F:\JH\HR3600\CANADY.001

agreed to

Agreed to 18-17 By House Judiciary

Amendment to H.R. 3600

19

Offered by Mr. Canady

Possible amendments that would narrow safe harbors and leave additional ones to Congress

Page 980, after line 16, insert the following (and make such technical and conforming changes as may be appropriate):

Subtitle G—Application of the Antitrust Laws to Health Care Services

SEC. 5601. EXEMPTION FROM ANTITRUST LAWS FOR CERTAIN COMPETITIVE AND COLLABORATIVE ACTIVITIES.

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

(1) the activity is within one of the categories of safe harbors described in subsection (b); or

(2) the activity is within an additional safe harbor designated ~~by the Attorney General~~ under subsection (c).

(b) SAFE HARBORS.—The following activities are safe harbors for purposes of subsection (a)(1):

(1) ACTIVITIES OF MEDICAL SELF-REGULATORY 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 solely 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 purposes of financial gain; or

#(i)

(ii) interferes with the provision of health care services by any provider who is not a member of the specific profession which is subject to the authority of the medical self-regulatory entity.

(2) PARTICIPATION IN SURVEYS.—The participation of a provider of health care services in a written survey of the prices of services, reimbursement levels, or the compensation and benefits of employees and personnel, but only if—

(A) the survey is conducted by a third party, such as a purchaser of health care services, governmental entity, institution of higher education, or trade association;

(B) the information provided by participants 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 disseminated, 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) JOINT VENTURES FOR HIGH TECHNOLOGY AND COSTLY EQUIPMENT AND SERVICES.—~~Any activity of~~ a health care cooperative venture relating to the purchase, operation, or marketing of high technology or other expensive medical equipment, or the provision of high cost or complex services, but only if the number of participants in the venture does not exceed the lowest number needed to support the venture together with any other providers for whom the participation in the venture is the only means of obtaining or operating such equipment or providing such services.

(4) HOSPITAL MERGERS.—Activities relating to a merger of 2 hospitals if, during the 3-year period preceding the merger, one of the hospitals had an average of 100 or fewer ~~staffed~~ licensed beds and an average

daily inpatient census of less than 50 percent of such beds.

(5) JOINT PURCHASING ARRANGEMENTS.—Any joint purchasing arrangement among health care providers if—

(A) the purchases under the arrangement represent less than 35 percent of the total sales of the product purchased in the relevant market area; and

(B) the amounts paid under the arrangement represent less than 20 percent of the total revenues of the supplier of the product purchased.

(6) PHYSICIAN NETWORK JOINT VENTURES.—~~Any activity of~~ a physician network joint venture comprised of 20 percent or less of the physicians in each physician specialty who practice in the relevant geographic market and share substantial financial risk.

~~(7) NEGOTIATIONS.—Activities consisting of good faith negotiations to carry out any activity—~~

~~(A) described in this subsection; or~~

~~(B) within an additional safe harbor designated by the Attorney General under subsection (c).~~

~~without regard to whether such an activity is carried out.~~

(c) DESIGNATION OF ADDITIONAL SAFE HARBORS.—

(1) IN GENERAL.—

(A) SOLICITATION OF PROPOSALS.—Not later than 30 days after the date of the enactment of this Act, the Attorney General shall publish a notice in the Federal Register soliciting proposals for additional safe harbors.

(B) REVIEW AND REPORT ON PROPOSED SAFE HARBORS.—Not later than 180 days after the date of the enactment of this Act, the Attorney General (in consultation with the Chair of the Federal Trade Commission) shall—

(i) review the proposed safe harbors submitted under subparagraph (A); and

(ii) submit a report to Congress describing the proposals recommended to Congress to be included in the ~~publication~~ enactment of additional safe harbors ~~described in subparagraph (C)~~ by Congress and the proposals that are not recommended to be so included, together with explanations therefore.

~~(C) PUBLICATION OF ADDITIONAL SAFE HARBORS.—Not later than 180 days after the date of the enactment of this Act, the Attorney~~

General (in consultation with the Chair of the Federal Trade Commission) shall publish in the Federal Register proposed additional safe harbors for purposes of subsection (a)(2) for providers of health care services. Not later than 180 days after publishing such proposed safe harbors in the Federal Register, the Attorney General shall issue final rules establishing such safe harbors.

(2) CRITERIA FOR SAFE HARBORS.—In ~~establishing~~ reviewing proposals for additional safe harbors under paragraph (1), the Attorney General shall take into account the following:

(A) The extent to which a competitive or collaborative activity will accomplish any of the following:

(i) An increase in access to health care services.

(ii) The enhancement of the quality of health care services.

(iii) The establishment of cost efficiencies that will be passed on to consumers, including economies of scale and reduced transaction and administrative costs.

~~(iv) An increase in the ability of health care facilities to provide services in~~

we as (:) →

~~medically underserved areas or to medically underserved populations.~~

(iv) An improvement in the utilization of health care resources or the reduction in the inefficient duplication of the use of such resources.

(B) Whether the designation of an activity as a safe harbor under paragraph (1) will result in the following outcomes:

(i) Health plans and other health care insurers, consumers of health care services, and health care providers will be better able to negotiate payment and service arrangements which will reduce costs to consumers.

(ii) Taking into consideration the characteristics of the particular purchasers and providers involved, competition will not be unduly restricted.

(iii) Equally efficient and less restrictive alternatives do not exist to meet the criteria described in subparagraph (A).

(iv) The activity will not unreasonably foreclose competition by denying competitors a necessary element of competition.

(d) DEFINITIONS.—For purposes of this section—

(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 laws referred to in subparagraph (A);

(2) the term "health care cooperative venture" means any activities, including attempts to enter into or perform a contract or agreement, carried out by 2 or more persons that share substantial financial risks for the purpose of providing health care services;

(3) the term "health care services" means any services for which payment may be made under a health benefit plan, including services related to the delivery or administration of such services;

(4) the term "medical self-regulatory entity" means a medical society or association, a specialty board, a recognized accrediting agency, or a hospital medical staff, and includes the members, officers, employees, consultants, and volunteers or committees of such an entity;

(5) 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; and

(6) the term "standard setting and enforcement activities" means—

(A) accreditation of health care practitioners, health care providers, medical education institutions, or medical education programs;

(B) technology assessment and risk management activities,

(C) the development and implementation of practice guidelines or practice parameters; or

(D) official peer review proceedings undertaken by a hospital medical staff (or committee thereof) or a medical society or association for purposes of evaluating the professional conduct or quality of health care provided by a medical professional.

DOJ POSITION DRAFT -- NOT PUBICALY RELEASED

OBJECTIONS TO CANADY ANTITRUST AMENDMENT TO H.R. 3600

The antitrust amendment to H.R. 3600 offered by Mr. Canady and agreed to by a vote of 18-17 by the House Judiciary Committee is objectionable for several reasons and should not be included in health care reform legislation.

The Canady amendment would provide antitrust exemptions for seven broad categories of conduct ("safe harbors") relating to the provision of health care services. It would also require the Attorney General to solicit proposals for additional safe harbors, review such proposals and report to Congress on them, and establish additional safe harbors through an administrative rulemaking process.

Objections to the Canady Amendment

1. Statutory and regulatory antitrust exemptions in the health care area are both unnecessary and potentially harmful. They are not necessary to correct existing law because the antitrust laws do not prohibit procompetitive, efficiency-enhancing mergers or joint ventures among health care providers.

2. Antitrust exemptions are also not necessary to resolve antitrust uncertainty. The Justice Department and the FTC issued several statements of antitrust enforcement policy in the health care area in 1993. Responding to comments from hospitals, physicians, non-physician providers, and other interested members of the health care community, the agencies will issue updated and expanded guidelines before Congress passes health care reform legislation. In addition, the agencies have committed to and have been providing expedited guidance on specific proposed conduct of health care providers through their business review and advisory opinion procedures.

3. Antitrust exemptions are potentially harmful because they could encumber sound law enforcement and the ability of consumers and other health care providers to obtain necessary antitrust relief in ways that are currently unforeseeable. Health care markets are evolving rapidly, and statutory and regulatory exemptions could only be revised or updated through protracted legislative or administrative proceedings. In contrast, the policy statements that have been issued by the agencies, which contain "safety zones," are more flexible and far less regulatory.

4. While the DOJ-FTC policy statements are not binding on the courts in private actions brought by consumers or other health care providers, they will exert a strong influence on potential plaintiffs not to bring meritless cases and on courts to make correct decisions in any cases that are brought. We are aware of no private cases challenging conduct covered by the safety zones in the policy statements.

5. Many of the safe harbors in the Canady amendment go beyond the safety zones in the DOJ-FTC policy statements and pose serious competitive risks.

- Activities of Medical Self-Regulatory Entities. There is no comparable DOJ-FTC policy statement. Standard setting can be procompetitive, but can also threaten competition, e.g., by imposing unreasonable competitive restraints on providers or excluding some providers from the market. Safe-harboring "any activity ... relating to standard setting or standard enforcement activities" could protect anticompetitive conduct. The amendment's safeguard requiring no purpose of financial gain is inadequate, as the reasonableness of such activities is not solely a matter of intent.

- Joint Ventures. This safe harbor is much broader than the safety zone in the DOJ-FTC policy statement. It covers any activity of a health care cooperative venture, broadly defined to include far more than the integrated, risk-sharing joint ventures covered by the DOJ-FTC policy statement. The amendment also provides a safe harbor for service joint ventures; while such joint ventures should be analyzed under a rule of reason, cost allocation problems make a safe harbor for service joint ventures inadvisable at this time.

