103D CONGRESS 2D SESSION **H. R. 3486**

To establish safe harbors from the application of the antitrust laws for certain activities of providers of health care services, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 10, 1993

Mr. ARCHER introduced the following bill; which was referred to the Committee on the Judiciary

May 12, 1994

Additional sponsors: Mr. CALLAHAN, Mr. BARCIA of Michigan, Mr. Goss, Mr. PARKER, Mr. PETRI, Mrs. FOWLER, Mr. CANADY, Mr. DUNCAN, Mr. DORNAN, Mr. DICKEY, Mr. SUNDQUIST, Mr. DERRICK, Mr. ALLARD, Mr. KLUG, Mr. GORDON, Mr. BONILLA, Mr. ZELIFF, Mr. INHOFE, Mr. DELAY, Mr. GOODLING, Mrs. LLOYD, Mr. HUTCHINSON, Mr. CRAPO, Mr. MANZULLO, Mr. TAYLOR of North Carolina, Mrs. UNSOELD, Mr. BREW-STER, Mr. FRANKS of Connecticut, Mr. FIELDS of Texas, Mr. SWETT, Mr. NUSSLE, Mr. THOMAS of Wyoming, Mr. UPTON, Mr. BOEHNER, Mr. SENSENBRENNER, Mr. RAVENEL, Mr. COMBEST, Mr. CRAMER, Mr. CLEMENT, Mr. LEVY, Mrs. VUCANOVICH, Mr. HALL of Ohio, Mr. MONT-GOMERY, Ms. PRYCE of Ohio, Mr. KNOLLENBERG, Mr. PETE GEREN of Texas, Mr. YOUNG of Alaska, Mr. HOEKSTRA, Mr. SMITH of Oregon, Mr. RAMSTAD, Mr. INSLEE, Mr. STUMP, Mr. McDade, Mr. Paxon, Mr. PORTMAN, Mr. SMITH of New Jersey, Mr. MCHUGH, Mr. BUNNING, Mr. BACHUS of Alabama, Mr. HOBSON, Mr. COBLE, Mrs. BYRNE, Mr. ROG-ERS, Mrs. JOHNSON of Connecticut, Mr. MOORHEAD, Mr. EWING, Mr. HANCOCK, Mr. INGLIS of South Carolina, Mr. SANGMEISTER, Mr. SHAYS, Mr. McCandless, Mr. Lightfoot, Mr. Jefferson, Mr. Lazio, Mr. Kyl, Mr. Ehlers, Mr. Bliley, Mr. Oxley, Mr. Machtley, Mr. Solo-MON, Mr. ARMEY, Mr. GOODLATTE, Mr. PACKARD, Mr. ZIMMER, Mr. PE-TERSON of Minnesota, Mr. DEFAZIO, Ms. MCKINNEY, Mr. ROTH, Mr. HANSEN, Mr. BARCA of Wisconsin, Mr. DEUTSCH, Mr. MICA, Mr. CAS-TLE, MS. DUNN, Mr. MCINNIS, Mr. JOHNSON of South Dakota, Mr. HUTTO, Mr. ROWLAND, Mr. STEARNS, Mr. PAYNE of Virginia, Mr. COL-LINS of Georgia, and Mr. TAUZIN

A BILL

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To establish safe harbors from the application of the antitrust laws for certain activities of providers of health care services, 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.

4 This Act may be cited as the "Health Care Antitrust5 Improvements Act of 1993".

6 SEC. 2. EXEMPTION FROM ANTITRUST LAWS FOR CERTAIN
7 COMPETITIVE AND COLLABORATIVE ACTIVI8 TIES.

9 (a) EXEMPTION DESCRIBED.—An activity relating to
10 the provision of health care services shall be exempt from
11 the antitrust laws if—

12 (1) the activity is within one of the categories13 of safe harbors described in section 3;

14 (2) the activity is within an additional safe har15 bor designated by the Attorney General under sec16 tion 4; or

(3) the activity is specified in and in compliance
with the terms of a certificate of review issued by
the Attorney General under section 5 and the activity occurs—

21 (A) while the certificate is in effect, or

1	(B) in the case of a certificate issued dur-
2	ing the 2-year period beginning on the date of
3	the enactment of this Act, at any time on or
4	after the first day of the 2-year period that
5	ends on the date the certificate takes effect.
6	(b) Award of Attorney's Fees and Costs of
7	Suit.—
8	(1) IN GENERAL.—If any person brings an ac-
9	tion alleging a claim under the antitrust laws and
10	the activity on which the claim is based is found by
11	the court to be exempt from such laws under sub-
12	section (a), the court shall, at the conclusion of the
13	action—
14	(A) award to a substantially prevailing
15	claimant the cost of suit attributable to such
16	claim, including a reasonable attorney's fee, or
17	(B) award to a substantially prevailing
18	party defending against such claim the cost of
19	such suit attributable to such claim, including
20	reasonable attorney's fee, if the claim, or the
21	claimant's conduct during litigation of the
22	claim, was frivolous, unreasonable, without
23	foundation, or in bad faith.
24	(2) Offset in cases of bad faith.—The
25	court may reduce an award made pursuant to para-

graph (1) in whole or in part by an award in favor
of another party for any part of the cost of suit (including a reasonable attorney's fee) attributable to
conduct during the litigation by any prevailing party
that the court finds to be frivolous, unreasonable,
without foundation, or in bad faith.

