ANTI-TRUST 1

CLINTON - TITLE V - SUBTITLE F

REPEAL OF MCCARRAN-FERGUSON EXEMPTION FOR HEALTH INSURANCE: Health insurance industry is now subject to The Sherman Act, The Clayton Act, FTC Act, and The Robinson-Patman Antidiscrimination Act.

CHAFEE - TITLE IV - SUBTITLE C

EXEMPTIONS: An entity or individual is exempt from antitrust laws if the activity falls within one of the categories of safe harbors outlined in Act or within an additional safe harbor designated by the Attorney General, or if it has been specified in a certificate of review.

SAFE HARBORS: Exemption from antitrust laws for: (1) combinations of providers if the number does not exceed 20 percent of market share of the provider type or specialty in the market area, (2) activities of medical self-regulatory agencies, (3) participation in surveys of prices, reimbursement levels, or compensation and benefits of employees, if survey conducted by third party and information is aggregated in a manner such that recipients of the survey may not identify individual provider's prices, etc., (4) joint ventures for high technology and costly equipment and services, (5) hospital mergers - one of the hospitals, during 3-year period preceding merger, had an average of 150 or fewer operational beds and average daily inpatient census of less than 50% of such beds, (6) joint purchasing arrangements if it represents less than 35% of total sales or services in the relevant market and cost of product or services accounts for less than 20% of revenue for participants, and (7) negotiations to carry out any activity described in this section, or in the process of obtaining a certificate of review.

DESIGNATION OF ADDITIONAL SAFE HARBORS: Attorney General shall publish in the Federal Register proposed additional safe

COOPER - TITLE I - SUBTITLE C

GUIDELINES FOR ACCOUNTABLE HEALTH PLANS: The President would be required to provide for the development of guidelines on the application of Federal anti-trust laws to AHP's. The Attorney General would establish a review process under which AHP can obtain an opinion from Department of Justice on conformity with Federal anti-trust laws.

CERTIFICATES OF PUBLIC ADVANTAGE: Attorney General shall issue certificates of public advantage to each health care joint venture that complies with anti-trust laws. Venture shall not be liable under any anti-trust law for conduct described in certificate. Requirements for certificate include: the benefits of the venture outweigh the reduction in competition, and the reduction in competition is necessary to obtain the benefits. Benefits include higher quality, increased access, greater efficiency and utilization of resources, preservation of location in underserved areas, and elimination of resource duplication. The Attorney General must grant or deny issuance of certificate within 30 days of application. Certificate can be revoked at any time if venture does not continue to meet standards. Exemption from anti-trust laws for conduct necessary to prepare certificate application or to join venture which has certificate in effect.

harbors and shall proscribe criteria to establish additional safe harbors. Criteria shall include: the beneficial effect of the proposed activity on access, quality, efficiency, utilization, and ability to provide services to medically under-served areas or populations.

CERTIFICATES OF REVIEW: Attorney General would issue certificates of review under an expedited waiver process. Attorney General shall establish procedures for applying for certificates of review and for approving the application. Activities described in certificates must satisfy criteria for safe harbors.

NOTIFICATIONS PROVIDING REDUCTIONS IN CERTAIN PENALTIES UNDER ANTITRUST LAWS FOR HEALTH CARE COOPERATIVE VENTURES: After entering into a joint venture, a party may within 90 days, provide written notification to the Attorney General disclosing the venture. Under certain conditions, joint ventures providing notifications of activities to the Attorney General would be subject to reduced penalties (i.e. actual damages and interest) under anti-trust laws. Application for certificate of review and certain ventures are activities deemed submission of notification.

GUIDELINES: The Attorney General shall promulgate such rules, regulations and guidelines as are necessary to carry out this Act, and to promote greater certainty regarding the application of the antitrust laws to activities in the health care market.

KENNEDY BILL

NO CHANGES TO HR 3600.

HOUSE EDUCATION AND LABOR

NO CHANGES TO HR 3600.

WAYS & MEANS

NO CHANGES TO HR 3600.

SENATE FINANCE

NO CHANGES TO HR 3600.