- Hospital Mergers. This safe harbor for mergers of small hospitals is also broader than the safety zone in the DOJ-FTC policy statement. It is keyed to staffed beds rather than licensed beds; thus, a hospital could qualify for the safe harbor merely through temporary staffing changes. This safe harbor also omits the requirement in the DOJ-FTC policy statement that the acquired hospital be at least five years old. The DOJ-FTC requirement guards against buyouts of potentially efficient, competitive hospitals in their formative years.

- Physician Network Joint Ventures. This safe harbor is potentially broader than the safety zone in the DOJ-FTC policy statement in that it covers "any activity" of such a venture. This language might protect price fixing, boycotts and other anticompetitive conduct. Also, while this safe harbor requires risk sharing, it leaves open what will constitute sufficient risk sharing, a key issue in distinguishing legitimate joint ventures from price-setting cartels.

- Negotiations. There is no comparable DOJ-FTC policy statement. This safe harbor could protect any anticompetitive arrangements developed in the course of the negotiations it covers. The "good faith" safeguard based on intent is insufficient to protect competition.

- In General - The broadly-worded safe harbors in the Canady amendment are absolute antitrust exemptions. While the DOJ and FTC believe that such circumstances will be rare, they have necessarily reserved the right to challenge conduct that might technically fall within the safety zones in their policy statements in extraordinary circumstances.

6. Minor changes to the safe harbors in the Canady amendment would not alter the fundamental objection: regulation of the competitive activities of health care providers through broad statutory and or regulatory antitrust exemptions should not be substituted for reasoned antitrust enforcement in this major sector of the economy.

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"(D) no individual affiliated with such society is liable for any damages or injury directly caused by the individual's actions in conducting such activities or review.

"(3) AGREEMENTS NOT MANDATORY.—Nothing in this subsection may be construed to require a State to enter into agreements with societies described in paragraph (1) to conduct the activities described in such paragraph.

"(4) EFFECT OF AGREEMENT.—

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to health care liability actions arising on or after January 1, 1995.

Subtitle C—Health Care Antitrust Improvements

SEC. 521. PROTECTION FROM ANTITRUST LAWS FOR CERTAIN COMPETITIVE AND COLLABORATIVE ACTIVITIES.

(a) PROTECTIONS DESCRIBED.—An activity relating to the provision of health care services shall receive the following protection from the antitrust laws:

(1) If the activity is within a safe harbor designated by the Attorney General under section 522, the safe harbor shall be a defense to all antitrust claims, except for claims for injunctive relief as-

serted by the Attorney General or the Chair in extraordinary circumstances.

(2) If the activity is specified in and in compliance with the terms of a certificate of review issued by the Attorney General under section 523 and the activity occurs while the certificate is in effect, the certificate shall be a defense to antitrust claims, other than claims for injunctive relief.

(b) AWARD OF ATTORNEY'S FEES AND COSTS OF SUIT.—

(1) IN GENERAL.—If any person brings an action alleging a claim under the antitrust laws and the activity on which the claim is based is found by the court to be protected from such laws under subsection (a), the court shall, at the conclusion of the action—

(A) award to a substantially prevailing claimant the cost of suit attributable to such claim, including a reasonable attorney's fee, or

(B) award to a substantially prevailing party defending against such claim the cost of such suit attributable to such claim, including reasonable attorney's fee, if the claim, or the claimant's conduct during litigation of the

claim, was frivolous, unreasonable, without foundation, or in bad faith.

(2) OFFSET IN CASES OF BAD FAITH.—The court may reduce an award made pursuant to paragraph (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.

SEC. 522. DESIGNATION OF SAFE HARBORS.

(a) IN GENERAL.—

(1) DESIGNATION BY ATTORNEY GENERAL.—The Attorney General, in consultation with the Secretary and the Chair, shall develop and designate pursuant to paragraph (C) safe harbors for purposes of section 521(a)(1) relating to—

(A) each category of activities referred to in paragraph (2); and

(B) such other categories of activities as the Attorney General may designate in accordance with the process described in this section.

(2) REQUIRED CATEGORIES OF ACTIVITIES SUBJECT TO SAFE HARBORS.—The categories of activities referred to in this paragraph are as follows:

(A) JOINT PURCHASING OF HEALTH CARE SERVICES.—Providing the terms under which consumers of health care services (patients or others acting on their behalf) may jointly negotiate and purchase health care services.

(B) SMALL HOSPITAL MERGERS.—Providing for small hospitals lawfully to merge under the antitrust laws without undue delay or review, taking into account the special needs and circumstances of rural health care markets.

(C) NETWORK FORMATION AND OPERATION.—Permitting activities related to the startup and operation of collaborations between State-licensed providers through partial or full integration, including multi-provider networks, hospital networks, physician-hospital organizations, and other efforts to provide health care services more efficiently.

(D) ACTIVITIES OF MEDICAL SELF-REGULATORY ENTITIES.—Permitting standard setting and enforcement activities by medical self-regulatory entities (such as hospital boards and medical societies) to promote health care quality, except that a safe harbor under this paragraph may not provide protection for any activ-

ity undertaken for financial gain or for anti-competitive reasons.

(E) PROVISION OF INFORMATION TO BUYERS AND CONSUMERS.—Permitting health care providers collectively to supply non-price medical information to buyers and consumers relating to the type, quality and efficiency of treatment, including joint views on procedures that should be covered by purchasers and medical protocols, except that a safe harbor under this subparagraph may not provide protection for any collective refusals to deal or collective attempts at coercion.

(F) PARTICIPATION IN SURVEYS.—Providing the terms under which health care providers may lawfully participate in written surveys of prices of services, reimbursements received, employee compensation, and other relevant areas.

(G) HIGH-TECHNOLOGY AND TERTIARY CARE JOINT VENTURES.—Permitting activities of health care joint ventures to purchase or use new or existing high technology or costly equipment, or to provide advanced tertiary care services.

(H) MARKET POWER SCREENS.—Providing market power screens at appropriate levels below which combinations of health care providers are too small to pose a realistic antitrust threat. There may be different levels for different activities and markets, taking into account the special needs of rural health care markets.

(I) JOINT PURCHASING ARRANGEMENTS.—Providing the terms under which health care providers may make joint purchases of products and services.

(J) GOOD FAITH NEGOTIATIONS.—Providing the terms under which health care providers may engage in discussions relating to legitimate collaborative activities contemplated by the safe harbors.

(b) PROCESS FOR DESIGNATION OF ADDITIONAL CATEGORIES OF ACTIVITIES.—

(1) SOLICITATION OF PROPOSALS.—Not later than 30 days after the date of the enactment of this Act, the Attorney General shall publish a notice in the Federal Register soliciting proposals for safe harbors.

(2) REVIEW OF PROPOSED SAFE HARBORS.—Not later than 180 days after the date of the enactment of this Act, the Attorney General (in consultation with the Secretary and the Chair) shall review the proposed safe harbors submitted under paragraph (1) and include a description of the safe harbors in the report under subsection (d).

(3) ADDITIONAL SAFE HARBORS.—After submitting the report under subsection (d), the Attorney General (in consultation with the Secretary and the Chair) may from time to time add additional safe harbors in accordance with the procedures described in this subsection.

(c) EFFECTIVE DATE OF SAFE HARBORS.—

(1) PUBLICATION.—Not later than 180 days after the date of the enactment of this Act, the Attorney General shall publish in the Federal Register for public comment the safe harbors proposed for designation under this section. Not later than 180 days after publishing such proposed safe harbors in the Federal Register, the Attorney General shall issue final rules establishing such safe harbors.

(2) EFFECTIVE DATE.—The safe harbors established under the final rules issued under paragraph

(1) shall take effect 90 days after issuance, unless disapproved by the Congress.

(d) REPORT ON PROPOSED SAFE HARBORS.—Not later than 180 days after the date of the enactment of this Act, the Attorney General (in consultation with the Secretary and the Chair) shall submit a report to Congress describing the proposals from subsections (a) and (b)(1) to be included in the publication of safe harbors described in subsection (c)(1) and the proposals from subsection (b)(1) that are not to be so included, together with explanations therefor.

(e) MODIFICATION OR REMOVAL OF SAFE HARBORS.—The Attorney General (in consultation with the Secretary and the Chair) may modify or remove a safe harbor following notice and comment upon a determination that the safe harbor does not meet the criteria of subsection (f).

(f) CRITERIA FOR SAFE HARBORS.—In establishing safe harbors under this section, the Attorney General shall take into account the following:

(1) The extent to which a competitive or collaborative activity will accomplish any of the following:

(A) An increase in access to health care services.

(B) The enhancement of the quality of health care services.

(C) The establishment of cost efficiencies that will be passed on to consumers, including economies of scale and reduced transaction and administrative costs.

(D) An increase in the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations.

(E) An improvement in the utilization of health care resources or the reduction in the inefficient duplication of the use of such resources.

(2) Whether the designation of an activity as a safe harbor will result in the following outcomes:

(A) Health plans and other health care insurers, consumers of health care services, and health care providers will be better able to negotiate payment and service arrangements which will reduce costs to consumers.

(B) Taking into consideration the characteristics of the particular purchasers and providers involved, competition will not be unduly restricted.

(C) Equally efficient and less restrictive alternatives do not exist to meet the criteria described in paragraph (1).