7 SEC. 3. SAFE HARBORS.

8 The following activities are safe harbors for purposes9 of section 2(a)(1):

10 (1)COMBINATIONS WITH MARKET SHARE 11 BELOW THRESHOLD.—Activities relating to health care services of any combination of health care pro-12 viders if the number of each type or specialty of pro-13 14 vider in question does not exceed 25 percent of the 15 total number of such type or specialty of provider in the relevant market area. 16

17 (2) ACTIVITIES OF MEDICAL SELF-REGULATORY
18 ENTITIES.—

(A) IN GENERAL.—Subject to subparagraph (B), any activity of a medical self-regulatory entity relating to standard setting or
standard enforcement activities that are designed to promote the quality of health care
provided to patients.

(B) EXCEPTION.—No activity of a medical
self-regulatory entity may be deemed to fall
under the safe harbor established under this
paragraph if the activity is conducted for pur-
poses of financial gain.
(3) PARTICIPATION IN SURVEYS.—The partici-
pation of a provider of health care services in a writ-
ten survey of the prices of services, reimbursement
levels, or the compensation and benefits of employ-
ees and personnel, but only if—
(A) the survey is conducted by a third
party, such as a purchaser of health care serv-
ices, governmental entity, institution of higher
education, or trade association;
(B) the information provided by partici-
pants in the survey is based on prices charged,
reimbursements received, or compensation and
benefits paid prior to the third month preceding
the month in which the information is provided;
and
(C) if the results of the survey are dissemi-
nated, the results are aggregated in a manner
that ensures that no recipient of the results
may identify the prices charged, reimbursement

received, or compensation and benefits paid by any particular provider.

3 (4) JOINT VENTURES FOR HIGH TECHNOLOGY 4 AND COSTLY EQUIPMENT AND SERVICES.—Any ac-5 tivity of a health care cooperative venture relating to 6 the purchase, operation, or marketing of high tech-7 nology or other expensive medical equipment, or the provision of high cost or complex services, but only 8 9 if the number of participants in the venture does not 10 exceed the lowest number needed to support the ven-11 ture together with any other providers for whom the 12 participation in the venture is the only means of ob-13 taining or operating such equipment or providing 14 such services.

15 (5) HOSPITAL MERGERS.—Activities relating to 16 a merger of 2 hospitals if, during the 3-year period 17 preceding the merger, one of the hospitals had an 18 average of 150 or fewer operational beds and an av-19 erage daily inpatient census of less than 50 percent 20 of such beds.

21 (6) JOINT PURCHASING ARRANGEMENTS.—Any
22 joint purchasing arrangement among health care
23 providers if—

24 (A) the purchases under the arrangement25 represent less than 35 percent of the total sales

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1	of the product purchased in the relevant market
2	area; and
3	(B) the amounts paid under the arrange-
4	ment represent less than 20 percent of the total
5	revenues of the supplier of the product pur-
6	chased.
7	(7) NEGOTIATIONS.—Activities consisting of
8	good faith negotiations to carry out any activity—
9	(A) described in this section,
10	(B) within an additional safe harbor des-
11	ignated by the Attorney General under section
12	4,
13	(C) that is the subject of an application for
14	a certificate of review under section 5, or
15	(D) that is deemed a submission of a noti-
16	fication under section $6(a)(2)(B)$,
17	without regard to whether such an activity is carried
18	out.
19	SEC. 4. DESIGNATION OF ADDITIONAL SAFE HARBORS.
20	(a) IN GENERAL.—
21	(1) Solicitation of proposals.—Not later
22	than 30 days after the date of the enactment of this
23	Act, the Attorney General shall publish a notice in
24	the Federal Register soliciting proposals for addi-
25	tional safe harbors.