Department of Justice

FOR IMMEDIATE RELEASE
WEDNESDAY, SEPTEMBER 15, 1993

AT
(202) 616-2771
TDD (202) 514-1888

ANTITRUST ENFORCEMENT POLICY STATEMENTS ISSUED FOR HEALTH CARE INDUSTRY

WASHINGTON, D.C. -- First Lady Hillary Rodham Clinton, Attorney General Janet Reno and Anne K. Bingaman, Assistant Attorney General for the Antitrust Division, were joined by Federal Trade Commission Chairman Janet D. Steiger and prominent members of Congress at the Department of Justice to announce steps to make health care more available and affordable to all Americans.

The Department of Justice and the Federal Trade Commission issued six antitrust enforcement policy statements to provide guidance to hospitals and health care providers to know whether they can enter into mergers and joint ventures without violating the antitrust laws. The policy statements will help alleviate uncertainty within the health care industry making it easier for mergers and joint ventures to take place, resulting in lower health care costs.

Assistant Attorney General Anne K. Bingaman said, "Many health care providers have delayed cooperative cost-cutting arrangements because of uncertainty about antitrust restrictions.

(MORE)

I wholeheartedly believe that these new policies will bring down costs to health care consumers while providing effective quality health care services."

The policy statements provide antitrust safety zones which describe circumstances under which the Department of Justice and the Federal Trade Commission will not challenge:

--Hospital mergers;

--Hospital joint ventures involving high-technology or other expensive medical equipment;

--Physicians' provision of information to purchasers of health care services;

--Hospital participation in exchanges of price and cost information;

--Joint purchasing arrangements among health care providers;

--Physician network joint ventures.

The Department of Justice and Federal Trade Commission are also committing themselves to an expedited business review procedure under which the agencies would provide responses within 90 days, after all necessary information is received, to requestors seeking guidance on health care joint ventures and information exchanges.

Today's announcement is part of the Administration's efforts to reform the nation's health care system. The Justice Department is also currently evaluating measures which may increase federal power to combat fraud and abuse. For example,

strengthening anti-kickback laws and making the heavy penalties against defrauding the government applicable to those who defraud the private health care system, as well.

Senator Howard Metzenbaum (D-OH) and Representative Jack Brooks (D-TX) took part in the announcement at the Department of Justice.

###

93-271

DEPARTMENT OF JUSTICE AND FTC ANTITRUST ENFORCEMENT POLICY STATEMENTS IN THE HEALTH CARE AREA

The Department of Justice and the FTC today issued six statements of their antitrust enforcement policies regarding mergers and other joint activities among health care providers.

The six statements address: (1) hospital mergers; (2) hospital joint ventures involving high-technology or other expensive medical equipment; (3) physicians' provision of information to purchasers of health care services; (4) hospital participation in exchanges of price and cost information; (5) joint purchasing arrangements among health care providers; and (6) physician network joint ventures.

The statements are designed to provide information to the health care community in a time of tremendous change, and to resolve, as completely as possible, any antitrust uncertainty that might deter beneficial mergers or joint ventures that promise to reduce health care costs. Sound antitrust enforcement will not impede efficient transactions, but it will continue to protect consumers against truly anticompetitive activities that lead to higher prices.

Antitrust analysis is inherently fact-intensive. The six policy statements give health care providers guidance, in the form of "antitrust safety zones," which describe the circumstances under which the Agencies will not challenge conduct under the antitrust laws. The statements also summarize the analysis the Agencies will use to review conduct which falls outside the antitrust safety zones.

Providers who wish to have the Agencies' views on specific joint activities that they plan to undertake may obtain a timely response through the Department's expedited business review procedure or the FTC's advisory opinion procedure for the health care community. In the policy statements, the Agencies commit to respond to requests within 90 days after all necessary information is received regarding any matter addressed in the statements except hospital mergers outside the antitrust safety zone. The Agencies make this commitment to swift and certain expedited review in an effort to reduce antitrust uncertainty for the health care industry in a time of fundamental and far-reaching change. The Agencies also recognize that, in light of such change, additional antitrust guidance may be desirable in the areas covered by these policy statements, as well as in other evolving health care contexts. Consequently, the Agencies will issue additional policy statements as warranted.

HOSPITAL MERGERS

The Agencies have challenged only eight of well over 200 hospital mergers in the last five years. Many hospital mergers do not present antitrust concerns because the merging hospitals are not significant competitors of each other. In other cases, where a merger substantially reduced the number of competing hospitals in an area, the Agencies in the past have refrained from bringing an action because the merger produced significant cost savings that could not otherwise be realized.