(D) The activity will not unreasonably foreclose competition by denying competitors a necessary element of competition.

SEC. 523. CERTIFICATES OF REVIEW.

(a) ESTABLISHMENT OF PROGRAM.—In consultation with the Secretary and the Chair, the Attorney General shall (not later than 180 days after the date of the enactment of this Act) issue certificates of review in accordance 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.

(b) PROCEDURES FOR APPLICATION FOR CERTIFICATE.—

(1) SUBMISSION OF APPLICATION.—

(A) FORM; CONTENT.—To apply for a certificate of review, a person shall submit to the Attorney General a written application which—

(i) specifies the activities relating to the provision of health care services which satisfy the criteria described in section 522(f) and which will be included in the certificate; and

(ii) 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 526.

(B) FILING FEE.—The Attorney General may require a filing fee to be submitted with the application to cover the cost of publication and the cost of review required by this section. The amount of the filing fee shall be determined on a sliding scale established by the Attorney General in consultation with the Chair (based on the monetary size of the transaction involved), except that such fee may not exceed $5,000.

(2) PUBLICATION OF NOTICE IN FEDERAL REGISTER.—Within 10 days after an application submitted under paragraph (1) is received by the Attorney General, the Attorney General shall publish in the Federal Register a notice that announces that an application for a certificate of review has been submitted, identifies each person submitting the application, and describes the conduct for which the application is submitted.

(3) ESTABLISHMENT OF PROCEDURES FOR ISSUANCE OF CERTIFICATE.—In consultation with the Chair and the Secretary, the Attorney General shall establish procedures to be used in applying for and in determining whether to approve an application for a certificate of review under this subtitle. Under such procedures the Attorney General, in consultation with the Secretary, shall approve an application if the Attorney General determines that the activities to be covered under the certificate will satisfy the criteria described in section 522(f) for safe harbors designated under such section and that the benefits of the issuance of the certificate will outweigh any disadvantages that may result from reduced competition. If the Attorney General, with the concurrence of the Secretary, determines that the requirements for a certificate are met, the Attorney General shall issue to the applicant a certificate of review. The certificate of review shall specify—

(i) the health care market activities to which the certificate applies,

(ii) the person to whom the certificate of review is issued, and

(iii) any terms and conditions the Attorney General or the Secretary deems nec-

essary to assure compliance with the applicable procedures described in paragraph (3).

(4) TIMING FOR DECISION ON APPLICATION.—Within 90 days after the Attorney General receives an application for a certificate of review, the Attorney General shall determine whether to grant or deny the certificate.

(5) NOTIFICATION OF DECISION.—The Attorney General shall notify the applicant of the Attorney General's determination and, if the application is denied, the reasons for the denial.

(6) FRAUDULENT PROCUREMENT.—A certificate of review shall be void ab initio with respect to any health care market activities for which the certificate was procured by fraud.

(c) AMENDMENT AND REVOCATION OF CERTIFICATES.—

(1) NOTIFICATION OF CHANGES.—Any applicant who receives a certificate of review—

(A) shall promptly report to the Attorney General any change relevant to the matters specified in the certificate; and

(B) may submit to the Attorney General an application to amend the certificate to re-

flect the effect of the change on the conduct specified in the certificate.

(2) AMENDMENT TO CERTIFICATE.—An application 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 shall be the date on which the application for the amendment is received by the Attorney General.

(3) REVOCATION.—

(A) GROUNDS FOR REVOCATION.—In accordance with this paragraph, the Attorney General, in consultation with the Secretary, may revoke in whole or in part a certificate of review issued under this section based on one or more of the following grounds:

(i) After the expiration of the 2-year period beginning on the date a person's certificate is issued, the activities of the person have not substantially accomplished the purposes for the issuance of the certificate.

(ii) The person has failed to comply with any of the terms or conditions imposed under the certificate by the Attorney

General or the Secretary under subsection (b)(4).

(iii) The activities covered under the certificate no longer satisfy the criteria set forth in section 522(f).

(B) REQUEST FOR COMPLIANCE INFORMATION.—If the Attorney General or the Secretary has reason to believe that any of the grounds for revocation of a certificate of review described in subparagraph (A) may apply to a person holding the certificate, the Attorney General shall request such information from such person as the Attorney General or the Secretary deems necessary to resolve the matter of compliance. Failure to comply with such request shall be grounds for revocation of the certificate under this paragraph.

(C) PROCEDURES FOR REVOCATION.—If the Attorney General or the Secretary determines that any of the grounds for revocation of a certificate of review described in subparagraph (A) apply to a person holding the certificate, or that such person has failed to comply with a request made under subparagraph (B), the Attorney General shall give written notice of

the determination to such person. The notice shall include a statement of the circumstances underlying, and the reasons in support of, the determination. In the 60-day period beginning 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 criteria set forth in section 522(f).

(D) INVESTIGATION AUTHORITY.—For purposes of carrying out this paragraph, the Attorney General may conduct investigations in the same manner as the Attorney General conducts investigations under section 3 of the Antitrust Civil Process Act, except that no civil investigative demand may be issued to a person to whom a certificate of review is issued if such person is the target of such investigation.

(d) REVIEW OF DETERMINATIONS.—

(1) AVAILABILITY OF REVIEW FOR CERTAIN ACTIONS.—If the Attorney General denies, in whole or in part, an application for a certificate of review or for an amendment to a certificate, or revokes or modifies a certificate pursuant to paragraph (3), the

applicant or certificate holder (as the case may be) may, within 30 days of the denial or revocation, bring an action in the United States District Court for the District of Columbia to set aside the determination on the ground that such determination is clearly erroneous.

(2) NO OTHER REVIEW PERMITTED.—Except as provided in paragraph (1), no action by the Attorney General, the Chair, or the Secretary pursuant to this subtitle shall be subject to judicial review.

(3) EFFECT OF REJECTED APPLICATION.—If the Attorney General denies, in whole or in part, an application for a certificate of review or for an amendment to a certificate, or revokes or amends a certificate, neither the negative determination nor the statement of reasons therefore shall be admissible in evidence, in any administrative or judicial proceeding, concerning any claim under the antitrust laws.

(e) PUBLICATION OF DECISIONS.—The Attorney General shall publish a notice in the Federal Register on a timely basis of each decision made with respect to an application for a certificate of review under this section or the amendment or revocation of such a certificate, in

a manner that protects the confidentiality of any proprietary 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 subsection (b) and a description of the activities of the holder under the certificate during the preceding year.

(g) RESTRICTIONS ON DISCLOSURE OF INFORMATION.—

(1) WAIVER OF DISCLOSURE REQUIREMENTS UNDER ADMINISTRATIVE PROCEDURE ACT.—Information submitted by any person in connection with the issuance, amendment, or revocation of a certificate of review shall be exempt from disclosure under section 552 of title 5, United States Code.

(2) RESTRICTIONS ON DISCLOSURE OF COMMERCIAL OR FINANCIAL INFORMATION.—

(A) IN GENERAL.—Except as provided in subparagraph (B), no officer or employee of the United States shall disclose commercial or financial information submitted in connection with the issuance, amendment, or revocation of a certificate of review if the information is priv-

ileged or confidential or if disclosure of the information would cause harm to the person who submitted the information.

(B) EXCEPTIONS.—Subparagraph (A) shall not apply with respect to information disclosed—

(i) upon a request made by the Congress or any committee of the Congress,

(ii) in a judicial or administrative proceeding, subject to appropriate protective orders,

(iii) with the consent of the person who submitted the information,

(iv) in the course of making a determination with respect to the issuance, amendment, or revocation of a certificate of review, if the Attorney General deems disclosure of the information to be necessary in connection with making the determination,

(v) in accordance with any requirement imposed by a statute of the United States, or

(vi) in accordance with any rule or regulation promulgated under subsection

(i) permitting the disclosure of the information to an agency of the United States or of a State on the condition that the agency will disclose the information only under the circumstances specified in clauses (i) through (v).

(3) PROHIBITION AGAINST USE OF INFORMATION TO SUPPORT OR ANSWER CLAIMS UNDER ANTITRUST LAWS.—Any information disclosed in an application for a certificate of review under this section shall only be admissible into evidence in a judicial or administrative proceeding for the sole purpose of establishing whether a person is entitled to the protections provided by such a certificate.

SEC. 524. NOTIFICATIONS PROVIDING REDUCTION IN CERTAIN PENALTIES UNDER ANTITRUST LAW FOR HEALTH CARE JOINT VENTURES.

(a) NOTIFICATIONS DESCRIBED.—

(1) SUBMISSION OF NOTIFICATION BY VENTURE.—Any party to a health care joint venture, acting on such venture's behalf, may, not later than 90 days after entering into a written agreement to form such venture or not later than 90 days after the date of the enactment of this Act, whichever is

later, file with the Attorney General a written notification disclosing—

(A) the identities of the parties to such venture,

(B) the nature and objectives of such venture, and

(C) such additional information as the Attorney General may require by regulation.

(2) FILING FEE.—The Attorney General may require a filing fee to be submitted with the notification to cover the cost of publication and the cost of administering this section, except that the amount of such fee shall not exceed $250.

(3) SUBMISSION OF ADDITIONAL INFORMATION.—

(A) REQUEST OF ATTORNEY GENERAL.—At any time after receiving a notification filed under paragraph (1), the Attorney General may require the submission of additional information or documentary material relevant to the proposed health care joint venture.