1	(2) Review and report on proposed safe
2	HARBORS.—Not later than 180 days after the date
3	of the enactment of this Act, the Attorney General
4	(in consultation with the Secretary of Health and
5	Human Services and the Chair of the Federal Trade
6	Commission) shall—
7	(A) review the proposed safe harbors sub-
8	mitted under paragraph (1); and
9	(B) submit a report to Congress describing
10	the proposals to be included in the publication
11	of additional safe harbors described in para-
12	graph (3) and the proposals that are not to be
13	so included, together with explanations there-
14	fore.
15	(3) Publication of additional safe har-
15	(J) I UDLICATION OF ADDITIONAL SAFE HAR-
16	BORS.—Not later than 180 days after the date of
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16 17 18 19 20 21	BORS.—Not later than 180 days after the date of the enactment of this Act, the Attorney General (in consultation with the Secretary of Health and Human Services and the Chair of the Federal Trade Commission) shall publish in the Federal Register proposed additional safe harbors for purposes of sec-

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1	torney General shall issue final rules establishing
2	such safe harbors.
3	(b) CRITERIA FOR SAFE HARBORS.—In establishing
4	safe harbors under subsection (a), the Attorney General
5	shall take into account the following:
6	(1) The extent to which a competitive or col-
7	laborative activity will accomplish any of the follow-
8	ing:
9	(A) An increase in access to health care
10	services.
11	(B) The enhancement of the quality of
12	health care services.
13	(C) The establishment of cost efficiencies
14	that will be passed on to consumers, including
15	economies of scale and reduced transaction and
16	administrative costs.
17	(D) An increase in the ability of health
18	care facilities to provide services in medically
19	underserved areas or to medically underserved
20	populations.
21	(E) An improvement in the utilization of
22	health care resources or the reduction in the in-
23	efficient duplication of the use of such re-
24	sources.

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1	(2) Whether the designation of an activity as a
2	safe harbor under subsection (a) will result in the
3	following outcomes:
4	(A) Health plans and other health care in-
5	surers, consumers of health care services, and
6	health care providers will be better able to ne-
7	gotiate payment and service arrangements
8	which will reduce costs to consumers.
9	(B) Taking into consideration the charac-
10	teristics of the particular purchasers and pro-
11	viders involved, competition will not be unduly
12	restricted.
13	(C) Equally efficient and less restrictive al-
14	ternatives do not exist to meet the criteria de-
15	scribed in paragraph (1).
16	(D) The activity will not unreasonably
17	foreclose competition by denying competitors a
18	necessary element of competition.
19	SEC. 5. CERTIFICATES OF REVIEW.
20	(a) ESTABLISHMENT OF PROGRAM.—In consultation

20 (a) ESTABLISHMENT OF TROGRAM.—In consultation
21 with the Secretary and the Chair, the Attorney General
22 shall (not later than 180 days after the date of the enact23 ment of this Act) issue certificates of review in accordance
24 with this section for providers of health care services and

advise and assist any person with respect to applying for
 such a certificate of review.

3 (b) PROCEDURES FOR APPLICATION FOR CERTIFI4 CATE.—

5 (1) FORM; CONTENT.—To apply for a certifi6 cate of review, a person shall submit to the Attorney
7 General a written application which—

8 (A) specifies the activities relating to the 9 provision of health care services which satisfy 10 the criteria described in section 4(b) and which 11 will be included in the certificate; and

(B) is in a form and contains any information, including information pertaining to the
overall market in which the applicant operates,
required by rule or regulation promulgated
under section 8.

17 (2) PUBLICATION OF NOTICE IN FEDERAL REG-18 ISTER.—Within 10 days after an application submit-19 ted under paragraph (1) is received by the Attorney 20 General, the Attorney General shall publish in the Federal Register a notice that announces that an 21 22 application for a certificate of review has been sub-23 mitted, identifies each person submitting the application, and describes the conduct for which the ap-24 plication is submitted. 25

1 (3) ESTABLISHMENT OF PROCEDURES FOR IS-2 SUANCE OF CERTIFICATE.—In consultation with the 3 Chair and the Secretary, the Attorney General shall 4 establish procedures to be used in applying for and in determining whether to approve an application for 5 6 a certificate of review under this title. Under such 7 procedures the Attorney General shall approve an application if the Attorney General determines that 8 the activities to be covered under the certificate will 9 10 satisfy the criteria described in section 4(b) for addi-11 tional safe harbors designated under such section 12 and that the benefits of the issuance of the certificate will outweigh any disadvantages that may result 13 from reduced competition. 14

15 (4) TIMING FOR DECISION ON APPLICATION.— 16 (A) IN GENERAL.—Within 90 days after 17 the Attorney General receives an application for 18 a certificate of review, the Attorney General 19 shall determine whether the applicant's health care market activities are in accordance with 20 the procedures described in paragraph (3). If 21 22 the Attorney General, with the concurrence of the Secretary, determines that such procedures 23 24 are met, the Attorney General shall issue to the

1	applicant a certificate of review. The certificate
2	of review shall specify—
3	(i) the health care market activities to
4	which the certificate applies,
5	(ii) the person to whom the certificate
6	of review is issued, and
7	(iii) any terms and conditions the At-
8	torney General or the Secretary deems nec-
9	essary to assure compliance with the appli-
10	cable procedures described in paragraph
11	(3).
12	(B) Applications deemed approved.—
13	If the Attorney General does not reject an ap-
14	plication before the expiration of the 90-period
15	beginning on the date the Attorney General re-
16	ceives the application, the Attorney General
17	shall be deemed to have approved the applica-
18	tion and to have issued a certificate of review
19	relating to the applicant's health care market
20	activities covered under the application.
21	(5) EXPEDITED ACTION.—If the applicant indi-
22	cates a special need for prompt disposition, the At-
23	torney General and the Secretary may expedite ac-
24	tion on the application, except that no certificate of
25	review may be issued within 30 days of publication

of notice in the Federal Register under subsection
 (b)(2).