The policy statement establishes an antitrust safety zone for mergers where one of the merging hospitals is small. Specifically, the Agencies commit not to challenge, absent extraordinary circumstances, a merger in which one of the merging hospitals has

less than 100 licensed beds and an average daily inpatient census of less than 40 patients. This antitrust safety zone will be especially helpful for small rural hospitals, who consider a merger necessary in order to continue providing services, but who fear the cost of an expensive investigation by federal antitrust authorities.

Hospitals which are unsure if they are within the safety zone may obtain timely advice from the Agencies through the expedited 90-day review procedure set forth in the policy statement.

HOSPITAL JOINT VENTURES INVOLVING HIGH-TECHNOLOGY OR OTHER EQUIPMENT

The Agencies have never challenged a joint venture among hospitals to purchase or operate high-technology or other expensive medical equipment. In most cases, these collaborative activities create procompetitive efficiencies that benefit consumers, which outweigh any potential anticompetitive harm. Although numerous hospitals presently participate in joint ventures, it has been suggested that fear of antitrust enforcement currently chills such ventures and forces hospitals to purchase expensive equipment individually, even though joint ventures clearly would be more efficient and less expensive.

The policy statement sets out an antitrust safety zone for joint ventures involving high-technology or other expensive equipment that must be shared in order to allow the hospitals to recover the cost of acquiring, operating and marketing the services provided by the equipment. As long as the joint venture is reasonably necessary to recover these costs and does not include a hospital or a group of hospitals that could have offered a

competing service to the planned joint venture, the Agencies will not challenge, absent extraordinary circumstances, the formation or operation of the venture. For example, joint ventures among rural hospitals to share MRIs or other expensive equipment and agreements among community hospitals to operate helicopter or other expensive services jointly normally will fall within the antitrust safety zone.

Joint ventures that fall outside the antitrust safety zone do not necessarily raise significant antitrust concerns. The policy statement, therefore, includes a brief description and examples of how these ventures will be analyzed. Hospitals considering joint ventures may obtain timely advice from the Agencies through the expedited 90-day review procedure set forth in the policy statement.

PHYSICIANS' PROVISION OF INFORMATION TO PURCHASERS OF HEALTH CARE SERVICES

This policy statement defines an antitrust safety zone that covers the collective provision of non-price information by physicians to purchasers of health care services. The collective provisio- of this type of information will have procompetitive benefits and allow physicians to work with health care purchasers to improve the quality of care that patients receive. The policy statements provide that the Agencies will not challenge, absent extraordinary circumstances, the collective provision of underlying medical data, including the development of suggested practice parameters.

The safety zone would not cover physicians who collectively threaten to or actually refuse to deal with a purchaser because they object to the purchaser's administrative, clinical or other terms governing the provision of services. In addition, it does not cover

the collective provision of fee-related information. The collective provision of price information is not, however, necessarily illegal. Physicians who wish collectively to provide such information may receive timely advice from the Agencies under the expedited 90-day review procedure.

HOSPITAL PARTICIPATION IN EXCHANGES OF PRICE AND COST INFORMATION

This policy statement defines an antitrust safety zone that covers hospital participation in written surveys of prices for hospital services or wages, salaries or benefits of hospital personnel. The safety zone applies where (1) the survey is managed by a third party, (2) the information collected for the survey is more than three months old, and (3) the price or cost data reported are based on data from at least five hospitals and aggregated so that the prices charged or compensation paid by particular hospitals cannot be identified.

The policy statement also includes a description of how the Agencies will evaluate information exchanges that fall outside the antitrust safety zone. Hospitals that are unsure of the legality of a proposed survey can obtain timely advice from the Agencies through the expedited 90-day review procedure set forth in the policy statement.

JOINT PURCHASING ARRANGEMENTS AMONG HEALTH CARE PROVIDERS

Most joint purchasing arrangements among hospitals or other health care providers do not raise antitrust concerns; indeed the Agencies have never challenged such a joint purchasing arrangement. Such collaborative activities typically allow the participants to

achieve efficiencies that will benefit consumers. This policy statement covers arrangements among providers to purchase such goods and services as laundry or food services, computer or data processing services, and prescription drug and other pharmaceutical products.

