under this subsection.
- 3 (b) Implementation of Risk Adjustment Sys-
- 4 TEM.—Each State shall establish and maintain a risk ad-
- 5 justment system that conforms with the model established
- 6 under this section by not later than January 1, 1997. A
- 7 State may establish and maintain such a system jointly
- 8 with one or more other States.

#### 9 **PART 4—CONSUMER PROTECTIONS**

- 10 SEC. 1031. REQUIREMENT FOR PROVISION OF INFORMA-
- 11 **TION.**
- 12 (a) CARRIERS.—
- 13 (1) IN GENERAL.—Each carrier that offers
- health insurance coverage to small employers (or
- qualifying employees of small employers) must dis-
- 16 close to such prospective enrollees, to brokers, and
- to health plan choice organizations the information
- that the Secretary may specify relating to the per-
- formance of the carrier in providing such coverage
- and relating to differences between the coverage pro-
- vided and the most similar model benefit package es-
- tablished under section 1104(b)(2). If a carrier of-
- fers to employers coverage the actuarial value of
- which is more than the actuarial value for high-de-
- ductible coverage but less than such value for stand-

- ard coverage, the carrier must disclose to such employers detailed information on how the coverage offered compares to any standard and high-deductible coverage offered by the carrier to such employers.
  - (2) Marketing material.—Each carrier that provides any health insurance coverage in a State shall file with the State those marketing materials relating to the offer and sale of health insurance coverage to be used for distribution before the materials are used. Such materials shall be in a uniform format specified under the standards established under section 1041.
- (b) GROUP HEALTH PLANS.—Each group health plan that provides health coverage must disclose to enrollees and potential enrollees information, similar to the information described in subsection (a), relating to performance of the plan in providing such coverage and relating
  to differences between the coverage provided and the most
  similar model benefit package established under section
  1104(b)(2).
- (c) Information Relating to Risk Adjust-22 Ment.—Each carrier or group health plan providing cov-23 erage in the small group market shall provide to the State 24 such information as the State may require in order to

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- 1 carry out section 1022 (relating to risk adjustment mecha-
- 2 nisms).
- 3 SEC. 1032. PROHIBITION OF IMPROPER INCENTIVES.
- 4 (a) Limitation on Financial Incentives.—No
- 5 carrier that provides health insurance coverage may vary
- 6 the commission or financial or other remuneration to a
- 7 person based on the claims experience or health status of
- 8 individuals enrolled by or through the person.
- 9 (b) Nondiscrimination in Agent Compensa-
- 10 TION.—A carrier—
- 11 (1) may not vary or condition the compensation
- provided to an agent or broker related to the sale or
- renewal of health insurance coverage because of the
- health status or claims experience of any individuals
- enrolled with the carrier through the agent or
- 16 broker; and
- 17 (2) may not terminate, fail to renew, or limit its
- contract or agreement of representation with an
- agent or broker for any reason related to the health
- status or claims experience of any individuals en-
- 21 rolled with the carrier through the agent or broker.
- 22 (c) Prohibition of Tie-in Arrangements.—No
- 23 carrier that offers health insurance coverage may require
- 24 the purchase of any other insurance or product as a condi-
- 25 tion for the purchase of such coverage.

1	SEC. 1033. WRITTEN POLICIES AND PROCEDURES RESPECT-
2	ING ADVANCE DIRECTIVES.
3	A carrier and a group health plan offering health cov-
4	erage shall meet the requirements of section 1866(f) of
5	the Social Security Act (relating to maintaining written
6	policies and procedures respecting advance directives), in-
7	sofar as such requirements would apply to the carrier or
8	plan if the carrier or plan were an eligible organization.
9	PART 5—STANDARDS AND CERTIFICATION; EN-
0	FORCEMENT; PREEMPTION; GENERAL PRO-
1	VISIONS
2	SEC. 1041. ESTABLISHMENT OF STANDARDS.
3	(a) Role of NAIC.—
4	(1) IN GENERAL.—The Secretary shall request
5	the NAIC to develop, within 9 months after the date
6	of the enactment of this Act, model regulations that
7	specify standards with respect to the requirements of
8	this subtitle as applicable to carriers and health in-
9	surance coverage.
20	(2) Review of Standards.—If the NAIC de-
21	velops recommended regulations specifying such
22	standards within such period, the Secretary shall re-
23	view the standards. Such review shall be completed
24	within 60 days after the date the regulations are de-
25	veloped. Unless the Secretary determines within

such period that the standards do not meet the re-

1	quirements, such standards shall serve as the stand-
2	ards under this subtitle, with such amendments as
3	the Secretary deems necessary.
4	(b) Contingency.—If the NAIC does not develop
5	such model regulations within such period or the Secretary
6	determines that such regulations do not specify standards
7	that meet the requirements described in subsection (a),
8	the Secretary shall specify, within 15 months after the
9	date of the enactment of this Act, standards to carry out
10	those requirements.
11	SEC. 1042. APPLICATION OF STANDARDS TO CARRIERS
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12	THROUGH STATES.
12	THROUGH STATES.
12 13	THROUGH STATES.  (a) APPLICATION OF STANDARDS.—
12 13 14	THROUGH STATES.  (a) APPLICATION OF STANDARDS.—  (1) IN GENERAL.—Each State shall submit to
12 13 14 15	THROUGH STATES.  (a) APPLICATION OF STANDARDS.—  (1) IN GENERAL.—Each State shall submit to the Secretary, by the deadline specified in paragraph
12 13 14 15 16	THROUGH STATES.  (a) APPLICATION OF STANDARDS.—  (1) IN GENERAL.—Each State shall submit to the Secretary, by the deadline specified in paragraph (2), a report on steps the State is taking to imple-
12 13 14 15 16 17	THROUGH STATES.  (a) APPLICATION OF STANDARDS.—  (1) IN GENERAL.—Each State shall submit to the Secretary, by the deadline specified in paragraph (2), a report on steps the State is taking to implement and enforce the standards established under
12 13 14 15 16 17	THROUGH STATES.  (a) APPLICATION OF STANDARDS.—  (1) IN GENERAL.—Each State shall submit to the Secretary, by the deadline specified in paragraph (2), a report on steps the State is taking to implement and enforce the standards established under section 1041 with respect to carriers and health in-
12 13 14 15 16 17 18 19	the Secretary, by the deadline specified in paragraph (2), a report on steps the State is taking to implement and enforce the standards established under section 1041 with respect to carriers and health insurance coverage offered or renewed not later than
12 13 14 15 16 17 18 19 20	through states.  (a) Application of Standards.—  (1) In General.—Each State shall submit to the Secretary, by the deadline specified in paragraph (2), a report on steps the State is taking to implement and enforce the standards established under section 1041 with respect to carriers and health insurance coverage offered or renewed not later than such deadline.
12 13 14 15 16 17 18 19 20 21	THROUGH STATES.  (a) APPLICATION OF STANDARDS.—  (1) IN GENERAL.—Each State shall submit to the Secretary, by the deadline specified in paragraph (2), a report on steps the State is taking to implement and enforce the standards established under section 1041 with respect to carriers and health insurance coverage offered or renewed not later than such deadline.  (2) DEADLINE FOR REPORT.—The deadline

(1) Notice of deficiency.—If the Secretary determines that a State has failed to submit a report by the deadline specified under subsection (a)(2) or finds that the State has not implemented and provided adequate enforcement of the standards established under section 1041, the Secretary shall notify the State and provide the State a period of 60 days in which to submit such report or to implement and enforce such standards.

#### (2) IMPLEMENTATION OF ALTERNATIVE.—

- (A) IN GENERAL.—If, after such 60-day period, the Secretary finds that such a failure has not been corrected, the Secretary shall provide for such mechanism for the implementation and enforcement of such standards in the State as the Secretary determines to be appropriate.
- (B) EFFECTIVE PERIOD.—Such implementation and enforcement shall take effect with respect to carriers, and health insurance coverage offered or renewed, on or after 3 months after the date of the Secretary's finding under subparagraph (A), and until the date the Secretary finds that such a failure has been corrected.

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1	SEC. 1043. APPLICATION TO GROUP HEALTH PLANS.
2	(a) In General.—Subject to subsection (b), sections
3	1041 and 1042 shall apply to group health plans providing
4	health coverage in the same manner as they apply to car-
5	riers providing health insurance coverage.
6	(b) Substitution of References.—For purposes
7	of subsection (a), any reference in section 1041 or 1042
8	to—
9	(1) a State is deemed a reference to the Sec-
10	retary, and
11	(2) a carrier or health insurance coverage is
12	deemed a reference to a group health plan and
13	health coverage, respectively.
14	SEC. 1044. ENFORCEMENT.
15	(a) IN GENERAL.—Chapter 43 of the Internal Reve-
16	nue Code of 1986 (relating to qualified pension plans, etc.)
17	is amended by adding at the end thereof the following new
18	section:
19	"SEC. 4980C. FAILURE OF CARRIER OR GROUP HEALTH
20	PLANS TO COMPLY WITH STANDARDS.
21	"(a) Imposition of Tax.—
22	"(1) IN GENERAL.—There is hereby imposed a
23	tax on the failure of a carrier or group health plan

to comply with the requirements applicable to the

carrier or group health plan under parts 1 through

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- 4 of subtitle A of title I of the Basic Health Care
   Reform Act of 1995.
- "(2) EXCEPTION.—Paragraph (1) shall not apply to a failure by a carrier in a State if the Secretary of Health and Human Services determines that the State has in effect a regulatory enforcement mechanism that provides adequate sanctions with respect to such a failure by such a carrier.

### 9 "(b) Amount of Tax.—

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- "(1) IN GENERAL.—Subject to paragraph (2), the amount of the tax imposed by subsection (a) shall be \$100 for each day during which such failure persists for each individual to which such failure relates. A rule similar to the rule of section 4980B(b)(3) shall apply for purposes of this section.
- "(2) LIMITATION.—The amount of the tax imposed by subsection (a) for a carrier with respect to health insurance coverage shall not exceed 25 percent of the amounts received for such coverage during the period such failure persists.
- 21 "(c) Liability for Tax.—The tax imposed by this
- 22 section shall be paid by the carrier or administrator of
- 23 the group health plan (as the case may be).
- 24 "(d) Exceptions.—

1	"(1) Corrections within 30 days.—No tax
2	shall be imposed by subsection (a) by reason of any
3	failure if—
4	"(A) such failure was due to reasonable
5	cause and not to willful neglect, and
6	"(B) such failure is corrected within the
7	30-day period beginning on the earliest date the
8	carrier or administrator of the group health
9	plan knew, or exercising reasonable diligence
10	would have known, that such failure existed.
11	"(2) WAIVER BY SECRETARY.—In the case of a
12	failure which is due to reasonable cause and not to
13	willful neglect, the Secretary may waive part or all
14	of the tax imposed by subsection (a) to the extent
15	that payment of such tax would be excessive relative
16	to the failure involved.
17	$\lq\lq$ (e) Definitions.—For purposes of this section, the
18	terms 'health insurance coverage', 'group health plan', and
19	'carrier' have the respective meanings given such terms
20	in section 1903 of the Basic Health Care Reform Act of
21	1995.''
22	(b) CLERICAL AMENDMENT.—The table of sections
23	for chapter 43 of such Code is amended by adding at the
24	end thereof the following new item:

 $\lq\lq Sec.~4980C.$  Failure of carrier or group health plans to comply with standards.  $\lq\lq$ 

#### 1 SEC. 1045. LIMITATION ON SELF INSURANCE FOR CERTAIN

- 2 EMPLOYER PLANS.
- 3 (a) IN GENERAL.—An employer plan (other than a
- 4 multiemployer plan, as defined in section 414(f) of the In-
- 5 ternal Revenue Code of 1986) may not offer health cov-
- 6 erage other than through a carrier unless the plan has
- 7 at least 50 qualifying employees.
- 8 (b) Exception.—Subsection (a) shall not apply to
- 9 an employer plan that offers health coverage through a
- 10 multiple employer welfare arrangement if the arrangement
- 11 covers at least 1,000 qualifying employees and meets sol-
- 12 vency standards established by the State.

#### 13 PART 6—MARKETPLACE FOR INDIVIDUALS

- 14 SEC. 1051. APPLICATION OF SIMILAR REQUIREMENTS.
- 15 (a) IN GENERAL.—Except as provided in subsection
- 16 (b), the provisions of this subtitle shall apply to carriers
- 17 offering health insurance coverage to qualifying individ-
- 18 uals in the individual market (as defined in section
- 19 1903(11)) in the same manner as such provisions apply
- 20 to carriers offering health insurance coverage to employ-
- 21 ers. For purposes of this subsection, any reference to an
- 22 employee or a qualifying employee is deemed a reference
- 23 to such an individual.
- 24 (b) Exception for Risk Adjustment.—Section
- 25 1022 (relating to risk adjustment systems) shall be ap-

1	plied under this part in a manner that is separate from
2	its application under part 3.
3	Subtitle B—Facilitating Establish-
4	ment of Health Plan Choice Or-
5	ganizations (HPCOs)
6	SEC. 1101. ESTABLISHMENT AND ORGANIZATION.
7	(a) In General.—Health plan choice organizations
8	(each in this part referred to as a "choice organization")
9	may be established in accordance with this part. Each
10	choice organization shall be chartered under State law and
11	operated as a not-for-profit corporation. A carrier may not
12	form, underwrite, or possess a majority vote of a choice
13	organization, but may administer such an organization.
14	(b) Board of Directors.—
15	(1) IN GENERAL.—Each choice organization
16	shall be governed by a Board of Directors. Such
17	Board shall initially be appointed under procedures
18	established by the State in which it operates. Subse-
19	quently, the Board shall be elected by the members
20	of the organization in accordance with paragraph
21	(3). Such Board shall be composed as follows:
22	(A) In the case of a choice organization of-
23	fering coverage in the small group market, the
24	Board shall be composed of small employers (or
25	representatives of small employers) and qualify-

1	ing employees of small employers (or represent-
2	atives of such employees) in the area in which
3	the organization operates.
4	(B) In the case of a choice organization of-
5	fering coverage in the individual market, the
6	Board shall be composed of qualifying individ-
7	uals in the area in which the organization oper-
8	ates.
9	(C) In the case of a choice organization of-
10	fering coverage in both the small group market
11	and the individual market, the Board shall be
12	composed of individuals described in subpara-
13	graph (A) and individuals described in subpara-
14	graph (B).
15	(2) Membership.—For each market for which
16	a choice organization offers coverage, the choice or-
17	ganization shall accept all small employers, qualify-
18	ing employees, and qualifying individuals who are in
19	the market within the area served by the organiza-
20	tion as members if such employers, employees, or in-
21	dividuals request such membership.
22	(3) VOTING.—Members of a choice organization
23	shall have voting rights consistent with the rules es-
24	tablished under the bylaws governing the organiza-

tion.