(6) Actions upon denial.—

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(A) NOTIFICATION.—If the Attorney General denies in whole or in part an application for a certificate, the Attorney General shall notify the applicant of the Attorney General's determination and the reasons for it.

9 (B) REQUEST FOR RECONSIDERATION. An applicant may, within 30 days of receipt of 10 notification that the application has been denied 11 12 in whole or in part, request the Attorney Gen-13 eral to reconsider the determination. The Attorney General, with the concurrence of the Sec-14 retary, shall notify the applicant of the deter-15 mination upon reconsideration within 30 days 16 17 of receipt of the request.

18 (C) RETURN OF DOCUMENTS.—If the At-19 torney General denies an application for the is-20 suance of a certificate of review and thereafter receives from the applicant a request for the re-21 22 turn of documents submitted by the applicant 23 in connection with the application for the certificate, the Attorney General and the Secretary 24 shall return to the applicant, not later than 30 25

days after receipt of the request, the documents 1 2 and all copies of the documents available to the Attorney General and the Secretary, except to 3 the extent that the information has been made 4 public under an exception to the rule against 5 described 6 public disclosure in subsection 7 (g)(2)(B).8 (7) FRAUDULENT PROCUREMENT.—A certificate of review shall be void ab initio with respect to 9 any health care market activities for which the cer-10 tificate was procured by fraud. 11 12 (c) Amendment and Revocation of Certifi-13 CATES.— (1) NOTIFICATION OF CHANGES.—Any appli-14 cant who receives a certificate of review— 15 16 (A) shall promptly report to the Attorney 17 General any change relevant to the matters 18 specified in the certificate; and 19 (B) may submit to the Attorney General 20 an application to amend the certificate to reflect the effect of the change on the conduct 21 22 specified in the certificate. 23 (2) AMENDMENT TO CERTIFICATE.—An appli-24 cation for an amendment to a certificate of review

shall be treated as an application for the issuance of

a certificate. The effective date of an amendment 1 2 shall be the date on which the application for the amendment is submitted to the Attorney General. 3 4 (3) REVOCATION.— (A) GROUNDS FOR REVOCATION.—In ac-5 cordance with this paragraph, the Attorney 6 7 General may revoke in whole or in part a certificate of review issued under this section. The 8 following shall be considered grounds for the 9 10 revocation of a certificate: 11 (i) After the expiration of the 2-year period beginning on the date a person's 12 13 certificate is issued, the activities of the 14 person have not substantially accomplished 15 the purposes for the issuance of the certifi-16 cate. 17 (ii) The person has failed to comply 18 with any of the terms or conditions im-19 posed under the certificate by the Attorney 20 General or the Secretary under subsection (b)(4).21 22 (iii) The activities covered under the certificate no longer satisfy the criteria set 23 24 forth in section 4(b).

1 (B) REQUEST FOR COMPLIANCE INFORMA-TION.—If the Attorney General or Secretary 2 has reason to believe that any of the grounds 3 for revocation of a certificate of review de-4 scribed in subparagraph (A) may apply to a 5 6 person holding the certificate, the Attorney 7 General shall request such information from such person as the Attorney General or the Sec-8 9 retary deems necessary to resolve the matter of 10 compliance. Failure to comply with such request 11 shall be grounds for revocation of the certificate 12 under this paragraph.

13 (C) PROCEDURES FOR REVOCATION.—If 14 the Attorney General or the Secretary deter-15 mines that any of the grounds for revocation of a certificate of review described in subpara-16 17 graph (A) apply to a person holding the certifi-18 cate, or that such person has failed to comply 19 with a request made under subparagraph (B), 20 the Attorney General shall give written notice of the determination to such person. The notice 21 22 shall include a statement of the circumstances 23 underlying, and the reasons in support of, the 24 determination. In the 60-day period beginning 25 30 days after the notice is given, the Attorney

General shall revoke the certificate or modify it as the Attorney General or the Secretary deems necessary to cause the certificate to apply only to activities that meet the procedures for the issuance of certificates described in subsection (b)(2).

7 (D) INVESTIGATION AUTHORITY.—For purposes of carrying out this paragraph, the 8 9 Attorney General may conduct investigations in 10 the same manner as the Attorney General con-11 ducts investigations under section 3 of the Anti-12 trust Civil Process Act, except that no civil investigative demand may be issued to a person 13 14 to whom a certificate of review is issued if such 15 person is the target of such investigation.