Under the policy statement, the Agencies will not challenge, absent extraordinary circumstances, a joint purchasing arrangement if the group's purchases account for less than 35 percent of the total purchases of the relevant product or service, and the cost of the product or service being jointly purchased accounts for less than 20 percent of the total revenues from all products or services sold by each participant in the joint purchasing arrangement.

PHYSICIAN NETWORK JOINT VENTURES

This policy statement sets forth the Agencies' analysis of the formation of physician network joint ventures that are controlled by physicians and that jointly market the services of their member physicians. These joint arrangements have the potential to provide quality services at reduced costs, and can offer significant procompetitive benefits for consumers. Physicians who participate in legitimate network joint ventures can collectively provide information to health care purchasers, and jointly negotiate with them.

The policy statement sets forth an antitrust safety zone that covers physician network joint ventures comprised of 20 percent or less of the physicians in each physician specialty in the relevant geographic market, when the members share substantial financial

risk. The statement includes examples of physician network joint ventures that would meet the requirement of sharing substantial financial risk.

The statement also includes a brief description and examples to illustrate how the Agencies will analyze a physician network joint venture that does not fall within the antitrust safety zone. Physicians forming network joint ventures can obtain timely antitrust advice from the Agencies under the expedited 90-day review procedure.

STATEMENT OF ANNE K. BINGAMAN
ASSISTANT ATTORNEY GENERAL
ANTITRUST DIVISION
UNITED STATES DEPARTMENT OF JUSTICE

Submitted to the Committee on Finance
United States Senate
On Competition and Antitrust Issues in Health Care Reform
May 12, 1994

I am pleased to have the opportunity to submit to the Committee the views of the Department of Justice on the role of competition and the antitrust laws as significant reform of our health care system is underway. My statement will also address the antitrust-related provisions of the President's proposed Health Security Act.

The Vital Importance of Competition and the Antitrust Laws

The President's proposed Health Security Act and most of the other major proposals for health care reform rely heavily on the forces of competition to increase the availability and improve the quality of health care services, foster efficiency in the delivery of those services, and control their spiralling costs. For too long, the salutary effects of competition in health care marketplaces have been inhibited. Third party payment mechanisms that do not stimulate cost-effective consumer and provider decisions, limitations on the ability of consumers to choose health care plans on the basis of quality and price, and consumer unawareness of the merits and costs of the choices they do have are examples of inhibitions on competition that need to be addressed.

The Health Security Act promotes competition in many ways. The health care delivery system it will create will stimulate increased competition between and among various types of health plans and between and among institutional and individual health care providers. Plans will compete to be selected by consumers by seeking ways to lower premiums and increase the quality of care through networks of qualified providers. Providers will compete to develop or participate in plans by demonstrating that they can provide high quality care at affordable prices, and by seeking innovative ways to offer that care. Consumers will have information that will make them better able to evaluate and select their health care coverage on the basis of cost and quality, and thus play their important role in stimulating effective competition among plans and providers. In short, the Health Security Act will promote competition to its rightful status as a major determinant in health care reform.

As we reform our health care system to rely heavily on increased competition, it is vital that we remember that promoting and protecting that competition requires effective prohibitions against private conduct that would undercut it. Fortunately, we do not have to invent such prohibitions. They have existed for a century in the form of our antitrust laws. Given the proposals for sweeping immunities from the antitrust laws or serious constraints on their effectiveness in some of the bills before the Congress, however, I fear that this simple connection between increasing competition and preserving the laws that protect it may be overlooked as health care reform is pursued. That is a mistake we must not make.

The antitrust laws of the United States and their enforcement by the Department and the Federal Trade Commission are sound, including as applied in the health care industry.

The antitrust laws have existed for over a century as the principal guarantor of effective competition in free marketplaces. They have proved, time and again, far superior to pervasive government review, regulation, and oversight of individual or collective activities that may have competitive consequences. Indeed, they have been termed the "Magna Carta" of our fundamental national economic system.