(B) PARTIES TO VENTURE.—Any party to a health care joint venture may submit such additional information on the venture's behalf as may be appropriate to ensure that the venture

will receive the protections provided under subsection (b).

(C) REQUIRED SUBMISSION OF INFORMATION ON CHANGES TO VENTURE.—A health care joint 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.—

(A) INFORMATION MADE PUBLICLY AVAILABLE.—Not later than 30 days after receiving a notification with respect to a venture under paragraph (1), the Attorney General shall publish in the Federal Register a notice with respect to the venture that identifies the parties to the venture and generally describes the purpose and planned activity of the venture. Prior to its publication, the contents of the notice shall be made available to the parties to the venture.

(B) RESTRICTION ON DISCLOSURE OF OTHER INFORMATION.—All information and documentary material submitted pursuant to this section and all information obtained by the

Attorney General in the course of any investigation or case with respect to a potential violation of the antitrust laws by the health care joint venture (other than information and material described in subparagraph (A)) shall be exempt from disclosure under section 552 of title 5, United States Code, and shall not be made publicly available by any agency of the United States to which such section applies except in a judicial proceeding in which such information and material is subject to any protective order.

(5) WITHDRAWAL OF NOTIFICATION.—Any person who files a notification pursuant to this section may withdraw such notification before a publication by the Attorney General pursuant to paragraph (4).

(6) NO JUDICIAL REVIEW PERMITTED.—Any action taken or not taken by the Attorney General with respect to notifications filed pursuant to this subsection shall not be subject to judicial review.

(b) PROTECTIONS FOR VENTURES SUBJECT TO NOTIFICATION.—

(1) IN GENERAL.—

(A) PROTECTIONS DESCRIBED.—Except as provided in subsection (c), the provisions of paragraphs (2), (3), (4), and (5) shall apply

with respect to any action under the antitrust laws challenging conduct within the scope of a notification which is in effect pursuant to subsection (a)(1).

(B) TIMING OF PROTECTIONS.—The protections described in this subsection shall apply to the venture that is the subject of a notification 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 during the period required under subsection (a)(4), the expiration of the 30-day period that begins on the date the Attorney General receives any necessary information required to be submitted under subsection (a)(1) or any additional information required by the Attorney General under subsection (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 relevant factors affecting competition, including, but not limited to, effects on competition in relevant markets.

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

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

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

(a), the court shall, at the conclusion of the action—

(i) award to a substantially prevailing claimant the cost of suit attributable to such claim, including a reasonable attorney's fee, or

(ii) award to a substantially prevailing party defending against such claim the cost of such suit attributable to such claim, including reasonable attorney's fee, if the claim, or the claimant's conduct during litigation of the claim, was frivolous, unreasonable, without foundation, or in bad faith.

(B) OFFSET IN CASES OF BAD FAITH.—The court may reduce an award made pursuant to subparagraph (A) 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.

(5) RESTRICTIONS ON ADMISSIBILITY OF INFORMATION.—

(A) IN GENERAL.—Any information disclosed in a notification submitted under subsection (a)(1) and the fact of the publication of a notification by the Attorney General under subsection (a)(4) shall only be admissible into evidence in a judicial or administrative proceeding for the sole purpose of establishing whether a party to a health care joint venture is entitled to the protections described in this subsection.

(B) ACTIONS OF ATTORNEY GENERAL.—No action taken by the Attorney General pursuant to this section shall be admissible into evidence in any judicial or administrative proceeding for the purpose of supporting or answering any claim under the antitrust laws.

(c) EXCEPTION FOR CERTAIN ACTIVITIES.—In the event the parties cannot show procompetitive aspects necessary to the success of the joint venture, the protections described in subsection (b) should not be construed to apply to conduct which constitutes per se price-fixing, bid-rigging, or market allocation.

SEC. 525. REVIEW AND REPORTS ON SAFE HARBORS, CERTIFICATES OF REVIEW, AND NOTIFICATIONS.

(a) IN GENERAL.—The Attorney General, in consultation with the Secretary and the Chair, shall periodi-

cally review the safe harbors designated under section 522, the certificates of review issued under section 523, and notification received under section 524, and—

(1) with respect to the safe harbors, issue modifications to such safe harbors in such manner as the Attorney General considers appropriate in accordance with the requirements of section 522(f), which modifications shall take effect 90 days after issuance, unless disapproved by the Congress; and

(2) with respect to the certificates of review and notifications, submit a report to Congress on the issuance of such certificates and receipt of notifications, including a description of the effect of such certificates and notifications on increasing access to high quality health care services at reduced costs.

(b) RECOMMENDATIONS FOR LEGISLATION.—The Attorney General shall include in the reports submitted under subsection (a)(2) any recommendations of the Attorney General for legislation to improve the programs for the issuance of certificates of review and receipt of notifications established under this subtitle.

SEC. 526. RULES, REGULATIONS, AND GUIDELINES.

(a) SAFE HARBORS, CERTIFICATES, AND NOTIFICATIONS.—The Attorney General, in consultation with the Secretary and the Chair, shall promulgate such rules, reg-

ulations, and guidelines as are necessary to carry out sections 522, 523, and 524.

(b) GUIDANCE FOR PROVIDERS.—

(1) IN GENERAL.—To promote greater certainty regarding the application of the antitrust laws to activities in the health care market, the Attorney General, in consultation with the Secretary and the Chair, shall (not later than 1 year after the date of the enactment of this Act), taking into account the criteria used to designate safe harbors under section 522 and to grant certificates of review under section 523, publish guidelines—

(A) to define or provide assistance in determining relevant geographic and product markets for health care services and providers of health care services;

(B) to further collaborative activities which may be helpful to enhance services in underserved and geographically disadvantaged areas such as rural markets and inner cities;

(C) to assist collaboration between providers (such as hospital networks, physician-hospital organizations, and other groups of providers) which will help provide health care services more efficiently;

(D) to further activities by which public health clinics (including community health centers and migrant health centers under title III of the Public Health Service Act) may participate in networks and other collaborative activities in order to enhance services in underserved areas;

(E) to assist providers of health care services in analyzing whether the activities of such providers may be subject to a safe harbor under section 522;

(F) to provide clarification for activities in the general subject matter areas described in the safe harbors in section 522, but which fall outside the safe harbors; and

(G) to describe specific types of activities which would meet the requirements for issuance of a certificate of review under section 523, and summarizing the factual and legal bases on which the activities would meet the requirements.

(2) PERIODIC UPDATE.—The Attorney General shall periodically update the guidelines published under paragraph (1) as the Attorney General considers appropriate.

(3) WAIVER OF ADMINISTRATIVE PROCEDURE ACT.—Section 553 of title 5, United States Code, shall not apply to the issuance of guidelines under paragraph (1).

SEC. 527. DEFINITIONS.

In this subtitle, the following definitions shall apply:

(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 laws referred to in subparagraph (A).

(2) The term "Chair" means the Chair of the Federal Trade Commission.

(3) The term "health benefit plan" means any hospital or medical expense incurred policy or certificate, hospital or medical service plan contract, or health maintenance subscriber contract, or a multiple employer welfare arrangement or employee benefit plan (as defined under the Employee Retirement Income Security Act of 1974) which provides benefits with respect to health care services.

(4) The term "health care joint venture" means a joint venture of 2 or more persons formed for the purpose of providing health care services, including attempts to enter into or perform a contract or agreement to provide such services.

(5) The term "health care services" means any services for which payment may be made under a health benefit plan, including services related to the delivery or administration of such services.

(6) The term "medical self-regulatory entity" means a medical society or association, a specialty board, a recognized accrediting agency, or a hospital medical staff, and includes the members, officers, employees, consultants, and volunteers or committees of such an entity.

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

(8) 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.

(9) The term "Secretary" means the Secretary of 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).

(11) The term "standard setting and enforcement activities" means—

(A) accreditation of health care practitioners, health care providers, medical education institutions, or medical education programs,

(B) technology assessment and risk management activities,

(C) the development and implementation of practice guidelines or practice parameters, or

(D) official peer review proceedings undertaken by a hospital medical staff (or committee thereof) or a medical society or association for purposes of evaluating the professional conduct or quality of health care provided by a medical professional.

TITLE VI—ADMINISTRATIVE SIMPLIFICATION AND PRIVACY

SEC. 601. ADMINISTRATIVE SIMPLIFICATION.

(a) HEALTH INFORMATION NETWORK.—

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DOJ DRAFT POSITION -- NOT RELEASED PUBICALY

OBJECTIONS TO HATCH ANTITRUST AMENDMENT
(REVISED S. 1658) -- ALSO ANTITRUST PROVISIONS OF DOLE BILL

THE PROPOSED ANTITRUST AMENDMENT, A REVISED VERSION OF S. 1658, SHOULD BE REJECTED. ANTITRUST EXEMPTIONS AND GOVERNMENT REGULATION OF COMPETITION IN HEALTH CARE MARKETS ARE UNNECESSARY AND WOULD HARM COMPETITION AND CONSUMERS.

1. The amendment would replace measured, limited antitrust enforcement with broad antitrust exemptions and extensive government regulation of the competitive aspects of the health care industry. Regulation of one-seventh of the economy in this way is unnecessary and potentially harmful, and would be extremely costly.

2. The amendment would defeat a principal goal of health care reform--bringing increased competition to bear in the health care industry--by constraining appropriate antitrust enforcement and deterrence that safeguard competition. For this reason, antitrust exemptions are widely opposed by consumer groups.