16 (d) REVIEW OF DETERMINATIONS.—

17 (1) AVAILABILITY OF REVIEW FOR CERTAIN AC-18 TIONS.—If the Attorney General denies, in whole or 19 in part, an application for a certificate of review or 20 for an amendment to a certificate, or revokes or 21 modifies a certificate pursuant to paragraph (3), the 22 applicant or certificate holder (as the case may be) 23 may, within 30 days of the denial or revocation, 24 bring an action in any appropriate district court of 25 the United States to set aside the determination on

the ground that such determination is erroneous 1 2 based on the preponderance of the evidence. 3 (2) NO OTHER REVIEW PERMITTED.—Except 4 as provided in paragraph (1), no action by the Attorney General or the Secretary pursuant to this 5 title shall be subject to judicial review. 6 7 (3) EFFECT OF REJECTED APPLICATION.—If the Attorney General denies, in whole or in part, an 8 application for a certificate of review or for an 9 amendment to a certificate, or revokes or amends a 10 11 certificate, neither the negative determination nor 12 the statement of reasons therefore shall be admissible in evidence, in any administrative or judicial pro-13 ceeding, concerning any claim under the antitrust 14

15 laws.

16 (e) PUBLICATION OF DECISIONS.—The Attorney 17 General shall publish a notice in the Federal Register on 18 a timely basis of each decision made with respect to an 19 application for a certificate of review under this section 20 or the amendment or revocation of such a certificate, in 21 a manner that protects the confidentiality of any propri-22 etary information relating to the application.

(f) ANNUAL REPORTS.—Every person to whom a certificate of review is issued shall submit to the Attorney
General an annual report, in such form and at such time

as the Attorney General may require, that contains any
 necessary updates to the information required under sub section (b) and a description of the activities of the holder
 under the certificate during the preceding year.

5 (g) RESTRICTIONS ON DISCLOSURE OF INFORMA-6 TION.—

7 (1) WAIVER OF DISCLOSURE REQUIREMENTS 8 UNDER ADMINISTRATIVE PROCEDURE ACT.—Infor-9 mation submitted by any person in connection with 10 the issuance, amendment, or revocation of a certifi-11 cate of review shall be exempt from disclosure under 12 section 552 of title 5, United States Code.

13 (2) RESTRICTIONS ON DISCLOSURE OF COM14 MERCIAL OR FINANCIAL INFORMATION.—

15 (A) IN GENERAL.—Except as provided in subparagraph (B), no officer or employee of the 16 17 United States shall disclose commercial or fi-18 nancial information submitted in connection 19 with the issuance, amendment, or revocation of 20 a certificate of review if the information is privileged or confidential and if disclosure of the in-21 22 formation would cause harm to the person who 23 submitted the information.

1	(B) EXCEPTIONS.—Subparagraph (A)
2	shall not apply with respect to information dis-
3	closed—
4	(i) upon a request made by the Con-
5	gress or any committee of the Congress,
6	(ii) in a judicial or administrative pro-
7	ceeding, subject to appropriate protective
8	orders,
9	(iii) with the consent of the person
10	who submitted the information,
11	(iv) in the course of making a deter-
12	mination with respect to the issuance,
13	amendment, or revocation of a certificate
14	of review, if the Attorney General deems
15	disclosure of the information to be nec-
16	essary in connection with making the
17	determination,
18	(v) in accordance with any require-
19	ment imposed by a statute of the United
20	States, or
21	(vi) in accordance with any rule or
22	regulation promulgated under subsection
23	(i) permitting the disclosure of the infor-
24	mation to an agency of the United States
25	or of a State on the condition that the

1	agency	will	disclose	the	information	only
2	under	the	circum	stanc	es specifie	d in
3	clauses	(i) tl	hrough (v	/).		

4 (3) PROHIBITION AGAINST USE OF INFORMA-5 TION TO SUPPORT OR ANSWER CLAIMS UNDER ANTI-TRUST LAWS.—Any information disclosed in an ap-6 7 plication for a certificate of review under this section shall only be admissible into evidence in a judicial or 8 administrative proceeding for the sole purpose of 9 establishing that a person is entitled to the protec-10 11 tions provided by such a certificate.

12 SEC. 6. NOTIFICATIONS PROVIDING REDUCTION IN CER-

13TAIN PENALTIES UNDER ANTITRUST LAW14FOR HEALTH CARE COOPERATIVE VEN-15TURES.