In the health care area, as is the case generally, the antitrust laws are enforced so as to take into account not only indications of possible competitive harm, but also the potential for procompetitive increases in efficiency, lowered administrative and other costs, improvements in quality, enhanced innovation, and other factors that are important to the cost-effective delivery of quality health care services. Many types of procompetitive industry activity are well recognized as highly unlikely to raise any significant competitive concern. For example, neither the Department nor the FTC has ever challenged a joint venture among hospitals to purchase, operate and market high-technology or other expensive medical equipment. Only those activities that would harm health care markets and consumers by raising prices, decreasing availability or quality of services, or discouraging innovation face potential antitrust challenge.

Antitrust Guidance to the Health Care Community

Although antitrust principles in the health care area are basically sound, the Department and the FTC have recognized that antitrust uncertainty in the health care community, particularly in these changing times, should be addressed. To that end, we have been working since last summer to provide antitrust guidance to the industry. In September

1993, we issued six Statements of Antitrust Enforcement Policy in the Health Care Area, covering matters that we know to be of concern to health care providers and others. Our statements cover six areas:

- Hospital mergers
- Hospital equipment joint ventures
- Physicians' provision of information to purchasers
- Hospitals' exchange of price and cost data
- Joint purchasing arrangements among providers, and
- Physician network joint ventures.

Our statements contain "safety zones" describing mergers, joint ventures, and other activities that the agencies have concluded are very unlikely to raise competitive concerns. The statements also make clear, however, that conduct that does not fall within the safety zones is not by implication likely to be challenged by the Department or the FTC. Indeed, much conduct not amenable to coverage by a safety zone because of the significance of the particular circumstances will be recognizably and demonstrably procompetitive in those circumstances. The statements set out the analysis the agencies use in evaluating conduct outside the safety zones so that health care providers may more confidently assess antitrust issues raised by proposed conduct even if the safety zones themselves are not applicable.

Both the safety zones and the agencies' analysis of other conduct are set out in our policy statements in simple, straightforward terms. Our goal is to provide antitrust guidance to health care providers themselves, and not only to the antitrust bar that advises the industry.

While our 1993 policy statements cover a lot of ground and, I believe, have contributed greatly to health care providers' understanding of antitrust issues, I also believe that we can and should do more. When we issued our policy statements last September, we recognized that additional antitrust guidance in the areas they cover as well as in other health care areas may be desirable. We are hard at work on such additional guidance right now, and have pledged to continue this effort. In this regard, I want to express my sincere appreciation for the advice and counsel we have received from representatives of the health care community in our ongoing efforts to develop useful antitrust enforcement policy statements. The legal and practical insights that have been shared with us by the American Hospital Association, the American Medical Association, and a variety of other interested and knowledgeable parties have been invaluable.

We have also instituted an expedited procedure to supplement the general antitrust guidance set forth in the Statements of Antitrust Enforcement Policy in the Health Care Area with more specific guidance on specific proposed conduct. We have committed to respond to requests for Department business reviews of specific health care activities within 90 or 120 days, depending on the nature of the conduct. The Federal Trade Commission has made the same commitment with respect to its advisory opinion procedure. Health care providers are taking advantage of these procedures, and we anticipate that they will result in significant further clarification of antitrust rules and guideposts to the advantage of all.

Antitrust Provisions in the Health Security Act

The Health Security Act contains two antitrust-related provisions. First, section 5501 of the Act repeals the broad antitrust immunity in the McCarran-Ferguson Act for the business of insurance to the extent that such business relates to the provision of health benefits. The current, broad immunity could allow health insurers to act anticompetitively and thereby interfere with the Health Security Act's goal of relying on competition between insurers to control health care costs.

The Health Security Act also provides that, in connection with the establishment by a regional alliance of a fee schedule for use in regional alliance fee-for-service health plans, health care providers may collectively negotiate the fee schedule with the regional alliance (section 1322(c)). This section recognizes that the establishment of such fee schedules by the alliances is basically a governmental function under the Act, and provides that the actions of the alliances in this regard and their negotiations with providers collectively shall be accorded the antitrust treatment due to government actions and efforts by private parties to influence those actions (section 1322(c)(5)). Such actions and efforts generally are not subject to the antitrust laws, but under section 1322, as is the case generally, there are important limits on what actions providers may take to influence an alliance's fee-for-service schedule decisions. The principal limitation is that providers may not threaten or engage in any boycott to force an alliance to adopt their suggestions or recommendations (section 1322(c)(6)). As used in section 1322, the term "boycott" is intended to include any threat or action through which providers collectively would decline initially to participate, or departicipate, in fee-for-service health care delivery unless fees were set at certain levels.