1	(c) DUTIES OF CHOICE ORGANIZATIONS.—
2	(1) In GENERAL.—Subject to paragraph (2),
3	each choice organization shall—
4	(A) market health insurance coverage in
5	the small group market, the individual market,
6	or in both the small group market and the indi-
7	vidual market throughout the entire area served
8	by the organization;
9	(B) enter into agreements under section
10	1102 with carriers offering qualified health cov-
11	erage under this subtitle;
12	(C) provide information and enter into
13	agreements under section 1103;
14	(D) enroll individuals with carriers offering
15	qualified health coverage, only in accordance
16	with section 1104;
17	(E) disseminate quality information under
18	section 4002; and
19	(F) carry out other functions provided for
20	under this part.
21	(2) Limitation on activities.—A choice or-
22	ganization shall not—
23	(A) perform any activity (including review,
24	approval, or enforcement) relating to payment
25	rates for providers;

1	(B) perform any activity (including certifi-
2	cation or enforcement) relating to compliance of
3	carriers (and health coverage provided by car-
4	riers) with the requirements of subtitle A;
5	(C) assume financial risk in relation to any
6	such carrier; or
7	(D) perform other activities identified by
8	the State as being inconsistent with the per-
9	formance of its duties under paragraph (1).
10	(3) Characteristics of Service Area.—
11	(A) IN GENERAL.—A choice organization
12	need not serve geographic areas that are contig-
13	uous, but the geographic boundaries of such
14	areas shall be consistent with the boundaries es-
15	tablished under section 1021 for fair rating
16	areas.
17	(B) SERVICE OF ENTIRE METROPOLITAN
18	STATISTICAL AREA.—If a choice organization
19	serves a part of a metropolitan statistical area
20	the organization shall serve the entire area.
21	(d) Establishment Not Required.—Nothing in
22	this section shall be construed as requiring—
23	(1) that a choice organization be established in
24	each area of a State in which it operates; and

1	(2) that there be only one choice organization
2	established with respect to any area.
3	SEC. 1102. AGREEMENTS TO OFFER QUALIFIED HEALTH
4	COVERAGE.
5	(a) AGREEMENTS.—
6	(1) In general.—Except as provided in para-
7	graph (3), each choice organization for an area shall
8	enter into an agreement under this section—
9	(A) with each carrier that desires to make
10	available qualified health coverage in the small
11	group market through the choice organization
12	(consistent with any procedures established by
13	the State);
14	(B) with each carrier that desires to make
15	available qualified health coverage in the indi-
16	vidual market through the choice organization
17	(consistent with any procedures established by
18	the State); or
19	(C) with each carrier described in subpara-
20	graph (A) or subparagraph (B).
21	(2) TERMINATION OF AGREEMENT.—An agree-
22	ment under paragraph (1) shall remain in effect for
23	a 12-month period, except that the choice organiza-
24	tion may terminate an agreement under paragraph
25	(1) if the carrier's license or certification under

1	State law is terminated or for other good cause
2	shown.
3	(b) RECEIPT OF PREMIUMS ON BEHALF OF CAR-
4	RIERS.—
5	(1) In GENERAL.—Under an agreement under
6	this section between a choice organization and a car-
7	rier—
8	(A) premiums shall be payable, and
9	(B) payment of premiums may be made by
10	individuals (or employers on their behalf) di-
11	rectly to the choice organization for the benefit
12	of the carrier.
13	(2) Timing of payment of premiums.—Pre-
14	miums may be payable on a monthly basis (or, at
15	the option of a qualifying employee or individual, on
16	a quarterly basis). The choice organization may pro-
17	vide for reasonable penalties and grace periods for
18	late payment.
19	(3) Carriers retain risk of
20	NONPAYMENT.—Nothing in this subsection shall be
21	construed as placing upon a choice organization any
22	risk associated with the failure of individuals and
23	employers to make prompt payment of premiums
24	(other than the portion of the premium representing
25	the choice organization administrative fee under sec-

- tion 1105). Each small employer and qualifying individual who enrolls with a carrier providing qualified health coverage through the choice organization is liable to the carrier for premiums.
  - (c) Forwarding of Premiums.—

- (1) IN GENERAL.—If, under an agreement under subsection (a), premium payments for qualified health coverage are made to the choice organization, the choice organization shall forward to the carrier the amount of the premiums.
- (2) Payments.—Payments shall be made by the choice organization under this subsection within a period of days (specified by the Secretary and not to exceed 7 days) after receipt of the premium from the small employer of the qualifying employee or the qualifying individual, as the case may be.

### (d) Payment of Commissions.—

- (1) IN GENERAL.—Subject to paragraph (2), nothing in this part shall be construed to preclude a carrier from paying a commission or other remuneration in connection with the purchase of health care coverage by individuals or groups, consistent with State law.
- (2) LIMITATION ON VARIATION.—A carrier may not vary such compensation or remuneration based,

1	directly or indirectly, on the anticipated or actual
2	claims experience associated with the group or indi-
3	viduals purchasing health care coverage.
4	SEC. 1103. PROVISION OF INFORMATION.
5	Each choice organization for an area shall make
6	available to small employers that employ individuals in the
7	area and to qualifying individuals who reside in the area—
8	(1) information provided to the choice organiza-
9	tion by the State or carriers, and
10	(2) the opportunity to enter into an agreement
11	with the organization for the purchase of qualified
12	health coverage (to the extent that the organization
13	offers coverage in the market through which the em-
13 14	offers coverage in the market through which the employer or individual seeks coverage).
14	ployer or individual seeks coverage).
14 15	ployer or individual seeks coverage).  SEC. 1104. ENROLLING INDIVIDUALS FOR QUALIFIED
<ul><li>14</li><li>15</li><li>16</li></ul>	ployer or individual seeks coverage).  SEC. 1104. ENROLLING INDIVIDUALS FOR QUALIFIED  HEALTH COVERAGE THROUGH A CHOICE OR-
<ul><li>14</li><li>15</li><li>16</li><li>17</li></ul>	ployer or individual seeks coverage).  SEC. 1104. ENROLLING INDIVIDUALS FOR QUALIFIED  HEALTH COVERAGE THROUGH A CHOICE OR- GANIZATION.
14 15 16 17 18	ployer or individual seeks coverage).  SEC. 1104. ENROLLING INDIVIDUALS FOR QUALIFIED  HEALTH COVERAGE THROUGH A CHOICE OR- GANIZATION.  A choice organization shall offer, on behalf of each
14 15 16 17 18 19	ployer or individual seeks coverage).  SEC. 1104. ENROLLING INDIVIDUALS FOR QUALIFIED  HEALTH COVERAGE THROUGH A CHOICE OR- GANIZATION.  A choice organization shall offer, on behalf of each carrier with which an agreement was entered into under
14 15 16 17 18 19 20 21	ployer or individual seeks coverage).  SEC. 1104. ENROLLING INDIVIDUALS FOR QUALIFIED  HEALTH COVERAGE THROUGH A CHOICE OR- GANIZATION.  A choice organization shall offer, on behalf of each carrier with which an agreement was entered into under section 1102 and in accordance with the enrollment proce-
14 15 16 17 18 19 20 21 22	ployer or individual seeks coverage).  SEC. 1104. ENROLLING INDIVIDUALS FOR QUALIFIED  HEALTH COVERAGE THROUGH A CHOICE OR- GANIZATION.  A choice organization shall offer, on behalf of each carrier with which an agreement was entered into under section 1102 and in accordance with the enrollment procedures of such carriers and the enrollment periods provided
14 15 16 17 18 19 20 21 22 23	ployer or individual seeks coverage).  SEC. 1104. ENROLLING INDIVIDUALS FOR QUALIFIED  HEALTH COVERAGE THROUGH A CHOICE OR- GANIZATION.  A choice organization shall offer, on behalf of each carrier with which an agreement was entered into under section 1102 and in accordance with the enrollment procedures of such carriers and the enrollment periods provided under section 1005, enrollment for the coverage only to

- 1 open enrollment periods (described in section 1005(c)) of
- 2 all carriers through which coverage is offered by the orga-
- 3 nization so that there is one common annual open enroll-
- 4 ment period for all such carriers with respect to each indi-
- 5 vidual enrolled for coverage through the organization.
- 6 Nothing in this section shall preclude a choice organiza-
- 7 tion from having different common annual open enroll-
- 8 ment periods for different individuals.

#### 9 SEC. 1105. RESTRICTION ON CHARGES.

- 10 (a) IN GENERAL.—A choice organization may impose
- 11 an administrative fee with respect to a qualifying employee
- 12 or qualifying individual enrolled for qualified health cov-
- 13 erage offered through the choice organization.
- 14 (b) Fee.—A choice organization that elects to impose
- 15 a fee under subsection (a) shall ensure that such fee is
- 16 set as a percentage of the premium for each such coverage
- 17 option, is imposed uniformly with respect to all coverage
- 18 options offered through the organization, and is disclosed
- 19 explicitly as an addition to the premium.

# 20 Subtitle C—Preemption of State

## 21 **Benefit Mandates and Anti-Man-**

## 22 aged Care Laws

- 23 SEC. 1201. PREEMPTION FROM STATE BENEFIT MANDATES.
- 24 Effective as of January 1, 1997, no State shall estab-
- 25 lish or enforce any law or regulation that—

1	(1) requires the offering, as part of health in-
2	surance coverage, of any services, category of care,
3	or services of any class or type of provider; or
4	(2) specifies the individuals to be provided
5	health insurance coverage or the duration of such
6	coverage.
7	SEC. 1202. PREEMPTION OF STATE LAW RESTRICTIONS ON
8	MANAGED CARE ARRANGEMENTS.
9	(a) Limitation on Restrictions on Network
10	Plans.—Effective as of January 1, 1997—
11	(1) a State may not prohibit or limit a carrier
12	or group health plan providing health coverage from
13	including incentives for enrollees to use the services
14	of participating providers;
15	(2) a State may not prohibit or limit such a
16	carrier or plan from limiting coverage of services to
17	those provided by a participating provider;
18	(3) a State may not prohibit or limit the nego-
19	tiation of rates and forms of payments for providers
20	by such a carrier or plan with respect to health cov-
21	erage;
22	(4) a State may not prohibit or limit such a
23	carrier or plan from limiting the number of partici-
24	pating providers;

1	(5) a State may not prohibit or limit such a
2	carrier or plan from requiring that services be pro-
3	vided (or authorized) by a practitioner selected by
4	the enrollee from a list of available participating pro-
5	viders or from requiring enrollees to obtain referral
6	in order to have coverage for treatment by a special-
7	ist or health institution; and
8	(6) a State may not prohibit or limit the cor-
9	porate practice of medicine.
10	(b) Definitions.—In this section:
11	(1) Managed care coverage.—The term
12	"managed care coverage" means health coverage to
13	the extent the coverage is provided through a man-
14	aged care arrangement (as defined in section
15	1903(12)(A)) that meets the applicable requirements
16	of such section.
17	(2) Participating provider.—The term
18	"participating provider" means an entity or individ-
19	ual which provides, sells, or leases health care serv-
20	ices as part of a provider network (as defined in sec-
21	tion 1903(12)(B)).
22	(c) Reference to Standards for Managed
23	CARE ARRANGEMENTS.—For requirements relating to

24 managed care arrangements, see section 1011.

#### 1 SEC. 1203. PREEMPTION OF STATE LAWS RESTRICTING UTI-

- 2 **LIZATION REVIEW PROGRAMS.**
- 3 (a) IN GENERAL.—Effective January 1, 1997, no
- 4 State law or regulation shall prohibit or regulate activities
- 5 under a utilization review program (as defined in sub-
- 6 section (b)).
- 7 (b) Utilization Review Program Defined.—In
- 8 this section, the term "utilization review program" means
- 9 a system of reviewing the medical necessity and appro-
- 10 priateness of patient services (which may include inpatient
- 11 and outpatient services) using specified guidelines. Such
- 12 a system may include preadmission certification, the appli-
- 13 cation of practice guidelines, continued stay review, dis-
- 14 charge planning, preauthorization of ambulatory proce-
- 15 dures, and retrospective review.
- 16 (c) Exemption of Laws Preventing Denial of
- 17 Lifesaving Medical Treatment Pending Transfer
- 18 TO ANOTHER HEALTH CARE PROVIDER.—Nothing in this
- 19 subtitle shall be construed to invalidate any State law that
- 20 has the effect of preventing involuntary denial of life-pre-
- 21 serving medical treatment when such denial would cause
- 22 the involuntary death of the patient pending transfer of
- 23 the patient to a health care provider willing to provide
- 24 such treatment.