16 (a) NOTIFICATIONS DESCRIBED.—

17 (1) SUBMISSION OF NOTIFICATION BY VEN-18 TURE.—Any party to a health care cooperative ven-19 ture, acting on such venture's behalf, may, not later 20 than 90 days after entering into a written agreement to form such venture or not later than 90 days after 21 22 the date of the enactment of this Act, whichever is later, file with the Attorney General a written notifi-23 24 cation disclosing—

1	(A) the identities of the parties to such
2	venture,
3	(B) the nature and objectives of such ven-
4	ture, and
5	(C) such additional information as the At-
6	torney General may require by regulation.
7	(2) Activities deemed submission of noti-
8	FICATION.—The following health care cooperative
9	ventures shall be deemed to have filed a written noti-
10	fication with respect to the venture under paragraph
11	(1):
12	(A) SUBMISSION OF APPLICATION FOR
13	CERTIFICATE OF REVIEW.—Any health care co-
14	operative venture for which an application for a
15	certificate of review is filed with the Attorney
16	General under section 4.
17	(B) Engaging in risk-sharing activi-
18	TIES UNDER VENTURE.—Any health care coop-
19	erative venture whose members engage in risk-
20	sharing arrangements, including (but not lim-
21	ited to)—
22	(i) the acceptance of capitation con-
23	tracts;
24	(ii) the acceptance of contracts with
25	fee withholding mechanisms relating to the

1	ability to meet established goals for utiliza-
2	tion review and management; and
3	(iii) the holding by members of signifi-
4	cant ownership or equity interests in the
5	venture, where the capital contributed by
6	the members is used to fund the oper-
7	ational costs of the venture such as admin-
8	istration, marketing, and computer-oper-
9	ated medical information, if the venture
10	develops and operates comprehensive pro-
11	grams for utilization management and
12	quality assurance that include controls
13	over the use of institutional, specialized,
14	and ancillary medical services.
15	(C) VENTURES BELOW CERTAIN SIZE.—
16	Any health care cooperative venture consisting
17	of a network of providers not greater than—
18	(i) in the case of a nonexclusive net-
19	work in which the participating members
20	are permitted to create or join other com-
21	peting networks, 50 percent of the provid-
22	ers of health care services in the relevant
23	geographic area and 50 percent of the
24	members of the provider specialty group in
25	the relevant market area; or

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1 (ii) in the case of an exclusive network
2 in which the participating members are not
3 permitted to create or join other competing
4 networks, 35 percent of the providers of
5 health care services in the relevant geo-
6 graphic area and 35 percent of the mem-
7 bers of the provider specialty group in the
8 relevant market area.
9 (3) SUBMISSION OF ADDITIONAL INFORMA-
0 TION.—
1 (A) Request of attorney general.—
2 At any time after receiving a notification filed
3 under paragraph (1), the Attorney General may
4 require the submission of additional information
5 or documentary material relevant to the pro-
6 posed health care cooperative venture.
7 (B) PARTIES TO VENTURE.—Any party to
8 a health care cooperative venture may submit
9 such additional information on the venture's be-
half as may be appropriate to ensure that the
venture will receive the protections provided
under subsection (b).
(C) Required submission of informa-
TION ON CHANGES TO VENTURE.—A health
care cooperative venture for which a notification

is in effect under this section shall submit information on any change in the membership of the venture not later than 90 days after such change occurs.

(4) PUBLICATION OF NOTIFICATION.—

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6 (A) INFORMATION MADE PUBLICLY AVAIL-7 ABLE.—Not later than 30 days after receiving 8 a notification with respect to a venture under 9 paragraph (1), the Attorney General shall pub-10 lish in the Federal Register a notice with re-11 spect to the venture that identifies the parties 12 to the venture and generally describes the pur-13 pose and planned activity of the venture. Prior 14 to its publication, the contents of the notice 15 shall be made available to the parties to the 16 venture.

17 (B) RESTRICTION ON DISCLOSURE OF 18 OTHER INFORMATION.—All information and 19 documentary material submitted pursuant to 20 this section and all information obtained by the Attorney General in the course of any investiga-21 22 tion or case with respect to a potential violation 23 of the antitrust laws by the health care coopera-24 tive venture (other than information and material described in subparagraph (A)) shall be ex-25

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1	empt from disclosure under section 552 of title
2	5, United States Code, and shall not be made
3	publicly available by any agency of the United
4	States to which such section applies except in
5	a judicial proceeding in which such information
6	and material is subject to any protective order.
7	(5) WITHDRAWAL OF NOTIFICATION.—Any per-
8	son who files a notification pursuant to this section
9	may withdraw such notification before a publication
10	by the Attorney General pursuant to paragraph (4).
11	Any person who is deemed to have filed a notifica-
12	tion under paragraph $(2)(A)$ shall be deemed to have
13	withdrawn the notification if the certificate of review
14	in question is revoked or withdrawn under section 5.
15	(6) No judicial review permitted.—Any
16	action taken or not taken by the Attorney General
17	with respect to notifications filed pursuant to this
18	subsection shall not be subject to judicial review.
19	(b) PROTECTIONS FOR VENTURES SUBJECT TO NO-
20	TIFICATION.—
21	(1) IN GENERAL.—
22	(A) PROTECTIONS DESCRIBED.—The pro-
23	visions of paragraphs (2), (3), (4), and (5) shall
24	apply with respect to any action under the anti-