* * *

Before concluding, I would like to underscore the one point I think is vital to keep in mind as antitrust issues are considered during health care reform. Among the primary goals of such reform is to bring the forces of competition effectively to bear in health care markets as never before. To accomplish this goal the efficacy of the antitrust laws must be preserved, and we seek the Committee's support in this effort. The Department of Justice must also continue to work with the FTC and the health care community to reduce unwarranted antitrust uncertainty in the health care area, which we have pledged to do.

Thank you again for the opportunity to submit to the Committee the views of the Department of Justice on these important issues.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503

URGENT

May 10, 1994

LEGISLATIVE REFERRAL MEMORANDUM

LRM #I-2670

TO: Legislative Liaison Officer -

COMMERCE - Michael A. Levitt - (202)482-3151 - 324
DEFENSE - Samuel T. Brick, Jr. - (703)697-1305 - 325
HHS - Frances White - (202)690-7760 - 328
LABOR - Robert A. Shapiro - (202)219-8201 - 330
TREASURY - Richard S. Carro - (202)622-1146 - 228
VA - Robert Coy - (202)273-6666 - 229

FROM: JANET R. FORSGREN (for)
Assistant Director for Legislative Reference

OMB CONTACT: Robert PELLICCI (395-4871)
Secretary's line (for simple responses): 395-7362

SUBJECT: JUSTICE Proposed Testimony RE: S 1757, Health Security Act

DEADLINE: 3:00 P.M. May 11, 1994

COMMENTS: Hearing is before the Senate Committee on Finance on Thursday, May 12th. The hearing deals with the antitrust related provisions of the Health Security Act.

OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President, in accordance with OMB Circular A-19.

Please advise us if this item will affect direct spending or receipts for purposes of the the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

CC:
Nancy-Ann Min
Ira Magaziner
Chris Jennings
Greg Lawler
Jack Lew
Lynn Margherio
Jennifer Klein
Clarissa Cerda
Bob Damus
Bob Boorstin
Jason Solomon
Meeghan Prunty
Barry Clendenin
Len Nichols
Steve Richetti
Janet Forsgren

LRM #I-2670

RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

If your response to this request for views is **simple** (e.g., concur/no comment) we prefer that you respond by **faxing** us this response sheet. If the response is **simple** and you prefer to call, please **call the branch-wide line** shown below (NOT the analyst's line) to leave a message with a secretary.

You may **also respond** by (1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); (2) sending us a memo or letter; or (3) if you are an OASIS user in the Executive Office of the President, sending an E-mail message. Please **include** the LRM number shown above, and the **subject** shown below.

TO: Robert PELLICCI
Office of Management and Budget
Fax Number: (202) 395-6148
Analyst/Attorney's Direct Number: (202) 395-4871
Branch-Wide Line (to reach secretary): (202) 395-7362

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

SUBJECT: JUSTICE Proposed Testimony RE: S 1757, Health Security Act

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No objection

_____ No comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of _____ pages, attached to this response sheet

STATEMENT OF ANNE K. BINGAMAN
ASSISTANT ATTORNEY GENERAL
ANTITRUST DIVISION
UNITED STATES DEPARTMENT OF JUSTICE

Submitted to the Committee on Finance
United States Senate
On Competition and Antitrust Issues in Health Care Reform
May 12, 1994

I am pleased to have the opportunity to submit to the Committee the views of the Department of Justice on the role of competition and the antitrust laws as significant reform of our health care system is underway. My statement will also address proposals for antitrust immunities in some of the health care reform bills before the Congress and the antitrust-related provisions of the President's proposed Health Security Act.

The Vital Importance of Competition and the Antitrust Laws

The President's proposed Health Security Act and most of the other major proposals for health care reform rely heavily on the forces of competition to increase the availability and improve the quality of health care services, foster efficiency in the delivery of those services, and control their spiralling costs. For too long, the salutary effects of competition in health care marketplaces have been inhibited. Third party payment mechanisms that do not stimulate cost-effective consumer and provider decisions, limitations on the ability of consumers to choose health care plans on the basis of quality and price, and consumer unawareness of the merits and costs of the choices they do have are examples of inhibitions on competition that need to be addressed.