3. The "safe harbors" that would be issued by the Department of Justice under the amendment would exempt a wide range of conduct from the antitrust laws. This is essentially government regulation as a substitute for the antitrust laws. The Justice Department and the FTC have issued enforcement policy statements that contain "safety zones" to provide guidance to the health care community, but safe harbors that provided complete antitrust exemptions and that could only be corrected or refined through a formal administrative rulemaking are far more inflexible and regulatory.

The amendment's revisions to the original safe harbor provisions in S. 1658 do not resolve their fundamental problems:

- The safe harbors will still effectively be antitrust exemptions, notwithstanding revisions that give the government the ability to seek injunctions against safe-harbored conduct in extraordinary circumstances.

- While the revisions eliminate statutory safe harbors, they preserve the basic safe harbor regulatory scheme by delegating the responsibility to issue such exemptions to the Justice Department. Regulation through generally applicable safe harbors presents many of the same problems as regulation through individual certificates of review.

- The amendment continues to mandate safe harbors in a wide variety of areas, some of which may not be amenable to safe harbor treatment at the current time. The Department of Justice and the FTC currently can decide on the basis of their experience and the evolution of health care markets whether or what types of safe harbors are safe to establish in their enforcement policy statements.

4. The broad, regulatory certificate-of-review program that would be established by the amendment would involve initial government approval of applications for antitrust immunity and continuing government oversight of certificated activities. The scope of such a program makes it totally impractical, liable to error that could harm competition, and virtually certain to impose great regulatory costs on the industry and the government.

The amendment's revisions to the certificate-of-review program originally proposed in S. 1658 do not address its fundamental problems:

- Permitting injunctive actions notwithstanding certification does not diminish the scope or basic nature of the certificate-of-review program. Certificate protection against antitrust damages would still be significant and result in a program with much the same risks and costs.

- Possible extension of the time for action on a proposed certificate and revisions regarding the details of judicial review do not eliminate the basic regulatory burden of the certificate-of-review program. The vast majority of the costs of the program would still be incurred. User fees would allocate these costs to the industry and in turn to consumers—they would not eliminate them.

5. The amendment's broad notification scheme would affect substantive antitrust rules and substantially diminish the practical ability of consumers, health plans, and other health care providers that may be harmed by antitrust violations to recover their losses. Anticompetitive conduct could be given legal protection that it does not deserve and appropriate antitrust deterrence of harmful behavior could be diminished.

The amendment's revisions to the notification scheme originally proposed in S. 1658 do not eliminate its possible adverse effects:

- Eliminating the provision that "deemed" notifications to have been filed on behalf of certain types of conduct even if they were not notified to the government addresses only one of the original scheme's most blatant flaws.

- Restricting the notification scheme to joint ventures and disqualifying patent antitrust violations such as price fixing does not assure that the amendment will not result in anticompetitive changes in substantive antitrust rules. Distinguishing legitimate, integrative joint ventures from simple collective decisions on price by independent competitors is an important issue that could be wrongly preempted by the amendment.

6. The amendment's mandate of Justice Department guidelines regarding collaborative activities in several areas is unnecessary and potentially harmful. The Department and the FTC have already issued several health care antitrust enforcement policy statements and are in the process of improving these and issuing more. A statutory mandate to issue guidelines is therefore unnecessary. Moreover, such a mandate could be harmful if it forced the Department to issue guidelines covering matters with which it was not sufficiently familiar. Such guidelines could be overly cautious, thereby deterring conduct that was not in fact anticompetitive, or even overly permissive, thereby causing competitive harm.

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ORIGINAL S. 1658 Analysis

S. 1658/H.R. 3486 - ANALYSIS

The following is a section-by section analysis of the health care antitrust immunity bill introduced by Sen. Hatch and Congressman Archer(S. 1658 and H.R. 3486). Each major section of the bill is described, followed (in bold) by an analysis of the problems it potentially creates. (Any significant substantive differences between the Senate and House bills are parenthethically noted.)

This analysis is consistent with, but more detailed than, the Justice Department's comments on the bills as contained in AAG Bingaman's April 14, 1994 letter to Sen. Metzenbaum and Chairman Brooks.

Sec. 2(a) - **Antitrust Exemptions** - Exempted are:

(1) safe harbor activities listed in Sec. 3;
(2) additional safe harbors established by the AG under Sec. 4 (these would be established through APA procedures); and
(3) activities specified in "certificates of review" issued by the AG with the concurrence of the Sec./HHS under Sec. 5.

Statutory safe harbors are hard to draft, subject to dangerous interpretations, hard to legislatively change. AG promulgation of new safe harbors under APA is effectively continuing regulation.

A certification scheme has many serious problems, as described below.

Sec. 2(b) - Attorneys' Fees - Awards attorney's fees in cases where activity found to be exempt under one of safe harbor provisions or certificate of review. Worded to match NCRPA (covers fees for plaintiffs and defendants), but because it is triggered by finding that conduct is exempt, will only function to award attorney's fees to prevailing defendants if P's claim was frivolous, unreasonable, without foundation, or in bad faith.

Depends on what if any antitrust safe harbors are enacted. Judgment call on whether to adjust American attorneys' fees rule as was done in NCRPA.

Note: Rule 11 already provides for defendants' attorneys' fees in egregious cases, but since the NCRA of 1984, this kind of provision has had support where overdeterrence is supposed to be a problem.

Sec. 3 - Safe Harbors - Sets out statutory safe harbors that would provide complete immunity.

In General: Statutory safe harbors are inherently problematic. There is a risk that interpretations of statutory terms and legislative history could lead to anticompetitive outcomes; this risk is less where litigation requires reasonable, competitively-based interpretations of enforcement policy statements.

Legislative give-and-take efforts to craft statutory safe harbors may yield competitively risky, hard-to-change immunities.

Statutory safe harbors also risk having the safe harbors drive the evolution of health care markets, rather than market forces and efficiencies. Government should not steer an industry in this way. Policy statements have this potential too, but not to the same extent. The balance between eliminating antitrust uncertainty and "steering" the industry is more favorable with policy statements.

(1) Activities of any combination of providers with market shares of less than 20% (25% in H.R. 3486). No need for any risk sharing or integration.

Much broader than policy statement's 20% network safety zone that requires risk sharing. Appears responsive to AMA request for chance to market physician-controlled networks that don't capitate or withhold. Safe harbor status provided even if network (or any other covered joint activity) might be held per se unlawful because of no integration or risk sharing at all. Far beyond claim that all that is sought is recognition of substantial risk sharing through capital contribution for rule-of-reason purposes.

Puts naked restraints at risk of being upheld on market share alone. While policy statements have market share tests, they do not cover naked restraints. Market share tests can be gerrymandered; risk of that happening sometimes is acceptable where there are procompetitive efficiencies at stake, but this risk should not be accepted for naked restraint.

(2) Activities of medical self-regulatory agencies. Covers standard setting or standard enforcement activities designed to promote the quality of health care services. Excludes activities conducted for purpose of financial gain.

There is no comparable policy statement. Safe harbor is broader than existing statutory exemption in Health Care

Quality Improvements Act of 1986 for peer review undertaken in good faith.

Safe harbor for standard-setting very dangerous as some "standards" may exclude types of providers, rigidify costs, thwart efforts to control costs through utilization review, etc. Some important antitrust cases have involved putative medical standards, e.g., Indiana Federation of Dentists. Rule of reason for standard setting is appropriate, but not safe harbor. Peer review less dangerous.

"Financial gain" purpose in this safe harbor is not adequate safeguard--would hinge all cases on intent and there will always be a good medical intent explanation.

(3) Participation in surveys of prices, reimbursement levels, compensation.

Generally follows requirements of policy statement, including requirement of aggregation so that data of particular providers cannot be backed out, but contains no requirement that there be at least 5 contributors, no one of whose data represents 25% of data on weighted basis.

(4) Any activity of a cooperative venture relating to purchase, operation, or marketing or high-tech or other expensive medical equipment, or the provision of high cost or complex services, if # of participants does not exceed lowest number needed to support the venture.

Much broader than policy statement. Covers equipment and services and "any activity relating to a venture". The bill's definition of health care cooperative ventures does not require integration or risk sharing; thus, this safe harbor could cover non-integrative market allocation of services.

(5) Hospital mergers, if during preceding 3 years, one of hospitals has less than 150 operational beds and daily inpatient census of less than 50% of such beds.

Broader than policy statement - covers operational rather than licensed beds, increases number to 150, and census can be more lenient. Also, policy statement only covers hospitals more than 5 years old.

(6) Joint purchasing arrangements among providers where (A) joint purchases are less than 35% of market, and (B) cost of products purchased jointly is less than 20% of total revenues of each participant. (Test (B) in H.R. 3486 is 20% of total revenues of the supplier of the product purchased.)

Senate version appears to match policy statement. House version has duplicative monopsony power tests and no cost competition test.

(7) Negotiations - good faith negotiations to carry out any activity described in safe harbor section, any activity within an additional safe harbor, any activity that is subject of application or certificate of review, or any activity that is deemed submitted for purposes of notice/rule of reason/detrebling section.

There is no comparable policy statement. This safe harbor could immunize discussions, information exchanges, etc., with anticompetitive effects. It could interfere with effective relief in antitrust cases. It could even effectively shield criminal behavior, notwithstanding good faith limitation. Providers should be able to discuss joining safe-harbored activities without this immunity.