25 trust laws challenging conduct within the scope

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of a notification which is in effect pursuant to
subsection (a)(1).
(B) TIMING OF PROTECTIONS.—The pro-
tections described in this subsection shall apply
to the venture that is the subject of a notifica-
tion under subsection $(a)(1)$ as of the earlier
of—
(i) the date of the publication in the
Federal Register of the notice published
with respect to the notification; or
(ii) if such notice is not published dur-
ing the period required under subsection
(a)(4), the expiration of the 30-day period
that begins on the date the Attorney Gen-
eral receives any necessary information re-
quired to be submitted under subsection
(a)(1) or any additional information re-

19 section (a)(3)(A).

(2)APPLICABILITY OF RULE OF REASON STANDARD.—In any action under the antitrust laws, the conduct of any person which is within the scope of a notification filed under subsection (a) shall not be deemed illegal per se, but shall be judged on the basis of its reasonableness, taking into account all

quired by the Attorney General under sub-

relevant factors affecting competition, including, but
 not limited to, effects on competition in relevant
 markets.

4 (3)LIMITATION ON RECOVERY TO ACTUAL 5 DAMAGES AND INTEREST.—Notwithstanding section 6 4 of the Clayton Act, any person who is entitled to 7 recovery under the antitrust laws for conduct that is within the scope of a notification filed under sub-8 section (a) shall recover the actual damages sus-9 10 tained by such person and interest calculated at the 11 rate specified in section 1961 of title 28, United 12 States Code, for the period beginning on the earliest date for which injury can be established and ending 13 14 on the date of judgment, unless the court finds that 15 the award of all or part of such interest is unjust under the circumstances. 16

17 (4) AWARD OF ATTORNEY'S FEES AND COSTS18 OF SUIT.—

(A) IN GENERAL.—In any action under the
antitrust laws brought against a health care cooperative venture for conduct that is within the
scope of a notification filed under subsection
(a), the court shall, at the conclusion of the action—

- 1(i) award to a substantially prevailing2claimant the cost of suit attributable to3such claim, including a reasonable attor-4ney's fee, or
- (ii) award to a substantially prevailing 5 party defending against such claim the 6 cost of such suit attributable to such claim, 7 including reasonable attorney's fee, if the 8 claim, or the claimant's conduct during 9 litigation of the claim, was frivolous, un-10 11 reasonable, without foundation, or in bad 12 faith.

13 (B) OFFSET IN CASES OF BAD FAITH.— 14 The court may reduce an award made pursuant 15 to subparagraph (A) in whole or in part by an award in favor of another party for any part of 16 17 the cost of suit (including a reasonable attor-18 ney's fee) attributable to conduct during the 19 litigation by any prevailing party that the court 20 finds to be frivolous, unreasonable, without 21 foundation, or in bad faith.

22 (5) RESTRICTIONS ON ADMISSIBILITY OF IN23 FORMATION.—

24 (A) IN GENERAL.—Any information dis-25 closed in a notification submitted under sub-

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1 section (a)(1) and the fact of the publication of 2 a notification by the Attorney General under subsection (a)(4) shall only be admissible into 3 4 evidence in a judicial or administrative proceeding for the sole purpose of establishing that a 5 6 party to a health care cooperative venture is entitled to the protections described in this sub-7 8 section.

9 (B) ACTIONS OF ATTORNEY GENERAL.— 10 No action taken by the Attorney General pursu-11 ant to this section shall be admissible into evi-12 dence in any judicial or administrative proceed-13 ing for the purpose of supporting or answering 14 any claim under the antitrust laws.

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 SEC. 7. REVIEW AND REPORTS ON SAFE HARBORS AND

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 CERTIFICATES OF REVIEW.

17 (a) IN GENERAL.—The Attorney General (in consultation with the Secretary and the Chair) shall periodi-18 cally review the safe harbors described in section 3, the 19 additional safe harbors designated under section 4, and 20 21 the certificates of review issued under section 5, and-22 (1) with respect to the safe harbors described in section 3, submit such recommendations to Congress 23 24 as the Attorney General considers appropriate for

25 modifications of such safe harbors;

(2) with respect to the additional safe harbors
 under designated under section 4, issue proposed re visions to such activities and publish the revisions in
 the Federal Register; and

5 (3) with respect to the certificates of review, 6 submit a report to Congress on the issuance of such 7 certificates, and shall include in the report a descrip-8 tion of the effect of such certificates on increasing 9 access to high quality health care services at reduced 10 costs.

11 (b) RECOMMENDATIONS FOR LEGISLATION.—The 12 Attorney General shall include in the reports submitted 13 under subsection (a)(3) any recommendations of the At-14 torney General for legislation to improve the program for 15 the issuance of certificates of review established under this 16 title.