1	SEC. 1204. PREEMPTION RELATING TO DIFFERENT INSUR-
2	ANCE STANDARDS.
3	A State may not establish or enforce standards for
4	health insurance coverage made available in the individual
5	and small group markets that are different from the
6	standards established under this title.
7	Subtitle D—Definitions; General
8	Provisions
9	SEC. 1901. GENERAL DEFINITIONS.
10	For purposes of this Act:
11	(1) Applicable regulatory authority.—
12	The term "applicable regulatory authority" means,
13	with respect to a carrier operating in a State—
14	(A) the State insurance commissioner, or
15	(B) the Secretary, in the case described in
16	section 1042(b)(2).
17	(2) Family member.—
18	(A) IN GENERAL.—Individuals are consid-
19	ered to be members of a family if—
20	(i) they are married, or
21	(ii) they have a legal parent-to-child
22	relationship (whether by natural birth or
23	adoption), if the child is—
24	(I) under 19 years of age,
25	(II) is under 25 years of age and
26	a full-time student, or

1	(III) an unmarried dependent re-
2	gardless of age who is incapable of
3	self-support because of mental or
4	physical disability which existed before
5	age 22.
6	(B) Special rules.—Family members—
7	(i) include an adopted child and a rec-
8	ognized natural child;
9	(ii) include a stepchild or foster child
10	with respect to an individual but only if
11	the child lives with the individual in a reg-
12	ular parent-child relationship; and
13	(iii) include such other children as the
14	Secretary may specify, but shall not in-
15	clude an emancipated minor.
16	(3) Prisoner.—The term "prisoner" means,
17	as specified by the Secretary, an individual during a
18	period of imprisonment under Federal, State, or
19	local authority after conviction as an adult.
20	(4) Secretary.—The term "Secretary" means
21	the Secretary of Health and Human Services.
22	(5) STATE.—The term "State" means the 50
23	States, the District of Columbia, Puerto Rico, the
24	Virgin Islands, Guam, American Samoa, and the
25	Northern Mariana Islands.

# 1 SEC. 1902. DEFINITIONS RELATING TO EMPLOYMENT.

2	For purposes of this title:
3	(1) COUNTABLE EMPLOYEE.—The term "count-
4	able employee" means, with respect to an employer
5	for a month, any employee other than an employee
6	whose normal work week is less than 10 hours.
7	(2) Employee.—The term "employee" means
8	any individual employed by an employer.
9	(3) Employer.—The term "employer" means
10	any person acting directly as an employer, or indi-
11	rectly in the interest of an employer, in relation to
12	an employee benefit plan; and includes a group or
13	association of employers acting for an employer in
14	such capacity.
15	(4) Large employer.—The term "large em-
16	ployer" means an employer that is not a small em-
17	ployer (as defined in paragraph (4)).
18	(5) Multiemployer plan.—The term "multi-
19	employer plan" has the meaning given such term in
20	section 414(f) of the Internal Revenue Code of
21	1986.
22	(6) Qualifying employee.—
23	(A) In GENERAL.—The term "qualifying
24	employee" means, with respect to an employer

for a month, any employee other than—

1	(i) a part-time, seasonal, or temporary
2	employee (as defined in subparagraph
3	(B)); or
4	(ii) an employee who is a child de-
5	scribed in section 1901(2)(A)(ii).
6	(B) PART-TIME, SEASONAL, OR TEM-
7	PORARY EMPLOYEE DEFINED.—For purposes of
8	subparagraph (A), the term "part-time, sea-
9	sonal, or temporary employee" means any of
10	the following employees with respect to a
11	month:
12	(i) CERTAIN PART-TIME EMPLOY-
13	EES.—Any employee whose normal work
14	week is reasonably expected as of the first
15	day of such month to be less than 20
16	hours.
17	(ii) Seasonal or temporary em-
18	PLOYEES.—Any employee who is not rea-
19	sonably expected as of the first day of such
20	month to be employed by the employer for
21	a period of 120 consecutive days during
22	any 365-day period that includes such first
23	day.
24	(iii) Delay for certain part-time
25	EMPLOYEES.—Any employee whose normal

1	work week is reasonably expected as of the
2	first day of such month to be at least 20
3	hours, but less than 35 hours, and the nor-
4	mal work week of the employee during the
5	preceding 3 months was less than 20
6	hours.
7	(7) Small employer.—The term "small em-
8	ployer" means, with respect to a calendar year, an
9	employer that normally employs more than 1 but
10	less than 51 countable employees on a typical busi-
11	ness day. For the purposes of this paragraph, the
12	term "employee" includes a self-employed individual.
13	For purposes of determining if an employer is a
14	small employer, rules similar to the rules of sub-
15	section (b) and (c) of section 414 of the Internal
16	Revenue Code of 1986 shall apply.
17	SEC. 1903. DEFINITIONS RELATING TO HEALTH COVERAGE,
18	PLANS, AND CARRIERS.
19	Except as otherwise provided, for purposes of this
20	Act:
21	(1) Benchmark coverage.—The term
22	"benchmark coverage" means the standard option of
23	the Blue Cross-Blue Shield plan offered under the
24	Federal Employees Health Benefits Program under

- chapter 89 of title 5, United States Code, as in effect during 1995.
  - (2) Carrier.—The term "carrier" means a licensed insurance company, an entity offering prepaid hospital or medical services, and a health maintenance organization, and includes a similar organization regulated under State law for solvency.
    - (3) CLASS OF FAMILY COVERAGE.—The term "class of family coverage" means the 4 classes described in section 1021(a)(3).
    - (4) Fair rating area.—The term "fair rating area" means a geographic area identified by a State for purposes of section 1021(a)(2).
    - (5) GROUP HEALTH PLAN.—The term "group health plan" has the meaning given such term in section 5000(b)(1) of the Internal Revenue Code of 1986, but does not include any type of coverage excluded from the definition of a health insurance coverage under paragraph (8)(B).
    - (6) HEALTH COVERAGE.—The term "health coverage" means health insurance coverage provided by a carrier or medical care provided under a group health plan.
- 24 (7) HEALTH INSURANCE COVERAGE.—

1	(A) IN GENERAL.—Except as provided in
2	subparagraph (B), the term "health insurance
3	coverage" means any hospital or medical service
4	policy or certificate, hospital or medical service
5	plan contract, or health maintenance organiza-
6	tion group contract offered by a carrier.
7	(B) Exception.—Such term does not in-
8	clude any of the following (or any combination
9	of the following):
10	(i) Coverage only for accident, dental,
11	vision, disability income, or long-term care
12	insurance, or any combination thereof.
13	(ii) Medicare supplemental health in-
14	surance.
15	(iii) Coverage issued as a supplement
16	to liability insurance.
17	(iv) Liability insurance, including gen-
18	eral liability insurance and automobile li-
19	ability insurance.
20	(v) Workers' compensation or similar
21	insurance.
22	(vi) Automobile medical-payment in-
23	surance.
24	(vii) Coverage for a specified disease
25	or illness

1	(viii) A hospital or fixed indemnity
2	policy.
3	(ix) Coverage provided exclusively to
4	individuals who are not eligible individuals.
5	(8) HEALTH MAINTENANCE ORGANIZATION.—
6	The term "health maintenance organization" in-
7	cludes, as defined in standards established under
8	section 1103, an organization that provides health
9	benefits coverage which meets specified standards
10	and provides (or arranges for the provision of) cov-
11	ered health benefits primarily through a defined set
12	of providers.
13	(9) HEALTH PLAN CHOICE ORGANIZATION.—
14	The term "health plan choice organization" means
15	an organization established under subtitle E.
16	(10) High deductible coverage.—The term
17	"high deductible coverage" means coverage provided
18	consistent with section 1011(b).
19	(11) Individual market.—The term "individ-
20	ual market" means the insurance market offered to
21	individuals seeking health insurance coverage on be-
22	half of themselves (and their dependents) insofar as
23	no employer is seeking such coverage on behalf of
24	the individual.
25	(12) Managed care arrangements.—

1	(A) MANAGED CARE ARRANGEMENT.—THE
2	term "managed care arrangement" means, with
3	respect to a group health plan or under health
4	insurance coverage, an arrangement under such
5	plan or coverage under which providers agree to
6	provide items and services covered under the ar-
7	rangement to individuals covered under the
8	plan or who have such coverage.
9	(B) Provider Network.—The term
10	"provider network" means, with respect to a
11	group health plan or health insurance coverage
12	providers who have entered into an agreement
13	described in subparagraph (A).
14	(13) Multiple employer welfare are
15	RANGEMENT.—The term "multiple employer welfare
16	arrangement" shall have the meaning applicable
17	under section 3(40) of the Employee Retirement In-
18	come Security Act of 1974.
19	(14) NAIC.—The term "NAIC" means the Na-
20	tional Association of Insurance Commissioners.
21	(15) Options.—Each of the following is a
22	"type of coverage option" in relation to standard
23	coverage:
24	(A) FEE-FOR-SERVICE OPTION.—Standard
25	coverage is considered to provide a "fee-for-

service option" if, regardless of whether covered individuals may receive benefits through a provider network, benefits with respect to the covered items and services in the coverage are made available for such items and services provided through any lawful provider of such covered items and services and payment is made to such a provider whether or not there is a contractual arrangement between the provider and the carrier or plan.

- (B) Managed care option.—Standard coverage is considered to provide a "managed care option" if benefits with respect to the covered items and services in the coverage are made available exclusively through a provider network, except in the case of emergency services and as otherwise required under law.
- (C) Point-of-service option.—Standard coverage is considered to provide a "point-of-service option" if the benefits with respect to covered items and services in the coverage are made available principally through a managed care arrangement, with the choice of the enrollee to obtain such benefits for items and services provided through any lawful provider of

1	such covered items and services. The coverage
2	may provide for different cost sharing schedules
3	based on whether the items and services are
4	provided through such an arrangement or out-
5	side such an arrangement.
6	(16) Qualified Health coverage.—The
7	term "qualified health coverage" means health cov-
8	erage that—
9	(1) provides standard coverage or high-deduct-
10	ible coverage, and
11	(2) meets other requirements of subtitle A ap-
12	plicable to the coverage and the carrier or group
13	health plan providing the coverage.
14	(17) Small group market.—The term "small
15	group market" means the insurance market offered
16	to small employers seeking health insurance coverage
17	on behalf of their employees (and their dependents),
18	regardless of whether or not such coverage is made
19	available directly or through a multiple employer
20	welfare arrangement, association, or otherwise.
21	(18) Standard Coverage.—The term "stand-
22	ard coverage" means coverage provided consistent

with section 1011(a).

1	(19) State commissioner of insurance.—
2	The term "State commissioner of insurance" in-
3	cludes a State superintendent of insurance.
4	SEC. 1904. DEFINITIONS RELATING TO RESIDENCE AND IM-
5	MIGRATION STATUS.
6	Except as otherwise provided, for purposes of this
7	Act:
8	(1) Alien permanently residing in the
9	UNITED STATES UNDER COLOR OF LAW.—The term
10	"alien permanently residing in the United States
11	under color of law" means an alien lawfully admitted
12	for permanent residence (within the meaning of sec-
13	tion 101(a)(20) of the Immigration and Nationality
14	Act), and includes any of the following (such status
15	not having changed):
16	(A) An alien who is admitted as a refugee
17	under section 207 of the Immigration and Na-
18	tionality Act.
19	(B) An alien who is granted asylum under
20	section 208 of such Act.
21	(C) An alien whose deportation is withheld
22	under section 243(h) of such Act.
23	(D) An alien whose deportation is sus-
24	pended pursuant to section 244 of such Act.

1	(E) An alien who is granted conditional
2	entry pursuant to section 203(a)(7) of such Act
3	as in effect before April 1, 1980.
4	(F) An alien who is admitted for tem-
5	porary residence under section 210, 210A, or
6	245A of such Act.
7	(G) An alien who is within a class of aliens
8	lawfully present in the United States pursuant
9	to any other provision of such Act, if (i) the At-
10	torney General determines that the continued
11	presence of such class of aliens serves a human-
12	itarian or other compelling public interest, and
13	(ii) the Secretary determines that such interest
14	would be further served by treating each such
15	alien within such class as a "legal permanent
16	resident" for purposes of this Act or who has
17	been granted extended voluntary departure as a
18	member of a nationality group.
19	(H) An alien who is the spouse or unmar-
20	ried child under 21 years of age of a citizen of
21	the United States, or the parent of such a citi-
22	zen if the citizen is over 21 years of age, and
23	with respect to whom an application for adjust-

ment to lawful permanent residence is pending.