Sec. 4 - Additional safe harbors - Directs AG to seek proposals for additional safe harbors through Federal Register, review (with Sec/HHS and FTC Chair), publish proposed new safe harbors, issue final rules establishing new safe harbors. Criteria for new safe harbors are very lengthy, keyed not only to competitive effects and efficiencies, but also to general effects on provision of health care.

Essentially requires AG to immunize additional activities through APA rulemaking. Judicial review of decisions to add or not add safe harbors would be available. Rules made through this administrative/regulatory process would supplant antitrust laws.

Strong step toward regulation of all collective health care industry activities. Criteria go beyond competitive effects -- detailed inquiry required on health care effects even if no competitive effects probable; thus, this provision changes antitrust standard and makes matters more complex than would be the case under standard antitrust enforcement.

Also risks having government decisions on safe harbors influence evolution of health care markets rather than market forces and efficiencies (comparable to effect of legislating safe harbors).

What about FTC? Under this bill, it is a consultant, but AG has final call.

Sec. 5 - Certificates of Review - Creates comprehensive certificate of review regulatory scheme involving:

- applications under same complex competitive and other criteria used for establishment of safe harbors under sec. 4;
- publication of notice in the Federal Register;
- decisions on applications by AG with concurrence of Sec./HHS within 90 days;
- issuance of certificates with any necessary terms and conditions;
- automatic approval of application for certificate after 90 days if not denied;
- expedited approval in some circumstances;
- reconsideration of denials;
- amendment and revocation of certificates if activities have not accomplished goals, or parties have failed to comply with terms and conditions, or activities no longer satisfy criteria for certificate issuance;
- requests by AG and Sec/HHS for compliance information;
- judicial review in appropriate district court of denial or revocation of certificate on ground that determination was erroneous based on preponderance of evidence;
- annual reports by certificate holders re activities;
- confidentiality restrictions.

This certificate of review program is a comprehensive regulatory scheme that would leave the AG and the Sec/HHS with the responsibility of overseeing competition and the achievement of health care benefits across an unknown and potentially very broad segment of the largest sector of the American economy. It covers any joint activity, and there could be thousands or hundreds of thousands of applications for certificates.

This scheme has all of the facets and costs of classic regulation--applications for approval, continuing oversight, possible revocation, judicial review, etc. Health care is a huge segment of the economy to try to regulate in this way. There can be no comparison to the far more limited Export Trading Company Act on which it is modeled, which affects only exports and only involves a few certificates a year.

Initial and continuing regulatory oversight of joint activities in the health care area is both impractical and not an adequate substitute for effective antitrust enforcement. Competition would be threatened because the Dept. likely would be unable effectively to deal initially with the myriad of applications, much less monitor and oversee the continuing competitive and other effects of certificated activities.

Clearly, this certification scheme would be immensely costly and competitively dangerous. It could seriously undermine

the basic goal of health care reform--to bring effective competitive forces to bear in the industry.

What about FTC? They are a consultant, but certificates issued by AG with concurrence of Sec/HHS.

Sec. 6 - Notification/Rule of Reason/Detrebling - Creates notification program similar to far more limited National Cooperative Research and Production Act (NCRPA) (which covers research and production joint ventures, but not joint marketing.)

Any "health care cooperative venture" (defined very broadly as any activities, including attempts to enter into an agreement, carried out by two or more persons for the purpose of providing health care services) could file a notification with the AG disclosing parties to and nature and objectives of a cooperative venture.

Some activities would be deemed to have filed a notification for purposes of section 6 even if they had not. Under both Senate and House versions, these would include cooperative ventures for which an application for a certificate of review had been sought. Under the Senate version, these would also include networks of non-institutional providers with less than certain market shares (50% non-exclusive, 35% exclusive) and that share financial risk (defined broadly to include not only capitation and withholds, but also ownership or equity interests). (Under the House version, H.R. 3486, these would include institutional or non-institutional cooperative ventures that either share risks as described above or meet the same market share tests.)

The effect of a notification would be to (i) guarantee rule of reason treatment; (ii) limit any successful plaintiffs' recovery to actual damages and attorneys' fees; and (iii) provide attorneys' fees to substantially prevailing defendants if the plaintiff's claim was frivolous, unreasonable, etc.

In general, this broad notification scheme could undermine per se rules and the important deterrent effects of treble damages. Other health care notification proposals are more limited, e.g., they would cover only certain types of joint ventures, or joint ventures where there is substantial risk sharing or integration. Note particularly: This version affords rule of reason treatment to networks where risk sharing is limited to significant ownership or equity interests, combined with some utilization management--the kind of network that the AMA has been proposing as having sufficient integration to qualify for rule of reason treatment and possible safety zone coverage under the policy statement. (Note also that under the House version,

H.R. 3486, a network would be covered if it met the market share tests, even if it did not share risks.)

The important concern to note about this notification provision is its breadth. It also provides rule of reason and detrebling benefits to some ventures that don't even file notifications--the purpose of the notification is to give the AG and the public notice of something and the opportunity to move against it promptly before competitive damage is done.

Although not nearly as costly as a certification scheme, a notification scheme as broad as this one could tax the Dept. by requiring review of a large number of notifications and publication of a large number of federal register notices. We have managed the NCRPA notification program (a few hundred notifications since 1984) with only limited resources, but this one would be a lot bigger.

What about FTC? Unlike NCRPA, notifications under this bill are filed only with the AG. How does this affect FTC enforcement role in health care area?

Sec. 7 - Review and Reports - This section requires the AG in consultation with the Sec/HHS and the FTC Chair to review safe harbors and certificates and report to congress on their effects, with any recommendations for additional legislation.

Reports required by statute can subtly but substantially increase workloads. These reports have that potential.

Sec. 8 - Rules, Regulations, and Guidelines - Requires AG with concurrence of Sec/HHS to promulgate necessary rules, regs, guidelines to carry out the entire bill. Guidelines must include those defining or relating to relevant markets. (Under the House version, H.R. 3486, there is no specific mention of guidelines for defining relevant markets.) Guidelines must also be promulgated to assist providers in determining whether their activities may fall into a safe harbor and to describe specific types of activities that would meet requirements for certificates.

Promulgating health care market definition guidelines would be extremely difficult in the abstract.

This section also effectively directs the AG and HHS to suggest collective activities in the delivery of health care services. It thus risks having government rather than the marketplace influence the evolution of health care service delivery - something the health reform effort is not supposed to do.

Antitrust Division

Office of the Assistant Attorney General Washington, D.C. 20530

APR 14 1994

DOJ OBJECTIONS TO S. 1658

The Honorable Howard W. Metzenbaum
Chairman
Subcommittee on Antitrust, Monopolies,
and Business Rights
Committee on the Judiciary
United States Senate
Washington, D.C. 20510-6275

Dear Mr. Chairman:

I am writing in response to your letter of March 22, 1994, also signed by Chairman Brooks, requesting the views of the Department of Justice on S. 1658 and its companion bill, H.R. 3486, the "Health Care Antitrust Improvements Act of 1993." These bills would create special new broad based statutory immunities from the antitrust laws for a wide range of health care activities.

The Department is committed to reasonable and responsible application of the antitrust laws in the health care area to promote new competition in evolving markets. We have established as a priority the issuance of antitrust enforcement policy statements in the health care area designed to bring down health care costs to consumers while providing effective quality health care services. Six such statements have already been issued and others will be considered. We are committed to ongoing review and supplementation of these statements.

Effective antitrust laws have for over a century been the principal guarantor of competition in the American system and have time and again proved far superior to pervasive government review, regulation, and oversight of collective activities that may have competitive consequences. Health reform should build on a commitment to competition in health care markets. Consequently, the Department of Justice opposes the broad new statutory antitrust immunities contained in these bills.

The antitrust laws are enforced so as to take fully into account increased efficiency, lower administrative and other costs, improvements in quality, and other factors that are important to the cost-effective delivery of health care services. Neither the Justice Department nor the Federal Trade Commission has ever challenged a joint venture among hospitals to purchase, operate and market high-technology or other expensive medical equipment. And of the more than 250 hospital mergers since 1987,

only 11 have been found by the Department or the FTC to have likely anticompetitive effects that warranted antitrust challenge. Only those combinations that will harm the American consumer by raising prices, decreasing quality or availability of services, or discouraging innovation face antitrust challenge.

The Department and the FTC have recognized that uncertainty over the application of the antitrust laws in the health care area should be addressed, and have issued specific antitrust guidance to the health care industry. In September 1993, the agencies issued several joint Statements of Antitrust Enforcement Policy in the Health Care Area. Moreover, recognizing that issues and circumstances may change over time, the agencies have committed to providing additional general guidance, and also developed an expedited process whereby health care providers can obtain the views of the Department or the FTC on specific proposed activities.

Private remedies have been an integral part of antitrust enforcement for over 100 years. Moreover, the "private" antitrust remedies are used by State attorneys general to protect consumers in their states from localized anticompetitive activity. Such actions are an important adjunct to federal enforcement: Our enforcement resources are limited, and cannot uncover or move against every anticompetitive practice that may be harming consumers. At the same time, however, there is no reason to expect that health care providers will face a multitude of baseless private antitrust suits. Private parties are unlikely to institute meritless lawsuits and even less likely to be successful in pursuing them. This is especially the case with regard to health care matters, where it can be expected that courts will take into account the views of the government, including those expressed in the DOJ-FTC Statements of Antitrust Enforcement Policy, in private antitrust actions. This will help ensure sound and reasoned decisions in private litigation.