17 SEC. 8. RULES, REGULATIONS, AND GUIDELINES.

(a) SAFE HARBORS, CERTIFICATES, AND NOTIFICATIONS.—The Attorney General, with the concurrence of
the Secretary, shall promulgate such rules, regulations,
and guidelines as are necessary to carry out sections 3,
4, 5, and 6, including guidelines relating to appropriate
geographic and product areas for health care services and
providers of health care services.

25 (b) GUIDANCE FOR PROVIDERS.—

1	(1) IN GENERAL.—To promote greater cer-
2	tainty regarding the application of the antitrust laws
3	to activities in the health care market, the Attorney
4	General, in consultation with the Secretary and the
5	Chair, shall (not later than 1 year after the date of
6	the enactment of this Act), taking into account the
7	criteria used to designate additional safe harbors
8	under section 4 and grant certificates of review
9	under section 5, publish guidelines—
10	(A) to assist providers of health care serv-
11	ices in analyzing whether the activities of such
12	providers may be subject to a safe harbor under
13	sections 3 or 4; and
14	(B) describing specific types of activities
15	which would meet the requirements for a cer-
16	tificate of review under section 5, and summa-
17	rizing the factual and legal bases on which the
18	activities would meet the requirements.
19	(2) PERIODIC UPDATE.—The Attorney General
20	shall periodically update the guidelines published
21	under paragraph (1) as the Attorney General consid-
22	ers appropriate.
23	(3) Waiver of administrative procedure
24	ACT.—Section 553 of title 5, United States Code,

shall not apply to the issuance of guidelines under
 paragraph (1).

3 SEC. 9. ESTABLISHMENT OF HHS OFFICE OF HEALTH CARE 4 COMPETITION POLICY.

5 (a) IN GENERAL.—There is established within the 6 Department of Health and Human Services an Office to 7 be known as the Office of Health Care Competition Policy 8 (hereafter in this section referred to as the "Office"). The 9 Office shall be headed by a director, who shall be ap-10 pointed by the Secretary.

11 (b) DUTIES.—The Office shall coordinate the respon-12 sibilities of the Secretary under this Act and otherwise as-13 sist the Secretary in developing policies relating to the 14 competitive and collaborative activities of providers of 15 health care services.

16 SEC. 10. DEFINITIONS.

17 In this Act, the following definitions shall apply:

18 (1) The term "antitrust laws"—

(A) has the meaning given it in subsection
(a) of the first section of the Clayton Act (15
U.S.C. 12(a)), except that such term includes
section 5 of the Federal Trade Commission Act
(15 U.S.C. 45) to the extent such section applies to unfair methods of competition; and

(B) includes any State law similar to the 1 2 laws referred to in subparagraph (A). (2) The term "Chair" means the Chair of the 3 Federal Trade Commission. 4 (3) The term "health benefit plan" means any 5 hospital or medical expense incurred policy or certifi-6 7 cate, hospital or medical service plan contract, or 8 health maintenance subscriber contract, or a mul-9 tiple employer welfare arrangement or employee benefit plan (as defined under the Employee Retirement 10 11 Income Security Act of 1974) which provides bene-12 fits with respect to health care services. (4) The term "health care cooperative venture" 13 14 means any activities, including attempts to enter 15 into or perform a contract or agreement, carried out 16 by 2 or more persons for the purpose of providing 17 health care services. 18 (5) The term "health care services" means any 19 services for which payment may be made under a 20 health benefit plan, including services related to the 21 delivery or administration of such services. 22 (6) The term "medical self-regulatory entity" means a medical society or association, a specialty 23 24 board, a recognized accrediting agency, or a hospital 25 medical staff, and includes the members, officers,

employees, consultants, and volunteers or commit tees of such an entity.

3 (7) The term "person" includes a State or unit4 of local government.

5 (8) The term "provider of health care services" 6 means any individual or entity that is engaged in the 7 delivery of health care services in a State and that 8 is required by State law or regulation to be licensed 9 or certified by the State to engage in the delivery of 10 such services in the State.

(9) The term "Secretary" means the Secretaryof Health and Human Services.

(10) The term "specialty group" means a medical specialty or subspecialty in which a provider of
health care services may be licensed to practice by
a State (as determined by the Secretary in consultation with the certification boards for such specialties
and subspecialties).

19 (11) The term "standard setting and enforce-20 ment activities" means—

21 (A) accreditation of health care practition22 ers, health care providers, medical education in23 stitutions, or medical education programs,

24 (B) technology assessment and risk man-25 agement activities,

(C) the development and implementation of 1 2 practice guidelines or practice parameters, or 3 (D) official peer review proceedings undertaken by a hospital medical staff (or committee 4 thereof) or a medical society or association for 5 purposes of evaluating the professional conduct 6 or quality of health care provided by a medical 7 professional. 8

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