1	(I) An alien within such other classification
2	of permanent resident aliens as the Secretary
3	may establish by regulation.
4	(2) Long-term nonimmigrant.—The term
5	"long-term nonimmigrant" means a nonimmigrant
6	described in subparagraph (E), (H), (I), (K), (L),
7	(N), (O), (Q), or (R) of section $101(a)(15)$ of the
8	Immigration and Nationality Act.
9	(3) Qualifying individual.—The term
10	"qualifying individual" means, an individual who is
11	a resident of the United States, who is not a pris-
12	oner, and is—
13	(A) a citizen or national of the United
14	States;
15	(B) an alien permanently residing in the
16	United States under color of law (as defined in
17	paragraph (1)); or
18	(C) a long-term nonimmigrant (as defined
19	in paragraph (2)).
20	SEC. 1905. EFFECTIVE DATES.
21	The requirements of this title shall apply with respect
22	to—
23	(1) group health plans for plan years beginning
24	on or after January 1, 1997, and

1	(2) carriers (with respect to coverage other than
2	under a group health plan) as of January 1, 1997.
3	TITLE II—ADMINISTRATIVE
4	SIMPLIFICATION
5	SEC. 2000. PURPOSE.
6	It is the purpose of this title to improve the efficiency
7	and effectiveness of the health care system, including the
8	medicare program under title XVIII of the Social Security
9	Act and the medicaid program under title XIX of such
10	Act, by encouraging the development of a health informa-
11	tion network through the adoption of standards and the
12	establishment of requirements for the electronic trans-
13	mission of certain health information.
14	SEC. 2001. DEFINITIONS.
15	For purposes of this title:
16	(1) Code set.—The term "code set" means
17	any set of codes used for encoding data elements,
18	such as tables of terms, medical concepts, medical
19	diagnostic codes, or medical procedure codes.
20	(2) Coordination of Benefits.—The term
21	"coordination of benefits" means determining and
22	coordinating the financial obligations of plan spon-
23	sors when health care benefits are payable by more
24	than one such sponsor.

1	(3) Health information.—The term "health
2	information" means any information that relates to
3	the past, present, or future physical or mental health
4	or condition or functional status of an individual,
5	the provision of health care to an individual, or pay-
6	ment for the provision of health care to an individ-
7	ual.
8	(4) Health information network.—The
9	term "health information network" means the health
10	information system that is formed through the appli-
11	cation of the requirements and standards established
12	under this title.
13	(5) Health information network serv-
14	ICE.—The term "health information network serv-
15	ice''—
16	(A) means a private entity or an entity op-
17	erated by a State that enters into contracts—
18	(i) to process or facilitate the process-
19	ing of nonstandard data elements of health
20	information into standard data elements;
21	(ii) to provide the means by which
22	persons are connected to the health infor-
23	mation network for purposes of meeting
24	the requirements of this title, including the

1	holding of standard data elements of
2	health information;
3	(iii) to provide authorized access to
4	health information through the health in-
5	formation network; or
6	(iv) to provide specific information
7	processing services, such as automated co-
8	ordination of benefits and claims trans-
9	action routing; and
10	(B) includes a health information security
11	organization.
12	(6) HEALTH INFORMATION SECURITY ORGANI-
13	ZATION.—The term "health information security or-
14	ganization" means a private entity or an entity oper-
15	ated by a State that accesses standard data elements
16	of health information through the health information
17	network, processes such information into non-identi-
18	fiable health information, and may store such infor-
19	mation.
20	(7) Health provider.—The term "health
21	provider" includes a provider of services (as defined
22	in section 1861(u) of the Social Security Act), a pro-
23	vider of medical or other health services (as defined
24	in section 1861(s) of such Act) and any other per-

1	son (other than a plan sponsor) furnishing health
2	care items or services.
3	(8) Individually identifiable health in-
4	FORMATION.—The term "individually identifiable
5	health information" means health information in the
6	health information network—
7	(A) that identifies an individual who is the
8	subject of the information; or
9	(B) with respect to which there is a rea-
10	sonable basis to believe that the information
11	can be used to identify such an individual.
12	(9) Non-identifiable health informa-
13	TION.—The term "non-identifiable health informa-
14	tion" means health information that is not individ-
15	ually identifiable health information.
16	(10) Plan sponsor.—The term "plan spon-
17	sor'' means—
18	(A) a carrier (as defined in section
19	1903(2)) providing health insurance coverage
20	(as defined in section 1903(7));
21	(B) a group health plan;
22	(C) an association or other entity which es-
23	tablishes or maintains a multiple employer wel-
24	fare arrangement (as defined in section
25	1903(13)) providing benefits consisting of medi-

1	cal care described in section 213(d) of the In-
2	ternal Revenue Code of 1986; and
3	(D) a State, or the Federal Government,
4	acting in a capacity as a provider of health ben-
5	efits to eligible individuals that is equivalent to
6	that of a carrier.
7	(11) Standard.—The term "standard", when
8	used with reference to a transaction or to data ele-
9	ments of health information, means that the trans-
10	action or data elements meet any standard adopted
11	by the Secretary under subtitle A that applies to the
12	transaction or data elements.
13	Subtitle A—Standards for Data
13 14	Subtitle A—Standards for Data Elements and Transactions
14	<b>Elements and Transactions</b>
<ul><li>14</li><li>15</li><li>16</li></ul>	Elements and Transactions SEC. 2101. GENERAL REQUIREMENTS ON SECRETARY.
14 15 16 17	Elements and Transactions  SEC. 2101. GENERAL REQUIREMENTS ON SECRETARY.  (a) IN GENERAL.—The Secretary shall adopt stand-
14 15 16 17	Elements and Transactions  SEC. 2101. GENERAL REQUIREMENTS ON SECRETARY.  (a) IN GENERAL.—The Secretary shall adopt standards and modifications to standards under this subtitle
14 15 16 17 18	Elements and Transactions  SEC. 2101. GENERAL REQUIREMENTS ON SECRETARY.  (a) IN GENERAL.—The Secretary shall adopt standards and modifications to standards under this subtitle that are—
14 15 16 17 18	Elements and Transactions  SEC. 2101. GENERAL REQUIREMENTS ON SECRETARY.  (a) IN GENERAL.—The Secretary shall adopt standards and modifications to standards under this subtitle that are—  (1) consistent with the objective of reducing the
14 15 16 17 18 19 20	Elements and Transactions  SEC. 2101. GENERAL REQUIREMENTS ON SECRETARY.  (a) IN GENERAL.—The Secretary shall adopt standards and modifications to standards under this subtitle that are—  (1) consistent with the objective of reducing the costs of providing and paying for health care; and
14 15 16 17 18 19 20 21	Elements and Transactions  SEC. 2101. GENERAL REQUIREMENTS ON SECRETARY.  (a) IN GENERAL.—The Secretary shall adopt standards and modifications to standards under this subtitle that are—  (1) consistent with the objective of reducing the costs of providing and paying for health care; and  (2) in use and generally accepted, developed, or

1 (b) Initial Standards.—The Secretary may de-

2	velop an expedited process for the adoption of initial
3	standards under this subtitle.
4	(c) Protection of Commercial Information.—
5	In adopting standards under this subtitle, the Secretary
6	may not require disclosure of trade secrets and confiden-
7	tial commercial information by any person.
8	SEC. 2102. STANDARDS FOR DATA ELEMENTS OF HEALTH
9	INFORMATION.
10	(a) IN GENERAL.—The Secretary shall adopt stand-
11	ards necessary to make uniform and compatible for elec-
12	tronic transmission through the health information net-
13	work the data elements of any health information that the
14	Secretary determines is appropriate for transmission in
15	connection with a transaction described in section 2201.
16	(b) Additions.—The Secretary may make additions
17	to any set of data elements adopted under subsection (a)
18	as the Secretary determines appropriate in a manner that
19	minimizes the disruption and cost of compliance with such
20	additions.
21	(c) Certain Data Elements.—
22	(1) Unique health identifiers.—The Sec-
23	retary shall establish a system to provide for a
24	standard unique health identifier for each individual,

1	employer, plan sponsor, and health provider for use
2	in the health care system.
3	(2) Code sets.—
4	(A) IN GENERAL.—The Secretary, in con-
5	sultation with experts from the private sector
6	and Federal agencies, shall—
7	(i) select code sets for appropriate
8	data elements from among the code sets
9	that have been developed by private and
10	public entities; or
11	(ii) establish code sets for such data
12	elements if no code sets for the data ele-
13	ments have been developed.
14	(B) DISTRIBUTION.—The Secretary shall
15	establish efficient and low-cost procedures for
16	distribution of code sets and modifications to
17	code sets.
18	SEC. 2103. INFORMATION TRANSACTION STANDARDS.
19	(a) IN GENERAL.—The Secretary shall adopt tech-
20	nical standards that are consistent with the health infor-
21	mation network privacy standards adopted under section
22	2104 relating to the method by which standard data ele-
23	ments of health information may be transmitted electroni-
24	cally, including standards with respect to the format in
25	which such data elements may be transmitted.

- 1 (b) Special Rule for Coordination of Bene-
- 2 FITS.—Any standard adopted by the Secretary under sub-
- 3 section (a) that relates to coordination of benefits shall
- 4 provide that a claim for reimbursement for health services
- 5 furnished shall be tested, by an algorithm specified by the
- 6 Secretary, against all records of enrollment and eligibility
- 7 for the individual who received such services that are avail-
- 8 able to the recipient of the claim through the health infor-
- 9 mation network to determine any primary and secondary
- 10 obligors for payment.
- 11 (c) ELECTRONIC SIGNATURE.—The Secretary, in co-
- 12 ordination with the Secretary of Commerce, shall promul-
- 13 gate regulations specifying procedures for the electronic
- 14 transmission and authentication of signatures, compliance
- 15 with which shall be deemed to satisfy State and Federal
- 16 statutory requirements for written signatures with respect
- 17 to transactions described in section 2201 and written sig-
- 18 natures on health records and prescriptions.
- 19 (d) STANDARDS FOR CLAIMS FOR CLINICAL LABORA-
- 20 TORY TESTS.—The standards under this section shall pro-
- 21 vide that claims for clinical laboratory tests for which ben-
- 22 efits are payable by a plan sponsor shall be submitted di-
- 23 rectly by the person or entity that performed (or super-
- 24 vised the performance of) the tests to the sponsor in a
- 25 manner consistent with (and subject to such exceptions

1	as are provided under) the requirement for direct submis-
2	sion of such claims under the medicare program.
3	SEC. 2104. HEALTH INFORMATION NETWORK PRIVACY
4	STANDARDS.
5	The Secretary shall adopt standards respecting the
6	privacy of individually identifiable health information that
7	is in the health information network. Such standards shall
8	include standards concerning at least the following:
9	(1) The rights of an individual who is the sub-
10	ject of such information.
11	(2) The procedures to be established for the ex-
12	ercise of such rights.
13	(3) The uses and disclosures of such informa-
14	tion that are authorized or required.
15	(4) Safeguards for the security of such informa-
16	tion and adequate security practices.
17	SEC. 2105. TIMETABLES FOR ADOPTION OF STANDARDS.
18	(a) Initial Standards for Data Elements.—
19	The Secretary shall adopt standards relating to—
20	(1) the data elements for the information de-
21	scribed in section 2102(a) not later than 9 months
22	after the date of the enactment of this Act (except
23	in the case of standards with respect to data ele-
24	ments for claims attachments, which shall be adopt-

- ed not later than 24 months after the date of the enactment of this Act); and
- 3 (2) any addition to a set of data elements, in 4 conjunction with making such an addition.
- 5 (b) Initial Privacy Standards.—The Secretary
- 6 shall adopt standards relating to the privacy of individ-
- 7 ually identifiable health information in the health informa-
- 8 tion network under section 2104 not later than 12 months
- 9 after the date of the enactment of this Act.
- 10 (c) Initial Standards for Information Trans-
- 11 ACTIONS.—The Secretary shall adopt standards relating
- 12 to information transactions under section 2103 not later
- 13 than 18 months after the date of the enactment of this
- 14 Act (except in the case of standards for claims attach-
- 15 ments, which shall be adopted not later than 24 months
- 16 after the date of the enactment of this Act).
- 17 (d) Modifications to Standards.—
- 18 (1) IN GENERAL.—Except as provided in para-
- graph (2), the Secretary shall review the standards
- adopted under this subtitle and shall adopt modified
- standards as determined appropriate, but not more
- frequently than once every 6 months. Any modifica-
- tion to standards shall be completed in a manner
- 24 which minimizes the disruption to, and costs of com-
- 25 pliance incurred by, a plan sponsor, health provider,

1	or health plan choice organization that is required
2	to comply with subtitle B.
3	(2) Special rules.—
4	(A) Modifications during first 12-
5	MONTH PERIOD.—Except with respect to addi-
6	tions and modifications to code sets under sub-
7	paragraph (B), the Secretary may not adopt
8	any modification to a standard adopted under
9	this subtitle during the 12-month period begin-
10	ning on the date the standard is adopted, un-
11	less the Secretary determines that the modifica-
12	tion is necessary in order to permit a plan spon-
13	sor, a health provider, or a health plan choice
14	organization to comply with subtitle B.
15	(B) Additions and modifications to
16	CODE SETS.—
17	(i) IN GENERAL.—The Secretary shall
18	ensure that procedures exist for the rou-
19	tine maintenance, testing, enhancement,
20	and expansion of code sets.
21	(ii) Additional rules.—If a code
22	set is modified under this subsection, the
23	modified code set shall include instructions
24	on how data elements that were encoded
25	prior to the modification are to be con-

1	verted or translated so as to preserve the
2	value of the data elements. Any modifica-
3	tion to a code set under this subsection
4	shall be implemented in a manner that
5	minimizes the disruption to, and costs of
6	compliance incurred by, a plan sponsor,
7	health provider, or health plan choice orga-
8	nization that is required to comply with
9	subtitle B.
10	(e) Evaluation of Standards.—The Secretary
11	may establish a process to measure or verify the consist-
12	ency of standards adopted or modified under this subtitle.
13	Such process may include demonstration projects and
14	analyses of the cost of implementing such standards and
15	modifications.
16	Subtitle B—Requirements with Re-
17	spect to Certain Transactions
18	and Information
19	SEC. 2201. STANDARD TRANSACTIONS AND INFORMATION.
20	(a) Transactions by Sponsors.—
21	(1) Transactions with providers.—If a
22	plan sponsor conducts any of the transactions de-
23	scribed in paragraph (3) with a health provider—
24	(A) the transaction shall be a standard
25	transaction; and

1	(B) the health information transmitted by
2	the sponsor to the provider or by the provider
3	to the sponsor in connection with the trans-
4	action shall be in the form of standard data ele-
5	ments.
6	(2) Transactions with sponsors.—If a plan
7	sponsor conducts any of the transactions described
8	in paragraph (3) with another plan sponsor—
9	(A) the transaction shall be a standard
10	transaction; and
11	(B) the health information transmitted by
12	either sponsor in connection with the trans-
13	action shall be in the form of standard data ele-
14	ments.
15	(3) Transactions.—The transactions referred
16	to in paragraphs (1) and (2) are the following:
17	(A) Verification of eligibility for benefits.
18	(B) Coordination of benefits.
19	(C) Claim submission.
20	(D) Claim attachment submission.
21	(E) Claim status notification.
22	(F) Claim status verification.
23	(G) Claim adjudication.
24	(H) Payment and remittance advice.