S. 1658 and H.R. 3486

S. 1658 and H.R. 3486[1] provide several types of broad immunities from the operation of the antitrust laws to the health care industry. Briefly, Section 2 of each bill provides antitrust immunity for any health care activity that:

(1) falls within one of the "safe harbors" described in Section 3 of the bill;

(2) falls within an additional safe harbor established by the Attorney General, after seeking public suggestions for

[1]The two bills are nearly identical. The Department objects equally to both S. 1658 and H.R. 3486.

further safe harbors via Federal Register notice under Section 4 of the bill; or

(3) is covered by a "certificate of review" issued by the Attorney General with the concurrence of the Secretary of Health and Human Services ("the Secretary") under Section 5 of the bill.

Additionally, Section 6 of each bill provides special antitrust protections in the form of guaranteed rule-of-reason treatment and the "detrebling" of any antitrust damages for a health care cooperative venture, if notice of the venture is provided to the Attorney General.

The broad new statutory antitrust immunities accorded by S. 1658 and H.R. 3486 are unnecessary and potentially harmful. The certificate of review immunity scheme in the bills, covering any activity relating to the provision of health care services, would create pervasive and continuing Federal government regulation of the competitive and other dimensions of an unknown and potentially vast number of health care provider activities. This task could well overwhelm the Justice Department, seriously impeding its ability to focus on any activities that actually would have anticompetitive effects. It likely would result in a massive new bureaucracy within the Department of Justice to administer such a program. Moreover, regulatory attempts to guard against anticompetitive behavior have consistently proved to be no substitute for the standard operation of the antitrust laws. The notification-based antitrust protections in the bills, broadly covering any collective activity among health care providers, could undercut sound antitrust substantive standards and skew the balance of antitrust remedies that has served so well for over a century. And the "safe harbor" immunities in the bills, based as they would be on hard-to-amend statutory or regulatory language and legislative or regulatory history, could have unintended anticompetitive effects, whereas enforcement policy statements based on common sense, basic competitive principles, would not.

Having summarized the Department's views on S. 1658 and H.R. 3486, I will address below our concerns with each aspect of the bills in more detail.

CERTIFICATE OF REVIEW PROVISIONS OF S.1658 AND H.R. 3486

The most comprehensive and complex new antitrust immunity scheme provided by S. 1658 and H.R. 3486 is the certificate of review process set out in Section 5 of each bill. This section provides complete antitrust immunity to successful applicants for a certificate of review that may cover any activity relating to the provision of health care services. In deciding whether to issue a certificate, the Attorney General and the Secretary are to take into account the extent to which a particular activity will:

A) lead to an increase in access to health care services;

B) enhance the quality of health care services;

C) establish cost efficiencies that will be passed on to consumers, including economies of scale and reduced transaction and administrative costs;

D) increase the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations; and

E) improve the utilization of health care resources or reduce inefficient duplication of such resources.

They must also consider whether:

A) the activity will help health plans and other health care insurers, consumers of health care services, and health care providers to better negotiate payment and service arrangements that will reduce costs to consumers;

B) taking into consideration the characteristics of the particular purchasers and providers involved, competition will not be unduly restricted;

C) equally efficient and less restrictive alternatives do not exist to meet the criteria described above; and

D) the activity will not unreasonably foreclose competition by denying competitors a necessary element of competition.

Section 5 requires the Attorney General, in consultation with the Secretary and the Chair of the FTC, to establish procedures to be used in applying for and approving certificates. It also requires published notice of each application in the Federal Register within 10 days of receipt, and action by the Attorney General and the Secretary within 90 days. If an

application for a certificate has not been denied within 90 days, it is deemed approved. There is also provision for expedited action if an applicant "indicates a special need for prompt disposition."

Further provisions in Section 5 deal with denial of applications, requests for reconsideration, fraudulent procurement, amendment and revocation of certificates, requests for compliance information, investigative authority, review of certification determinations in federal court, the effect of rejected applications, publication of decisions, annual reports, restrictions on disclosure of information, and prohibition against use of information to support or answer claims under the antitrust laws. In short, section 5 replaces the normal operation of the antitrust laws with ongoing government review and regulation of certificated activities under the comprehensive standards set out above.

Objections to the Certificate of Review Provisions

Antitrust immunity for any and all activities relating to the provision of health care services pursuant to the complex certificate of review process contained in S. 1658 and H.R. 3486 is unnecessary and potentially harmful. There is no evidence that establishment of such a pervasive regulatory scheme or such a substantial departure from the antitrust standards and procedures applicable in virtually all other sectors of the economy is necessary to foster the innovative health care delivery systems envisioned by the Health Security Act and most of the other reform proposals currently before the Congress. Justice Department and FTC policy and practice have accorded favorable treatment to the vast majority of cooperative activities in the health care area. Nor does the ability of health care providers, consumers or third party payers to seek redress of antitrust grievances through private litigation warrant the substitution of continuing government oversight of health care activities for the discriminating application of sound antitrust law.

The dangers of a comprehensive certification/antitrust immunity scheme are manifest. First, such a scheme would place the entire responsibility of initially and prospectively detecting anticompetitive threats and continually monitoring approved health care activities on the Departments of Justice and HHS. In light of the breadth of the scheme, analyzing and processing certification applications could be overwhelming, impeding the Justice Department's ability to screen proposed activities for anticompetitive effects, and diverting its staff from their primary mission--the detection and prosecution of antitrust violations and the prevention of anticompetitive mergers and joint ventures. Competitive harm in such circumstances is entirely predictable.

The certification scheme provided by S. 1658 and H.R. 3486 also would require unwarranted and continuing government oversight of an unknown and potentially vast number of day-to-day activities of health care providers. Government agencies would have the ability to approve a wide range of individual or collaborative activities, perhaps on condition that they be altered in a particular way. In addition, the agencies would have the power, and indeed the obligation, after certification to intervene in a regulatory manner whenever they determined that the complex and judgmental criteria in the bill were no longer met. Constant monitoring of existing certificate holders would be required to determine whether a certificate should be amended or revoked. To effectively administer such a scheme would require a massive new bureaucracy within the Department of Justice. Finally, the certification scheme in the bills likely would impose increased costs on the health care industry as providers spent substantial sums preparing and filing requests for certificates for activities that typically raise no colorable antitrust issues.

NOTIFICATION PROVISIONS OF S. 1658 AND H.R. 3486

Section 6 of each bill would create a notification procedure whereby any "health care cooperative venture" would be guaranteed a "rule-of-reason" antitrust analysis if challenged under the antitrust laws, and any antitrust relief granted against such a venture would be limited to actual rather than treble damages. Parties could obtain such protection by affirmatively notifying the Attorney General of their activities, but in addition many types of ventures would be "deemed" to have submitted such a notification. These include any ventures that have applied for a certificate of review under Section 5, and any health care cooperative ventures of a certain size[2] among non-institutional providers who share risks.[3]

Objections to the Notification Provisions

As with certification schemes, rule-of-reason/single damage protection via notification for unknown and potentially broad

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[2]For a nonexclusive network, any group including 50 percent or fewer of the providers in a relevant market and 50 percent or fewer of the members of any one specialty within that group; for an exclusive network, any group including 35 percent or fewer of the providers or specialists in a relevant market.

[3]H.R. 3486 deems either ventures below the size limits in Note 2 supra or ventures wherein providers share risks to have been notified; S. 1658 imposes both size limits and risk sharing before ventures will be deemed to have been notified. H.R. 3486 also omits the "non-institutional" qualifier.

categories of collaborative health care activities is unnecessary and potentially harmful. There is no indication, in light of the sound enforcement policies applied to health care activities, that cost-saving or otherwise efficient joint ventures in the health care area are unusually vulnerable to antitrust attack. In fact, quite the opposite is clear from the record. There is no sound reason to extend antitrust protection to joint ventures that present no anticompetitive risks and that would not be in danger of challenge in the first place. Moreover, such a provision could actually increase costs in the health care industry as the costs of notifications were passed on to consumers.

A notification scheme such as that set out in S. 1658 and H.R. 3486 could be harmful to competition and consumers by providing unwarranted rule-of-reason or single damage protection to potentially anticompetitive activities. There is no indication that procompetitive joint activity in the health care area is being placed at unusual or undue antitrust risk. Moreover, there is no legitimate distinction between health care and other industries such that potential treble damages should not produce the same salutary compensatory and deterrent effects in the health care area that they do generally.

Absent clear and convincing evidence of aberrations or abuse, antitrust standards and remedies should not be abrogated by special industry-specific protection for broad ranges of activities. Blanket, automatic protection for any "health care cooperative venture," which is defined in the two bills as "any activities, including attempts to enter into or perform a contract or agreement, carried out by two or more persons for the purpose of providing health care services," and for broad categories of activities that without any notice at all would be "deemed" to have filed a notification, would significantly constrain appropriate antitrust enforcement and deterrence. The rationale behind notification schemes is to give the government an opportunity to step in and stop potentially harmful activities, and the trade-off is that parties who notify are given rule-of-reason and single damages protection if they come forward. In light of the thousands of ventures that could potentially be presented to the Department under a notification scheme, there is a very real danger that potentially harmful arrangements would be granted a degree of protection that they do not deserve, and that could result in substantial harm to consumers.