1	(I) Certification or authorization of a re-
2	ferral to a health provider who is not part of a
3	provider network.
4	(b) Transactions by Choice Organizations.—
5	(1) IN GENERAL.—If a health plan choice orga-
6	nization conducts any of the transactions described
7	in paragraph (2) with a plan sponsor—
8	(A) the transaction shall be a standard
9	transaction; and
10	(B) the health information transmitted by
11	the organization to the sponsor or by the spon-
12	sor to the organization in connection with the
13	transaction shall be in the form of standard
14	data elements.
15	(2) Transactions.—The transactions referred
16	to in paragraph (1) are the following:
17	(A) Enrollment and disenrollment.
18	(B) Premium payment.
19	(c) Use of Health Information Network Serv-
20	ICES.—A plan sponsor, a health provider, or a health plan
21	choice organization may comply with any provision of this
22	section by entering into an agreement or other arrange-
23	ment with a health information network service certified
24	under section 2301 pursuant to which the service under-

1	takes the duties applicable to the sponsor, provider, or or-
2	ganization under the provision.
3	SEC. 2202. ACCESSING HEALTH INFORMATION FOR AU-
4	THORIZED PURPOSES.
5	(a) PROCUREMENT RULE FOR GOVERNMENT AGEN-
6	CIES.—
7	(1) IN GENERAL.—A health information secu-
8	rity organization that is certified under section 2301
9	shall make available to a Federal or State agency,
10	pursuant to a cost-type contract (as defined under
11	the Federal Acquisition Regulation), any non-identi-
12	fiable health information, including non-identifiable
13	health information that is derived from individually
14	identifiable health information, that—
15	(A) is held by the service or may be ob-
16	tained by the service under paragraph (2) or
17	subsection (b);
18	(B) consists of data elements that are sub-
19	ject to a standard under subtitle A; and
20	(C) is requested by the agency to fulfill a
21	requirement under this Act.
22	(2) CERTAIN INFORMATION AVAILABLE AT LOW
23	COST.—If a health information security organization
24	requires health information consisting of data ele-
25	ments that are subject to a standard under subtitle

1	A from a plan sponsor or a health provider in order
2	to comply with a request made by a Federal or State

- agency under paragraph (1), the sponsor or provider
- 4 shall make such information available to such orga-
- 5 nization for a charge that does not exceed the rea-
- 6 sonable cost of transmitting the information.
- 7 (b) Procurement Rule for Information Secu-
- 8 RITY ORGANIZATIONS.—A health information security or-
- 9 ganization that makes non-identifiable health information
- 10 available to a Federal or State agency under subsection
- 11 (a) shall make such non-identifiable information available,
- 12 for a charge that does not exceed the reasonable cost of
- 13 transmitting the information, to any other health informa-
- 14 tion security organization that—
- 15 (A) is certified under section 2301; and
- 16 (B) requests the information.
- 17 SEC. 2203. ENSURING AVAILABILITY OF INFORMATION.
- 18 The Secretary shall establish a procedure under
- 19 which a plan sponsor or health provider that does not have
- 20 the ability to transmit standard data elements directly,
- 21 and does not have access to a health information network
- 22 service certified under section 2301, may comply with the
- 23 provisions of this subtitle.

1	SEC.	2304.	<b>TIMETABLES</b>	<b>FOR</b>	<b>COMPLIANCE</b>	<b>WITH</b>	REQUIRE
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### (a) Initial Compliance.—

- (1) IN GENERAL.—Not later than 12 months after the date on which standards are adopted under subtitle A with respect to a type of transaction, or data elements for a type of health information, a plan sponsor, health provider, or health plan choice organization shall comply with the requirements of this subtitle with respect to such transaction or information.
- (2) Additional data elements.—Not later than 12 months after the date on which the Secretary adopts an addition to a set of data elements for health information under section 2102, a plan sponsor, health provider, or health plan choice organization shall comply with the requirements of this subtitle using such data elements.

## (b) Compliance With Modified Standards.—

(1) IN GENERAL.—If the Secretary adopts a modified standard under section 2105(c), a plan sponsor, health provider, or health plan choice organization shall comply with the modified standard at such time as the Secretary determines appropriate, taking into account the time needed to comply due to the nature and extent of the modification.

1	(2) Special rule.—In the case of a modifica-
2	tion to a standard that does not occur within the 12-
3	month period beginning on the date the standard is
4	adopted, the time determined appropriate by the
5	Secretary under paragraph (1) may not be—
6	(A) earlier than the last day of the 90-day
7	period beginning on the date the modified
8	standard is adopted; or
9	(B) later than the last day of the 12-
10	month period beginning on the date the modi-
11	fied standard is adopted.
12	Subtitle C—Miscellaneous
13	Provisions
14	SEC. 2301. STANDARDS AND CERTIFICATION FOR HEALTH
15	INFORMATION NETWORK SERVICES.
16	(a) Standards for Operation.—The Secretary
17	shall establish standards with respect to the operation of
18	health information network services, including standards
19	ensuring that such services—
20	(1) develop, operate, and cooperate with one an-
21	other to form the health information network;
22	(2) meet all of the standards adopted under
23	part 1 that are applicable to the services;
24	(3) make public information concerning their
25	performance, as measured by uniform indicators

- such as accessibility, transaction responsiveness, administrative efficiency, reliability, dependability, and any other indicator determined appropriate by the Secretary; and
  - (4) if they are part of a larger organization, have policies and procedures in place which isolate their activities with respect to processing information in a manner that prevents access to such information by such larger organization.

#### (b) CERTIFICATION BY THE SECRETARY.—

- (1) ESTABLISHMENT.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall establish a certification procedure for health information network services which ensures that certified services are qualified to meet the requirements of this title and the standards established by the Secretary under this section. Such certification procedure shall be implemented in a manner that minimizes the costs and delays of operations for such services.
- (2) APPLICATION.—Each entity desiring to be certified as a health information network service shall apply to the Secretary for certification in a form and manner determined appropriate by the Secretary.

25 Secretary.

- (3) AUDITS AND REPORTS.—The procedure established under paragraph (1) shall provide for audits by the Secretary and reports by an entity certified under this section as the Secretary determines appropriate in order to monitor such entity's compliance with the requirements of this subtitle and the standards established by the Secretary under this section.
  - (4) RECERTIFICATION.—A health information network service shall be recertified under this subsection at least every 3 years.

# (c) Loss of Certification.—

- (1) Mandatory termination.—Except as provided in paragraph (2), if a health information network service violates a health information network privacy standard adopted under section 2104 that is applicable to the service, its certification under this section shall be terminated unless the Secretary determines that appropriate corrective action has been taken.
- (2) CONDITIONAL CERTIFICATION.—The Secretary may establish a procedure under which a health information network service may remain certified on a conditional basis if the service is operating consistently with a plan intended to correct any

- 1 violations described in paragraph (1). Such proce-
- 2 dure may provide for the appointment of a trustee
- 3 to continue operation of the service until the require-
- 4 ments for full certification are met.
- 5 (d) Certification by Private Entities.—The
- 6 Secretary may designate private entities to conduct the
- 7 certification procedures established by the Secretary under
- 8 this section. A health information network service certified
- 9 by such an entity in accordance with such designation
- 10 shall be considered to be certified by the Secretary.
- 11 (e) Information Held by Health Information
- 12 NETWORK SERVICES.—If a health information network
- 13 service certified under this section loses its certified status
- 14 or takes any action that would threaten the continued
- 15 availability of the standard data elements of health infor-
- 16 mation held by such service, such data elements shall be
- 17 transferred to another health information network service
- 18 certified under this section that has been designated by
- 19 the Secretary.
- 20 SEC. 2302. IMPOSITION OF ADDITIONAL REQUIREMENTS.
- 21 (a) IN GENERAL.—Except as provided in subsection
- 22 (c), after the Secretary has established standards under
- 23 section 2102 that are necessary to make uniform and com-
- 24 patible for electronic transmission the data elements that
- 25 the Secretary determines are appropriate for transmission

1	in connection with a transaction described in subtitle B,
2	an individual or entity may not require an individual or
3	entity, to provide in any manner any additional data ele-
4	ment in connection with—
5	(1) the transaction; or
6	(2) an inquiry with respect to the transaction.
7	(b) Transmission Method.—Except as provided in
8	subsection (c), after the Secretary has established stand-
9	ards under section 2103 relating to the method by which
10	data elements that the Secretary determines are appro-
11	priate for transmission in connection with a transaction
12	described in subtitle B may be transmitted electronically,
13	an individual or entity may not require an individual or
14	entity to transmit any data element in a manner inconsist-
15	ent with the standards in connection with—
16	(1) the transaction; or
17	(2) an inquiry with respect to the transaction.
18	(c) Exception.—Subsections (a) and (b) do not
19	apply if—
20	(1) an individual or entity voluntarily agrees to
21	provide the additional data element; or
22	(2) a waiver is granted under subsection (d) to
23	permit the requirement to be imposed.
24	(d) Conditions for Waivers.—

(1) IN GENERAL.—An individual or entity may
request a waiver from the Secretary in order to im-
pose on an individual or entity a requirement other-
wise prohibited under subsection (a) or (b). Subject
to paragraph (2), the Secretary may grant such a
waiver.

(2) Consideration of waiver requests.—A waiver may not be granted under this subsection to impose an otherwise prohibited requirement unless the Secretary determines that the value of any additional information to be provided under the requirement for research or other purposes significantly outweighs the administrative cost of the imposition of the requirement, taking into account the burden of the timing of the imposition of the requirement.

(e) Anonymous Reporting.—If an individual or entity attempts to impose on an individual or entity a requirement prohibited under subsection (a) or (b), the individual or entity on whom the requirement is being imposed
may contact the Secretary. The Secretary shall develop a
procedure under which an individual or entity that contacts the Secretary under the preceding sentence shall remain anonymous. The Secretary shall notify the individual
or entity imposing the requirement that the requirement
may not be imposed unless the other individual or entity

- 1 voluntarily agrees to such requirement or a waiver is ob-
- 2 tained under subsection (d).
- 3 SEC. 2303. EFFECT ON STATE LAW.
- 4 (a) IN GENERAL.—Except as otherwise provided in
- 5 this section, a provision, requirement, or standard under
- 6 this subtitle shall supersede any contrary provision of
- 7 State law.
- 8 (b) State "Quill and Pen" Laws.—A State may
- 9 not establish, continue in effect, or enforce any provision
- 10 of State law that requires medical or health plan records
- 11 (including billing information) to be maintained or trans-
- 12 mitted in written rather than electronic form, except
- 13 where the Secretary determines that the provision is nec-
- 14 essary to prevent fraud and abuse, with respect to con-
- 15 trolled substances, or for other purposes.
- 16 (c) Public Health Reporting.—Nothing in this
- 17 title shall be construed to invalidate or limit the authority,
- 18 power, or procedures established under any law providing
- 19 for the reporting of disease or injury, child abuse, birth,
- 20 or death, public health surveillance, or public health inves-
- 21 tigation or intervention.
- 22 (d) Public Use Functions.—Nothing in this title
- 23 shall be construed to limit the authority of a Federal or
- 24 State agency to make non-identifiable health information
- 25 available for public use.