CODIFICATION OF SAFE HARBORS

Section 3 of each bill would create several categories of statutory health care antitrust immunities that are in part patterned on the safety zones described in the six Department of Justice/FTC Statements of Antitrust Enforcement Policy in the

Health Care Area issued in September 1993. The "safe harbor" immunities in S. 1658 and H.R. 3486, however, are broader, and there are seven categories of exemptions instead of six. Section 4 of each bill would create a process whereby the public could submit suggestions for additional safe harbors to be established by the Attorney General, in consultation with the Secretary and the Chair of the FTC.

Objections to Codification of Safe Harbors

Statutory "safe harbors" from antitrust scrutiny for health care providers would be both unnecessary and potentially harmful. Such protections are unnecessary because the Department and the FTC have already set out significant safety zones in their joint Statements of Antitrust Enforcement Policy in the Health Care Area that inform health care providers of activities that are clearly lawful. We have committed to continuing review and supplementation of these Statements, and have complemented them with an expedited process through which health care providers may obtain the views of the Department or FTC on specific proposed health care activities, whether or not they are covered by the existing policy statements.

The harm that the Department foresees from codification of health care antitrust safety zones is that it could have unforeseen consequences and needlessly encumber law enforcement and development in areas that may require fine tuning for some time to come. Consumers, health care providers and enforcement officials all need leeway to adjust to changes in relevant markets as health care systems evolve and competition and efficiencies in health care delivery become better understood. Statutory antitrust immunities are not easily amended, and their intended effects can be distorted by interpretations of both statutory language and legislative history. On the other hand, the articulation of safety zones in flexible, competition-oriented enforcement policy statements such as those set out by the agencies last September is a process much more geared to an optimal outcome for both providers and consumers. What looks like a perfectly reasonable activity today could have unforeseen anticompetitive ramifications in the future and, similarly, what appears to be a problematic activity today may be perfectly reasonable in the future. Although it is extraordinary for one particular industry to have a set of specific guidelines put forth for its benefit, the Department and the FTC have done so for the health care industry. It would be totally unprecedented for such guidelines to be codified.[1]

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[1]We would also note that some of the particular safe harbors defined in the two bills are substantially broader than the safety zones in the DOJ/FTC Statements of Enforcement Policy, and (continued...)

In sum, the Department of Justice opposes S. 1658 and H.R. 3486. I appreciate very much your interest in the importance of sound antitrust enforcement and the preservation of competitive health care markets. The Department is committed to reasonable and responsible application of the antitrust laws in the health care area and will continue to work to promote a fair and competitive health care marketplace; however the broad new statutory antitrust immunities in these bills could be detrimental to the goals of health care reform.

This Department has been advised by the Office of Management and Budget that there is no objection to the submission of this report from the standpoint of the Administration's program.

Sincerely,

Anne K. Bingaman
Assistant Attorney General

'(...continued)
may protect anticompetitive conduct that significantly harms consumers.

SLIDE PRESENTATION

ANTITRUST PROVISIONS

OF THE

HEALTH SECURITY ACT

INDEX

HEALTH SECURITY ACT
ANTITRUST HIGHLIGHTS

- Competition is the cornerstone of the Act
- The Department of Justice and the Federal Trade Commission issued antitrust guidance to health care providers in the fall of 1993 as called for in the Administration's preliminary plan
- The Agencies will provide further guidance
- The Act recognizes that providers may jointly negotiate fee-for-service reimbursement levels with regional alliances
- The Act repeals the McCarran-Ferguson antitrust exemption for health insurers

COMPETITION IS THE CORNERSTONE OF THE HEALTH SECURITY ACT

- Competition will yield the best allocation of resources, the lowest prices, the highest quality and the most innovation

- The Act promotes competition between health plans and providers as a way to control health care costs

- Health plans will compete to be selected by consumers by seeking ways to lower premiums and offer quality care through a network of providers

- In order to obtain and retain business, health plans will have to be cost-effective in delivering care and administering their networks and be innovative in developing plans that consumers desire

- Providers will compete to be included in networks offered by health plans by demonstrating that they can provide high quality care at affordable prices

- Providers will also have incentives to look for innovative ways to prevent and treat medical conditions

THE HEALTH SECURITY ACT PROMOTES COMPETITION

- The Act encourages providers and health plans to compete on the basis of price, quality and innovation

- The Act standardizes benefits offered by plans so that consumers can easily see which plans are more expensive and plans will be forced to compete on price and quality

- The Act requires alliances to provide more information to consumers -- better informed consumers will reward cost-effective plans and providers with their business

- The Act allows small businesses to lower the cost of covering their employees by allowing them to purchase health insurance through the alliances

BROAD-BASED ANTITRUST IMMINITIES WOULD HARM COMPETITION AND ARE UNNECESSARY

- Broad-based immunities can harm competition, and thus increase costs, decrease quality, and discourage innovation

- Broad-based immunities are unnecessary because the antitrust laws are sufficiently flexible to permit efficient cooperative activities

- Antitrust uncertainty raised as a justification for broad-based immunities has been addressed by the DOJ-FTC September 1993 Health Care Antitrust Enforcement Policy Statements, supplemented by the Agencies' Business Review and Advisory Opinion procedures

- Granting broad-based immunities substitutes government intervention for the natural workings of the market, and takes away needed enforcement discretion where joint action harms competition

- Industry-specific antitrust immunities are rare and have always been disfavored.

STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN THE HEALTH CARE AREA

- Joint product of the DOJ and FTC (Sept. 1993)

- Statements cover 6 areas:

  (1) Hospital mergers
  (2) Hospital equipment joint ventures
  (3) Physicians' provision of information to purchasers
  (4) Hospitals' exchange of price and cost data
  (5) Joint purchasing arrangements
  (6) Physician network joint ventures

- Statements contain safety zones and "rule of reason" analyses for conduct outside the safety zones

- Statements establish an expedited review process whereby any member of health care industry can quickly get the views of the DOJ and FTC on the antitrust implications of proposed activities

HOSPITAL MERGERS: SAFETY ZONE

- **Agencies will not challenge any merger between hospitals, as long as one hospital :**

  -- **Averages 100 Licensed beds or less over 3 years;**

  -- **Averages 40 inpatients or less over 3 years; and**

  -- **Is at least 5 years old.**

HOSPITAL EQUIPMENT JOINT VENTURES: SAFETY ZONE

- Agencies will not challenge any joint venture among hospitals to purchase, operate and market the services of high-technology or other expensive medical equipment if the venture includes only the number of hospitals necessary to support the equipment

- Background: Agencies have never challenged a joint venture among hospitals to purchase, operate and market high-technology or other expensive medical equipment

PHYSICIANS' PROVISION OF INFORMATION TO PURCHASERS OF HEALTH CARE SERVICES: SAFETY ZONE

- Agencies will not challenge the collective provision of information related to:

  -- mode of treatment

  -- quality of treatment

  -- efficiency of treatment

  This would include such information as suggested practice parameters and outcome data

- Specifically excluded from the safety zone are:

  -- Implying or threatening a boycott

  -- Collective provision of fee-related information

HOSPITAL PARTICIPATION IN EXCHANGES OF PRICE AND COST INFORMATION: SAFETY ZONE

- No challenge to written surveys of prices or costs if:
  - -- Survey is managed by a third party;
  - -- Information is historical (3 months old); and
  - -- Information is aggregated so individual competitors' data can not be identified

JOINT PURCHASING ARRANGEMENTS: SAFETY ZONE

- No challenge by the Agencies if:
  - -- Joint purchases account for less than 35 percent of the total sales of the purchased product or service; and
  - -- Cost of the joint purchases accounts for less than 20 percent of the total revenues from all products or services sold by each competing participant in the joint purchasing arrangement

PHYSICIAN NETWORK JOINT VENTURES: SAFETY ZONE

- **No challenge by the Agencies if:**

  -- **20 percent or less of the physicians in each specialty with active hospital staff privileges (in areas with less than 5 physicians in a specialty, can always include 1 physician); and**

  -- **Physicians share substantial financial risk**

AGENCIES WILL PROVIDE FURTHER GUIDANCE

- The Health Care Antitrust Enforcement Policy Statements commit the Agencies to provide ongoing guidance in the form of additional Statements as warranted

- The Agencies are always open to requests from interested parties for additional topics to be covered

- The Agencies have established an expedited review process which allows any member of the health care industry to request the Agencies' views regarding the antitrust implications of proposed conduct. The Agencies have committed to answer these requests within 90 or 120 days

- A number of parties have already availed themselves of this opportunity and have received prompt responses from the Agencies

JOINT PROVIDER NEGOTIATIONS

- The Health Security Act recognizes that providers may negotiate jointly with alliances with respect to reimbursement levels on the fee-for-service plan

- This allows alliances to have as much information as possible to avoid potential errors that could undermine the purposes of health care reform

- It also allows providers to have a say in a vital determination made by an entity of the state that has total control over the level of reimbursement

- It is consistent with existing antitrust doctrine -- Under the antitrust laws parties have the right to collectively provide information to an entity of the state (the so called "Noerr-Pennington" doctrine), but may not threaten or engage in any boycott

REPEAL OF MCCARRAN-FERGUSON ACT ANTITRUST EXEMPTION FOR HEALTH INSURERS

- The McCarran-Ferguson Act currently immunizes the business of insurance, including health insurance, from the antitrust laws, to the extent regulated by state law

- This broad exemption could allow health insurers to act anticompetitively and thereby interfere with the Health Security Act's reliance on competition between insurers to control health care costs

- The Health Security Act repeals the exemption for health insurers

- Repeal will not prevent health insurers from engaging in procompetitive collective activities