1	(e) Payment for Health Care Services or Pre-
2	MIUMS.—Nothing in this title shall be construed to pro-
3	hibit a consumer from paying for health care items or
4	services, or plan or health insurance coverage premiums,
5	by debit, credit, or other payment cards or numbers or
6	other electronic payment means.
7	TITLE III—FRAUD AND ABUSE
8	<b>REFORM: ADVISORY OPINIONS</b>
9	SEC. 3001. AUTHORIZING THE SECRETARY OF HEALTH AND
10	HUMAN SERVICES TO ISSUE ADVISORY OPIN-
11	IONS UNDER TITLE XI.
12	Title XI of the Social Security Act (42 U.S.C. 1301
13	et seq.) is amended by inserting after section 1128B the
14	following new section:
15	"ADVISORY OPINIONS
16	"Sec. 1129. (a) Issuance of Advisory Opin-
17	IONS.—The Secretary shall issue advisory opinions as pro-
18	vided in this section.
19	"(b) Matters Subject to Advisory Opinions.—
20	The Secretary shall issue advisory opinions as to the fol-
21	lowing matters:
22	"(1) What constitutes prohibited remuneration
23	within the meaning of section 1128B(b).
24	"(2) Whether an arrangement or proposed ar-
25	rangement satisfies the criteria set forth in section

1	1128B(b)(3) for activities which do not result in
2	prohibited remuneration.
3	"(3) Whether an arrangement or proposed ar-
4	rangement satisfies the criteria which the Secretary
5	has established, or shall establish by regulation for
6	activities which do not result in prohibited remu-
7	neration.
8	"(4) What constitutes an inducement to reduce
9	or limit services to individuals entitled to benefits
10	under title XVIII or title XIX within the meaning
11	of section 1128B(b).
12	"(5) Whether an arrangement, activity or pro-
13	posed arrangement or proposed activity violates any
14	other provision of this Act.
15	"(c) Matters Not Subject to Advisory Opin-
16	IONS.—Such advisory opinions shall not address the fol-
17	lowing matters:
18	"(1) Whether the fair market value shall be, or
19	was paid or received for any goods, services or prop-
20	erty.
21	"(2) Whether an individual is a bona fide em-
22	ployee within the requirements of section 3121(d)(2)
23	of the Internal Revenue Code of 1986.
24	"(d) Effect of Advisory Opinions.—

1	"(1) Each advisory opinion issued by the Sec-
2	retary shall be binding as to the Secretary and the
3	party or parties requesting the opinion.
4	"(2) The failure of a party to seek an advisory
5	opinion may not be introduced into evidence to prove
6	that the party intended to violate the provisions of
7	sections 1128, 1128A, or 1128B.
8	"(e) Regulations.—The Secretary within 180 days
9	of the date of enactment, shall issue regulations establish-
10	ing a system for the issuance of advisory opinions. Such
11	regulations shall provide for—
12	"(1) the procedure to be followed by a party ap-
13	plying for an advisory opinion;
14	"(2) the procedure to be followed by the Sec-
15	retary in responding to a request for an advisory
16	opinion;
17	"(3) the interval in which the Secretary shall
18	respond;
19	"(4) the reasonable fee to be charged to the
20	party requesting an advisory opinion; and
21	"(5) the manner in which advisory opinions will
22	be made available to the public.
23	"(f) Interval for Issuance of Advisory Opin-
24	IONS —Under no circumstances shall the interval in which

1	the Secretary shall respond to a party requesting an advi-
2	sory opinion exceed 30 days.".
3	SEC. 3002. AUTHORIZING THE SECRETARY OF HEALTH AND
4	HUMAN SERVICES TO ISSUE ADVISORY OPIN-
5	IONS RELATING TO PHYSICIAN OWNERSHIP
6	AND REFERRAL.
7	Section 1877 of the Social Security Act (42 U.S.C.
8	1395nn) is amended by the addition of the following new
9	subsection:
10	"(i) Advisory Opinions.—
11	"(1) In general.—The Secretary shall issue
12	advisory opinions on whether an arrangement or
13	proposed arrangement will result in a prohibited re-
14	ferral within the meaning of this section.
15	"(2) Effect of advisory opinions.—
16	"(A) Each advisory opinion issued by the
17	Secretary shall be binding as to the Secretary
18	and the party or parties requesting the opinion.
19	"(B) The failure of a party to seek an ad-
20	visory opinion may not be introduced into evi-
21	dence to prove that the party intended to vio-
22	late the provisions of this section.
23	"(3) REGULATIONS.—The Secretary within one
24	hundred and eighty days of the date of enactment,
25	shall issue regulations establishing a system for the

1	issuance of advisory opinions. Such regulations shall
2	provide for—
3	"(A) the procedure to be followed by a
4	party applying for an advisory opinion;
5	"(B) the procedure to be followed by the
6	Secretary in responding to a request for an ad-
7	visory opinion;
8	"(C) the interval in which the Secretary
9	shall respond;
10	"(D) the reasonable fee to be charged to
11	the party requesting an advisory opinion; and
12	"(E) the manner in which advisory opin-
13	ions will be made available to the public.
14	"(4) Interval for issuance of advisory
15	OPINIONS.—Under no circumstances shall the inter-
16	val in which the Secretary shall respond to a party
17	requesting an advisory opinion exceed thirty days.".
18	SEC. 3003. EFFECTIVE DATE.
19	Unless otherwise specified, the amendments made by
20	this title shall be effective upon the enactment of this Act.

1	TITLE IV—MALPRACTICE
2	REFORM AND ANTITRUST
3	Subtitle A—Malpractice Reform
4	PART 1—UNIFORM STANDARDS FOR
5	MALPRACTICE CLAIMS
6	SEC. 4001. APPLICABILITY.
7	Except as provided in section 4021, this part shall
8	apply to any medical malpractice liability action brought
9	in a Federal or State court, and to any medical mal-
10	practice claim subject to an alternative dispute resolution
11	system, that is initiated on or after January 1, 1996.
12	SEC. 4002. REQUIREMENT FOR INITIAL RESOLUTION OF AC-
13	TION THROUGH ALTERNATIVE DISPUTE RES-
14	OLUTION.
15	(a) In General.—
16	(1) STATE CASES.—A medical malpractice li-
17	ability action may not be brought in any State court
18	during a calendar year unless the medical mal-
19	practice liability claim that is the subject of the ac-
20	tion has been initially resolved under an alternative
21	dispute resolution system certified for the year by
22	the Secretary under section 4012(a), or, in the case
23	of a State in which such a system is not in effect
24	for the year, under the alternative Federal system
25	established under section 4022(h)

(2) Federal diversity actions.—A medical malpractice liability action may not be brought in any Federal court under section 1332 of title 28, United States Code, during a calendar year unless the medical malpractice liability claim that is the subject of the action has been initially resolved under the alternative dispute resolution system referred to in paragraph (1) that applied in the State whose law applies in such action.

## (3) CLAIMS AGAINST UNITED STATES.—

(A) ESTABLISHMENT OF PROCESS FOR CLAIMS.—The Attorney General shall establish an alternative dispute resolution process for the resolution of tort claims consisting of medical malpractice liability claims brought against the United States under chapter 171 of title 28, United States Code. Under such process, the resolution of a claim shall occur after the completion of the administrative claim process applicable to the claim under section 2675 of such title.

(B) REQUIREMENT FOR INITIAL RESOLU-TION UNDER PROCESS.—A medical malpractice liability action based on a medical malpractice liability claim described in subparagraph (A)

1	may not be brought in any Federal court unless
2	the claim has been initially resolved under the
3	alternative dispute resolution process estab-
4	lished by the Attorney General under such sub-
5	paragraph.
6	(b) Initial Resolution of Claims Under
7	ADR.—For purposes of subsection (a), an action is "ini-
8	tially resolved" under an alternative dispute resolution
9	system if—
10	(1) the ADR reaches a decision on whether the
11	defendant is liable to the plaintiff for damages; and
12	(2) if the ADR determines that the defendant
13	is liable, the ADR reaches a decision on the amount
14	of damages assessed against the defendant.
15	(c) Procedures for Filing Actions.—
16	(1) Notice of intent to contest deci-
17	SION.—Not later than 60 days after a decision is is-
18	sued with respect to a medical malpractice liability
19	claim under an alternative dispute resolution system,
20	each party affected by the decision shall submit a
21	sealed statement to a court of competent jurisdiction
22	indicating whether or not the party intends to con-

test the decision.

1	(2) Deadline for filing action.—A medical
2	malpractice liability action may not be brought by a
3	party unless—
4	(A) the party has filed the notice of intent
5	required by paragraph (1); and
6	(B) the party files the action in a court of
7	competent jurisdiction not later than 90 days
8	after the decision resolving the medical mal-
9	practice liability claim that is the subject of the
10	action is issued under the applicable alternative
11	dispute resolution system.
12	(3) Court of competent jurisdiction.—
13	For purposes of this subsection, the term "court of
14	competent jurisdiction" means—
15	(A) with respect to actions filed in a State
16	court, the appropriate State trial court; and
17	(B) with respect to actions filed in a Fed-
18	eral court, the appropriate United States dis-
19	trict court.
20	(d) Legal Effect of Uncontested ADR Deci-
21	SION.—The decision reached under an alternative dispute
22	resolution system shall, for purposes of enforcement by a
23	court of competent jurisdiction, have the same status in
24	the court as the verdict of a medical malpractice liability
25	action adjudicated in a State or Federal trial court. The

- 1 previous sentence shall not apply to a decision that is con-
- 2 tested by a party affected by the decision pursuant to sub-
- 3 section (c)(1).
- 4 SEC. 4003. OPTIONAL APPLICATION OF PRACTICE GUIDE-
- 5 LINES.
- 6 (a) DEVELOPMENT AND CERTIFICATION OF GUIDE-
- 7 LINES.—Each State may develop, for certification by the
- 8 Secretary, a set of specialty clinical practice guidelines,
- 9 based on recommended guidelines from national specialty
- 10 societies, to be updated annually. In the absence of rec-
- 11 ommended guidelines from such societies, each State may
- 12 develop such guidelines based on such criteria as the State
- 13 considers appropriate (including based on recommended
- 14 guidelines developed by the Agency for Health Care Policy
- 15 and Research).
- 16 (b) Provision of Health Care Under Guide-
- 17 LINES.—Notwithstanding any other provision of law, in
- 18 any medical malpractice liability action arising from the
- 19 conduct of a health care provider or health care profes-
- 20 sional, if such conduct was in accordance with a guideline
- 21 developed by the State in which the conduct occurred and
- 22 certified by the Secretary under subsection (a), the guide-
- 23 line—

1	(1) may be introduced by any party to the ac-
2	tion (including a health care provider, health care
3	professional, or patient); and
4	(2) if introduced, shall establish a rebuttable
5	presumption that the conduct was in accordance
6	with the appropriate standard of medical care, which
7	may only be overcome by the presentation of clear
8	and convincing evidence on behalf of the party
9	against whom the presumption operates.
10	SEC. 4004. TREATMENT OF NONECONOMIC AND PUNITIVE
11	DAMAGES.
12	(a) Limitation on Noneconomic Damages.—The
13	total amount of noneconomic damages that may be award-
14	ed to a claimant and the members of the claimant's family
15	for losses resulting from the injury which is the subject
16	of a medical malpractice liability action may not exceed
17	\$250,000, regardless of the number of parties against
18	whom the action is brought or the number of actions
19	brought with respect to the injury.
20	(b) No Award of Punitive Damages Against
21	MANUFACTURER OF MEDICAL PRODUCT.—In the case of
22	a medical malpractice liability action in which the plaintiff
23	alleges a claim against the manufacturer of a medical
24	product, no punitive or exemplary damages may be award-

25 ed against such manufacturer.

1	(c) Joint and Several Liability for Non-
2	ECONOMIC DAMAGES.—The liability of each defendant for
3	noneconomic damages shall be several only and shall not
4	be joint, and each defendant shall be liable only for the
5	amount of noneconomic damages allocated to the defend-
6	ant in direct proportion to the defendant's percentage of
7	responsibility (as determined by the trier of fact).
8	(d) Use of Punitive Damage Awards for Oper-
9	ATION OF ADR SYSTEMS IN STATES.—
10	(1) IN GENERAL.—The total amount of any pu-
11	nitive damages awarded in a medical malpractice li-
12	ability action shall be paid to the State in which the
13	action is brought (or, in a case brought in Federa
14	court, in the State in which the health care services
15	that caused the injury that is the subject of the ac-
16	tion were provided), and shall be used by the State
17	solely to implement and operate the State alternative
18	dispute resolution system certified by the Secretary
19	under section 4022 (except as provided in paragraph
20	(2)).
21	(2) Use of remaining amounts for pro-
22	VIDER LICENSING AND DISCIPLINARY ACTIVITIES.—
23	If the amount of punitive damages paid to a State
24	under paragraph (1) for a year is greater than the

State's costs of implementing and operating the

1	State alternative dispute resolution system during
2	the year, the balance of such punitive damages paid
3	to the State shall be used solely to carry out activi-
4	ties to assure the safety and quality of health care
5	services provided in the State, including (but not
6	limited to)—
7	(A) licensing or certifying health care pro-
8	fessionals and health care providers in the
9	State; and
10	(B) carrying out programs to reduce mal-
11	practice-related costs for providers volunteering
12	to provide services in medically underserved
13	areas.
14	(3) Maintenance of Effort.—A State shall
15	use any amounts paid pursuant to paragraph (1) to
16	supplement and not to replace amounts spent by the
17	State for implementing and operating the State al-
18	ternative dispute resolution system or carrying out
19	the activities described in paragraph (2).
20	SEC. 4005. PERIODIC PAYMENTS FOR FUTURE LOSSES.
21	(a) IN GENERAL.—In any medical malpractice liabil-
22	ity action in which the damages awarded for future eco-
23	nomic loss exceed \$100,000, a defendant may not be re-
24	quired to pay such damages in a single, lump-sum pay-
25	ment, but may be permitted to make such payments on

- 1 a periodic basis. The periods for such payments shall be
- 2 determined by the court, based upon projections of when
- 3 such expenses are likely to be incurred.
- 4 (b) WAIVER.—A court may waive the application of
- 5 subsection (a) with respect to a defendant if the court de-
- 6 termines that it is not in the best interests of the plaintiff
- 7 to receive payments for damages on such a periodic basis.
- 8 SEC. 4006. TREATMENT OF ATTORNEY'S FEES AND OTHER
- 9 **COSTS.**
- 10 (a) REQUIRING PARTY CONTESTING ADR RULING
- 11 To Pay Attorney's Fees and Other Costs.—
- 12 (1) IN GENERAL.—The court in a medical mal-
- practice liability action shall require the party that
- 14 (pursuant to section 4002(c)(1)) contested the ruling
- of the alternative dispute resolution system with re-
- spect to the medical malpractice liability claim that
- is the subject of the action to pay to the opposing
- party the costs incurred by the opposing party under
- the action, including attorney's fees, fees paid to ex-
- 20 pert witnesses, and other litigation expenses (but not
- including court costs, filing fees, or other expenses
- paid directly by the party to the court, or any fees
- or costs associated with the resolution of the claim
- under the alternative dispute resolution system), but
- only if—

1	(A) in the case of an action in which the
2	party that contested the ruling is the claimant,
3	the amount of damages awarded to the party
4	under the action is less than the amount of
5	damages awarded to the party under the ADR
6	system; and
7	(B) in the case of an action in which the
8	party that contested the ruling is the defendant,
9	the amount of damages assessed against the
10	party under the action is greater than the
11	amount of damages assessed under the ADR
12	system.
13	(2) Exceptions.—Paragraph (1) shall not
14	apply if—
15	(A) the party contesting the ruling made
16	under the previous alternative dispute resolu-
17	tion system shows that—
18	(i) the ruling was procured by corrup-
19	tion, fraud, or undue means,
20	(ii) there was partiality or corruption
21	under the system,
22	(iii) there was other misconduct under
23	the system that materially prejudiced the
24	party's rights, or

1	(iv) the ruling was based on an error
2	of law;
3	(B) the party contesting the ruling made
4	under the alternative dispute resolution system
5	presents new evidence before the trier of fact
6	that was not available for presentation under
7	the ADR system;
8	(C) the medical malpractice liability action
9	raised a novel issue of law; or
10	(D) the court finds that the application of
11	such paragraph to a party would constitute an
12	undue hardship, and issues an order waiving or
13	modifying the application of such paragraph
14	that specifies the grounds for the court's deci-
15	sion.
16	(3) Limit on attorneys' fees paid.—Attor-
17	neys' fees that are required to be paid under para-
18	graph (1) by the contesting party shall not exceed
19	the amount of the attorneys' fees incurred by the
20	contesting party in the action. If the attorneys' fees
21	of the contesting party are based on a contingency
22	fee agreement, the amount of attorneys' fees for
23	purposes of the preceding sentence shall not exceed
24	the reasonable value of those services.

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1	(4) RECORDS.—In order to receive attorneys'
2	fees under paragraph (1), counsel of record in the
3	medical malpractice liability action involved shall
4	maintain accurate, complete records of hours worked
5	on the action, regardless of the fee arrangement
6	with the client involved.
7	(b) Contingency Fee Defined.—As used in this
8	section, the term "contingency fee" means any fee for pro-
9	fessional legal services which is, in whole or in part, con-
10	tingent upon the recovery of any amount of damages,
11	whether through judgment or settlement.
12	SEC. 4007. UNIFORM STATUTE OF LIMITATIONS.
13	(a) IN GENERAL.—Except as provided in subsection
14	(b), no medical malpractice claim may be initiated after
15	the expiration of the 2-year period that begins on the date
16	on which the alleged injury that is the subject of such
17	claim was discovered, but in no event may such a claim
18	be initiated after the expiration of the 4-year period that
19	begins on the date on which the alleged injury that is the
20	subject of such claim occurred.
21	(b) Exception for Minors.—In the case of an al-

21 (b) EXCEPTION FOR MINORS.—In the case of an al-22 leged injury suffered by a minor who has not attained 6 23 years of age, a medical malpractice claim may not be initi-24 ated after the expiration of the 2-year period that begins 25 on the date on which the alleged injury that is the subject

- 1 of such claim was discovered or should reasonably have
- 2 been discovered, but in no event may such a claim be initi-
- 3 ated after the date on which the minor attains 12 years
- 4 of age.

## 5 SEC. 4008. SPECIAL PROVISION FOR CERTAIN OBSTETRIC

- 6 SERVICES.
- 7 (a) IN GENERAL.—In the case of a medical mal-
- 8 practice claim relating to services provided during labor
- 9 or the delivery of a baby, if the health care professional
- 10 or health care provider against whom the claim is brought
- 11 did not previously treat the claimant for the pregnancy,
- 12 the trier of fact may not find that such professional or
- 13 provider committed malpractice and may not assess dam-
- 14 ages against such professional or provider unless the mal-
- 15 practice is proven by clear and convincing evidence.
- 16 (b) Applicability to Group Practices or
- 17 AGREEMENTS AMONG PROVIDERS.—For purposes of sub-
- 18 section (a), a health care professional shall be considered
- 19 to have previously treated an individual for a pregnancy
- 20 if the professional is a member of a group practice whose
- 21 members previously treated the individual for the preg-
- 22 nancy or is providing services to the individual during
- 23 labor or the delivery of a baby pursuant to an agreement
- 24 with another professional.

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2 Nothing in this part shall be construed to establ
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- 3 any jurisdiction over any medical malpractice liability ac-
- 4 tion in the district courts of the United States on the basis
- 5 of section 1331 or 1337 of title 28, United States Code.

## 6 SEC. 4010. PREEMPTION.

- 7 (a) IN GENERAL.—The provisions of this part shall
- 8 preempt any State law to the extent such law is inconsist-
- 9 ent with such provisions, except that the provisions of this
- 10 part shall not preempt any State law that provides for de-
- 11 fenses or places limitations on a person's liability in addi-
- 12 tion to those contained in this part, places greater limita-
- 13 tions on the amount of attorneys' fees that can be col-
- 14 lected, or otherwise imposes greater restrictions than those
- 15 provided in this part.
- 16 (b) Effect on Sovereign Immunity and Choice
- 17 OF LAW OR VENUE.—Nothing in this part shall be con-
- 18 strued to—
- 19 (1) waive or affect any defense of sovereign im-
- 20 munity asserted by any State under any provision of
- 21 law;
- 22 (2) waive or affect any defense of sovereign im-
- 23 munity asserted by the United States;
- 24 (3) affect the applicability of any provision of
- 25 the Foreign Sovereign Immunities Act of 1976;

1	(4) preempt State choice-of-law rules with re-
2	spect to claims brought by a foreign nation or a citi-
3	zen of a foreign nation; or
4	(5) affect the right of any court to transfer
5	venue or to apply the law of a foreign nation or to
6	dismiss a claim of a foreign nation or of a citizen
7	of a foreign nation on the ground of inconvenient
8	forum.
9	PART 2—REQUIREMENTS FOR STATE ALTER-
10	NATIVE DISPUTE RESOLUTION SYSTEMS
11	(ADR)
12	SEC. 4021. BASIC REQUIREMENTS.
13	(a) In General.—A State's alternative dispute reso-
14	lution system meets the requirements of this section if the
15	system—
16	(1) applies to all medical malpractice liability
17	claims under the jurisdiction of the courts of that
18	State;
19	(2) requires that a written opinion resolving the
20	dispute be issued not later than 6 months after the
21	date by which each party against whom the claim is
22	filed has received notice of the claim (other than in
23	exceptional cases for which a longer period is re-
24	quired for the issuance of such an opinion), and that
25	the opinion contain—

1	(A) findings of fact relating to the dispute,
2	and
3	(B) a description of the costs incurred in
4	resolving the dispute under the system (includ-
5	ing any fees paid to the individuals hearing and
6	resolving the claim), together with an appro-
7	priate assessment of the costs against any of
8	the parties;
9	(3) requires individuals who hear and resolve
10	claims under the system to meet such qualifications
11	as the State may require (in accordance with regula-
12	tions of the Secretary);
13	(4) is approved by the State or by local govern-
14	ments in the State;
15	(5) with respect to a State system that consists
16	of multiple dispute resolution procedures—
17	(A) permits the parties to a dispute to se-
18	lect the procedure to be used for the resolution
19	of the dispute under the system, and
20	(B) if the parties do not agree on the pro-
21	cedure to be used for the resolution of the dis-
22	pute, assigns a particular procedure to the par-
23	ties;
24	(6) provides for the transmittal to the State
25	agency responsible for monitoring or disciplining

23	BILITY OF ALTERNATIVE FEDERAL SYSTEM.
22	SEC. 4022. CERTIFICATION OF STATE SYSTEMS; APPLICA-
21	the State.
20	respect to medical malpractice liability actions brought in
19	system in the same manner as such provisions apply with
18	native dispute resolution system or the alternative Federal
17	apply with respect to claims brought under a State alter-
16	The provisions of part 1 (other than section 4002) shall
15	STANDARDS TO ALTERNATIVE DISPUTE RESOLUTION.—
14	(b) Application of Malpractice Liability
13	the parties to a dispute shall not be revealed.
12	tem, in a manner that assures that the identity of
11	of information on disputes resolved under the sys-
10	Administrator for Health Care Policy and Research
9	(7) provides for the regular transmittal to the
8	the system; and
7	brings an action contesting the decision made under
6	sional or provider, the professional or provider
5	the system resolves the claim against the profes-
4	less, during the 90-day period beginning on the date
3	professional or provider committed malpractice, un-
2	of any findings made under the system that such a
1	health care professionals and health care providers

(a) CERTIFICATION.—

- (1) IN GENERAL.—Not later than October 1 of each year (beginning with 1995), the Secretary, in consultation with the Attorney General, shall determine whether a State's alternative dispute resolution system meets the requirements of this part for the following calendar year.
- (2) Basis for Certification.—The Secretary shall certify a State's alternative dispute resolution system under this subsection for a calendar year if the Secretary determines under paragraph (1) that the system meets the requirements of section 4021, including the requirement described in section 4004 that punitive damages awarded under the system are paid to the State for the uses described in such section.
- 16 (b) Applicability of Alternative Federal Sys-17 tem.—
- ESTABLISHMENT AND APPLICABILITY.— Not later than October 1, 1995, the Secretary, in consultation with the Attorney General, shall estab-lish by rule an alternative Federal ADR system for the resolution of medical malpractice liability claims during a calendar year in States that do not have in effect an alternative dispute resolution system certified under subsection (a) for the year.

1	(2) REQUIREMENTS FOR SYSTEM.—Under the
2	alternative Federal ADR system established under
3	paragraph (1)—
4	(A) paragraphs (1), (2), (6), and (7) of
5	section 4021(a) shall apply to claims brought
6	under the system;
7	(B) if the system provides for the resolu-
8	tion of claims through arbitration, the claims
9	brought under the system shall be heard and
10	resolved by arbitrators appointed by the Sec-
11	retary in consultation with the Attorney Gen-
12	eral; and
13	(C) with respect to a State in which the
14	system is in effect, the Secretary may (at the
15	State's request) modify the system to take into
16	account the existence of dispute resolution pro-
17	cedures in the State that affect the resolution
18	of medical malpractice liability claims.
19	(3) Treatment of states with alter-
20	NATIVE SYSTEM IN EFFECT.—If the alternative Fed-
21	eral ADR system established under this subsection is
22	applied with respect to a State for a calendar year,
23	the State shall make a payment to the United States
24	(at such time and in such manner as the Secretary

may require) in an amount equal to 110 percent of

1	the costs incurred by the United States during the
2	year as a result of the application of the system with
3	respect to the State.
4	SEC. 4023. REPORTS ON IMPLEMENTATION AND EFFEC-
5	TIVENESS OF ALTERNATIVE DISPUTE RESO-
6	LUTION SYSTEMS.
7	(a) IN GENERAL.—Not later than 5 years after the
8	date of the enactment of this Act, the Secretary shall pre-
9	pare and submit to the Congress a report describing and
10	evaluating State alternative dispute resolution systems op-
11	erated pursuant to this part and the alternative Federal
12	system established under section 4022(b).
13	(b) CONTENTS OF REPORT.—The Secretary shall in-
14	clude in the report prepared and submitted under sub-
15	section (a)—
16	(1) information on—
17	(A) the effect of the alternative dispute
18	resolution systems on the cost of health care
19	within each State,
20	(B) the impact of such systems on the ac-
21	cess of individuals to health care within the
22	State, and
23	(C) the effect of such systems on the qual-
24	ity of health care provided within the State; and

1	(2) to the extent that such report does not pro-
2	vide information on no-fault systems operated by
3	States as alternative dispute resolution systems pur-
4	suant to this part, an analysis of the feasibility and
5	desirability of establishing a system under which
6	medical malpractice liability claims shall be resolved
7	on a no-fault basis.
8	PART 3—DEFINITIONS
9	SEC. 4031. DEFINITIONS.
10	As used in this subtitle:
11	(1) ALTERNATIVE DISPUTE RESOLUTION SYS-
12	TEM.—The term "alternative dispute resolution sys-
13	tem" means a system that is enacted or adopted by
14	a State to resolve medical malpractice claims other
15	than through a medical malpractice liability action.
16	(2) CLAIMANT.—The term "claimant" means
17	any person who brings a health care liability action
18	and, in the case of an individual who is deceased, in-
19	competent, or a minor, the person on whose behalf

21 (3) CLEAR AND CONVINCING EVIDENCE.—The 22 term "clear and convincing evidence" is that meas-23 ure or degree of proof that will produce in the mind

such an action is brought.

of the trier of fact a firm belief or conviction as to

25 the truth of the allegations sought to be established,

- except that such measure or degree of proof is more than that required under preponderance of the evidence, but less than that required for proof beyond a reasonable doubt.
  - (4) Economic damages.—The term "economic damages" means damages paid to compensate an individual for losses for hospital and other medical expenses, lost wages, lost employment, and other pecuniary losses.
  - (5) HEALTH CARE PROFESSIONAL.—The term "health care professional" means any individual who provides health care services in a State and who is required by State law or regulation to be licensed or certified by the State to provide such services in the State.
  - (6) HEALTH CARE PROVIDER.—The term "health care provider" means any organization or institution that is engaged in the delivery of health care services in a State that 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.
  - (7) Injury.—The term "injury" means any illness, disease, or other harm that is the subject of a medical malpractice claim.

(8) Medical malpractice liability ac-
TION.—The term "medical malpractice liability ac-
tion" means any civil action brought pursuant to
State law in which a plaintiff alleges a medical mal-
practice claim against a health care provider or
health care professional, but does not include any
action in which the plaintiff's sole allegation is an al-
legation of an intentional tort.
(9) MEDICAL MALPRACTICE CLAIM.—The term

(9) MEDICAL MALPRACTICE CLAIM.—The term "medical malpractice claim" means any claim relating to the provision of (or the failure to provide) health care services or the use of a medical product, without regard to the theory of liability asserted, and includes any third-party claim, cross-claim, counterclaim, or contribution claim in a medical malpractice liability action.

## (10) Medical product.—

(A) IN GENERAL.—The term "medical product" means, with respect to the allegation of a claimant, a drug (as defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)) or a medical device (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) if—

1	(i) such drug or device was subject to
2	premarket approval under section 505,
3	507, or 515 of the Federal Food, Drug,
4	and Cosmetic Act (21 U.S.C. 355, 357, or
5	360e) or section 351 of the Public Health
6	Service Act (42 U.S.C. 262) with respect
7	to the safety of the formulation or per-
8	formance of the aspect of such drug or de-
9	vice which is the subject of the claimant's
10	allegation or the adequacy of the packag-
11	ing or labeling of such drug or device, and
12	such drug or device is approved by the
13	Food and Drug Administration; or
14	(ii) the drug or device is generally rec-
15	ognized as safe and effective under regula-
16	tions issued by the Secretary of Health
17	and Human Services under section 201(p)
18	of the Federal Food, Drug, and Cosmetic
19	Act (21 U.S.C. 321(p)).
20	(B) EXCEPTION IN CASE OF MISREPRE-
21	SENTATION OR FRAUD.—Notwithstanding sub-
22	paragraph (A), the term "medical product"
23	shall not include any product described in such
24	subparagraph if the claimant shows that the
25	product is approved by the Food and Drug Ad-

1	ministration for marketing as a result of with-
2	held information, misrepresentation, or an ille-
3	gal payment by the manufacturer of the prod-
4	uct.
5	(11) Noneconomic damages.—The term
6	"noneconomic damages" means damages paid to
7	compensate an individual for losses for physical and
8	emotional pain, suffering, inconvenience, physical
9	impairment, mental anguish, disfigurement, loss of
10	enjoyment of life, loss of consortium, and other
11	nonpecuniary losses, but does not include punitive
12	damages.
13	(12) Punitive damages.—The term "punitive
14	damages" means compensation, in addition to com-
15	pensation for actual harm suffered, that is awarded
16	for the purpose of punishing a person for conduct
17	deemed to be malicious, wanton, willful, or exces-
18	sively reckless.
19	Subtitle B—Antitrust
20	SEC. 4101. PUBLICATION OF ANTITRUST GUIDELINES ON
21	ACTIVITIES OF HEALTH PLANS.
22	(a) IN GENERAL.—The Attorney General shall pro-
23	vide for the development and publication of explicit guide-
24	lines on the application of antitrust laws to the activities
25	of health plans. The guidelines shall be designed to facili-

1	tate development and operation of plans, consistent with
2	the antitrust laws.
3	(b) REVIEW PROCESS.—The Attorney General shall
4	establish a review process under which the administrator
5	or sponsor of a health plan (or organization that proposes
6	to administer or sponsor a health plan) may submit a re-
7	quest to the Attorney General to obtain a prompt opinion
8	(but in no event later than 60 days after the Attorney
9	General receives the request) from the Department of Jus-
10	tice on the plan's conformity with the Federal antitrust
11	laws.
12	(c) Definitions.—In this section—
13	(1) the term "antitrust laws"—
14	(A) has the meaning given it in subsection
15	(a) of the first section of the Clayton Act (15
16	U.S.C. 12(a)), except that such term includes
17	section 5 of the Federal Trade Commission Act
18	(15 U.S.C. 45) to the extent such section ap-
19	plies to unfair methods of competition, and
20	(B) includes any State law similar to the
21	laws referred to in subparagraph (A); and
22	(2) the term "health plan" means any contract
23	or arrangement under which an entity bears all or
24	part of the cost of providing health care items and
25	services, including a hospital or medical expense in-

1	curred policy or certificate, hospital or medical serv-
2	ice plan contract, or health maintenance subscriber
3	contract, but does not include—
4	(A) coverage only for accident, dental, vi-
5	sion, disability, or long term care, medicare
6	supplemental health insurance, or any combina-
7	tion thereof,
8	(B) coverage issued as a supplement to li-
9	ability insurance,
10	(C) workers' compensation or similar in-
11	surance, or
12	(D) automobile medical-payment insur-
13	ance.
14	SEC. 4102. ISSUANCE OF HEALTH CARE CERTIFICATES OF
15	PUBLIC ADVANTAGE.
16	(a) Issuance and Effect of Certificate.—The
17	Attorney General, after consultation with the Secretary,
18	shall issue in accordance with this section a certificate of
19	public advantage to each eligible health care collaborative
20	activity that complies with the requirements in effect
21	under this section on or after the expiration of the 1-year
22	period that begins on the date of the enactment of this
23	Act (without regard to whether or not the Attorney Gen-
24	eral has promulgated regulations to carry out this section
25	by such date). Such activity, and the parties to such activ-

1	ity, shall not be liable under any of the antitrust laws for
2	conduct described in such certificate and engaged in by
3	such activity if such conduct occurs while such certificate
4	is in effect.
5	(b) REQUIREMENTS APPLICABLE TO ISSUANCE OF
6	CERTIFICATES.—
7	(1) Standards to be met.—The Attorney
8	General shall issue a certificate to an eligible health
9	care collaborative activity if the Attorney General
10	finds that—
11	(A) the benefits that are likely to result
12	from carrying out the activity outweigh the re-
13	duction in competition (if any) that is likely to
14	result from the activity, and
15	(B) such reduction in competition is nec-
16	essary to obtain such benefits.
17	(2) Factors to be considered.—
18	(A) Weighing of Benefits against re-
19	DUCTION IN COMPETITION.—For purposes of
20	making the finding described in paragraph
21	(1)(A), the Attorney General shall consider
22	whether the activity is likely—
23	(i) to maintain or to increase the
24	quality of health care by providing new

1	services not currently offered in the rel-
2	evant market,
3	(ii) to increase access to health care,
4	(iii) to achieve cost efficiencies that
5	will be passed on to health care consumers,
6	such as economies of scale, reduced trans-
7	action costs, and reduced administrative
8	costs, that cannot be achieved by the provi-
9	sion of available services and facilities in
10	the relevant market,
11	(iv) to preserve the operation of
12	health care facilities located in underserved
13	geographical areas,
14	(v) to improve utilization of health
15	care resources, and
16	(vi) to reduce inefficient health care
17	resource duplication.
18	(B) NECESSITY OF REDUCTION IN COM-
19	PETITION.—For purposes of making the finding
20	described in paragraph (1)(B), the Attorney
21	General shall consider—
22	(i) the ability of the providers of
23	health care services that are (or likely to
24	be) affected by the health care collabo-
25	rative activity and the entities responsible

1	for making payments to such providers to
2	negotiate societally optimal payment and
3	service arrangements,
4	(ii) the effects of the health care col-
5	laborative activity on premiums and other
6	charges imposed by the entities described
7	in clause (i), and
8	(iii) the availability of equally effi-
9	cient, less restrictive alternatives to achieve
10	the benefits that are intended to be
11	achieved by carrying out the activity.
12	(c) Establishment of Criteria and Proce-
13	DURES.—Subject to subsections (d) and (e), not later than
14	1 year after the date of the enactment of this Act, the
15	Attorney General and the Secretary shall establish jointly
16	by rule the criteria and procedures applicable to the issu-
17	ance of certificates under subsection (a). The rules shall
18	specify the form and content of the application to be sub-
19	mitted to the Attorney General to request a certificate,
20	the information required to be submitted in support of
21	such application, the procedures applicable to denying and
22	to revoking a certificate, and the procedures applicable to
23	the administrative appeal (if such appeal is authorized by
24	rule) of the denial and the revocation of a certificate. Such
25	information may include the terms of the health care col-

- 1 laborative activity (in the case of an activity in existence
- 2 as of the time of the application) and implementation plan
- 3 for the collaborative activity.
- 4 (d) Eligible Health Care Collaborative Ac-
- 5 TIVITY.—To be an eligible health care collaborative activ-
- 6 ity for purposes of this section, a health care collaborative
- 7 activity shall submit to the Attorney General an applica-
- 8 tion that complies with the rules in effect under subsection
- 9 (c) and that includes—
- 10 (1) an agreement by the parties to the activity
- that the activity will not foreclose competition by en-
- tering into contracts that prevent health care provid-
- ers from providing health care in competition with
- the activity,
- 15 (2) an agreement that the activity will submit
- to the Attorney General annually a report that de-
- scribes the operations of the activity and information
- regarding the impact of the activity on health care
- and on competition in health care, and
- 20 (3) an agreement that the parties to the activity
- will notify the Attorney General and the Secretary of
- the termination of the activity not later than 30
- days after such termination occurs.
- 24 (e) REVIEW OF APPLICATIONS FOR CERTIFICATES.—
- 25 Not later than 90 days after an eligible health care col-

1	laborative activity submits to the Attorney General an ap-
2	plication that complies with the rules in effect under sub-
3	section (c) and with subsection (d), the Attorney General
4	shall issue or deny the issuance of such certificate. If, be-
5	fore the expiration of such 90-day period, the Attorney
6	General may extend the time for issuance for good cause.
7	(f) REVOCATION OF CERTIFICATE.—Whenever the
8	Attorney General finds that a health care collaborative ac-
9	tivity with respect to which a certificate is in effect does
10	not meet the standards specified in subsection (b), the At-
11	torney General shall revoke such certificate.
12	(g) Written Reasons; Judicial Review.—
13	(1) Denial and revocation of certifi-
14	CATES.—If the Attorney General denies an applica-
15	tion for a certificate or revokes a certificate, the At-
16	torney General shall include in the notice of denial
17	or revocation a statement of the reasons relied upon
18	for the denial or revocation of such certificate.
19	(2) Judicial review.—
20	(A) AFTER ADMINISTRATIVE PROCEED-
21	ING.—(i) If the Attorney General denies an ap-
22	plication submitted or revokes a certificate is-
23	sued under this section after an opportunity for
24	hearing on the record, then any party to the
25	health care collaborative activity involved may

commence a civil action, not later than 60 days
after receiving notice of the denial or revoca-
tion, in an appropriate district court of the
United States for review of the record of such
denial or revocation.
(ii) As part of the Atterney Canonal's an

- (ii) As part of the Attorney General's answer, the Attorney General shall file in such court a certified copy of the record on which such denial or revocation is based. The findings of fact of the Attorney General may be set aside only if found to be unsupported by substantial evidence in such record taken as a whole.
- (B) Denial or revocation without administrative proceeding.—If the Attorney General denies an application submitted or revokes a certificate issued under this section without an opportunity for hearing on the record, then any party to the health care collaborative activity involved may commence a civil action, not later than 60 days after receiving notice of the denial or revocation, in an appropriate district court of the United States for de novo review of such denial or revocation.
- 24 (h) EXEMPTION.—A person shall not be liable under 25 any of the antitrust laws for conduct necessary—

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1	(1) to prepare, agree to prepare, or attempt to
2	agree to prepare an application to request a certifi-
3	cate under this section, or
4	(2) to attempt to enter into any health care col-
5	laborative activity with respect to which such a cer-
6	tificate is in effect.
7	(i) Definitions.—In this section:
8	(1) The term "antitrust laws" has the meaning
9	given it in subsection (a) of the first section of the
10	Clayton Act (15 U.S.C. 12(a)), except that such
11	term includes section 5 of the Federal Trade Com-
12	mission Act (15 U.S.C. 45) to the extent such sec-
13	tion applies to unfair methods of competition.
14	(2) The term "certificate" means a certificate
15	of public advantage authorized to be issued under
16	subsection (a).
17	(3) The term "health care collaborative activ-
18	ity" means an agreement (whether existing or pro-
19	posed) between 2 or more providers of health care
20	services that is entered into solely for the purpose of
21	sharing in the provision and coordination of health
22	care services and that involves substantial integra-
23	tion and financial risk-sharing between the parties,
24	but does not include the exchanging of information,

the entering into of any agreement, or the engage-

- ment in any other conduct that is not reasonably required to carry out such agreement.
  - (4) The term "health care services" includes services related to the delivery or administration of health care services.
  - (5) The term "liable" means liable for any civil or criminal violation of the antitrust laws.
  - (6) The term "provider of health care services" means any individual or entity that is engaged in the delivery of health care services in a State and that 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.

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