The Health Security Act promotes competition in many ways. The health care delivery system it will create will stimulate increased competition between and among various types of health plans and between and among institutional and individual health care providers. Plans will compete to be selected by consumers by seeking ways to lower premiums and increase the quality of care through networks of qualified providers. Providers will compete to develop or participate in plans by demonstrating that they can provide high quality care at affordable prices, and by seeking innovative ways to offer that care. Consumers will have information that will make them better able to evaluate and select their health care coverage on the basis of cost and quality, and thus play their important role in stimulating effective competition among plans and providers. In short, the Health Security Act will promote competition to its rightful status as a major determinant in health care reform.

As we reform our health care system to rely heavily on increased competition, it is vital that we remember that promoting and protecting that competition requires effective prohibitions against private conduct that would undercut it. Fortunately, we do not have to invent such prohibitions: They have existed for a century in the form of our antitrust laws. Given the proposals for sweeping immunities from the antitrust laws or serious constraints on their effectiveness in some of the bills before the Congress, however, I fear that this simple connection between increasing competition and preserving the laws that protect it may be overlooked as health care reform is pursued. That is a mistake we must not make.

The antitrust laws of the United States and their enforcement by the Department and the Federal Trade Commission are sound, including as applied in the health care industry.

The antitrust laws have existed for over a century as the principal guarantor of effective competition in free marketplaces. They have proved, time and again, far superior to pervasive government review, regulation, and oversight of individual or collective activities that may have competitive consequences. Indeed, they have been termed the "Magna Carta" of our fundamental national economic system.

In the health care area, as is the case generally, the antitrust laws are enforced so as to take into account not only indications of possible competitive harm, but also the potential for procompetitive increases in efficiency, lowered administrative and other costs, improvements in quality, enhanced innovation, and other factors that are important to the cost-effective delivery of quality health care services. Many types of procompetitive industry activity are well recognized as highly unlikely to raise any significant competitive concern. For example, neither the Department nor the FTC has ever challenged a joint venture among hospitals to purchase, operate and market high-technology or other expensive medical equipment. Only those activities that would harm health care markets and consumers by raising prices, decreasing availability or quality of services, or discouraging innovation face potential antitrust challenge.

Antitrust Guidance to the Health Care Community

Although antitrust principles in the health care area are basically sound, the Department and the FTC have recognized that antitrust uncertainty in the health care community, particularly in these changing times, should be addressed. To that end, we have been working since last summer to provide antitrust guidance to the industry. In September

1993, we issued six Statements of Antitrust Enforcement Policy in the Health Care Area, covering matters that we knew to be of concern to health care providers and others. Our statements cover six areas:

- Hospital mergers
- Hospital equipment joint ventures
- Physicians' provision of information to purchasers
- Hospitals' exchange of price and cost data
- Joint purchasing arrangements among providers, and
- Physician network joint ventures.

Our statements contain "safety zones" describing mergers, joint ventures, and other activities that the agencies have concluded are very unlikely to raise competitive concerns. The statements also make clear, however, that conduct that does not fall within the safety zones is not by implication likely to be challenged by the Department or the FTC. Indeed, much conduct not amenable to coverage by a safety zone because of the significance of the particular circumstances will be recognizably and demonstrably procompetitive in those circumstances. The statements set out the analysis the agencies use in evaluating conduct outside the safety zones so that health care providers may more confidently assess antitrust issues raised by proposed conduct even if the safety zones themselves are not applicable.

Both the safety zones and the agencies' analysis of other conduct are set out in our policy statements in simple, straightforward terms. Our goal is to provide antitrust guidance to health care providers themselves, and not only to the antitrust bar that advises the industry.

While our 1993 policy statements cover a lot of ground and, I believe, have contributed greatly to health care providers' understanding of antitrust issues, I also believe that we can and should do more. When we issued our policy statements last September, we recognized that additional antitrust guidance in the areas they cover as well as in other health care areas may be desirable. We are hard at work on such additional guidance right now, and have pledged to continue this effort. In this regard, I want to express my sincere appreciation for the advice and counsel we have received from representatives of the health care community in our ongoing efforts to develop useful antitrust enforcement policy statements. The legal and practical insights that have been shared with us by the American Hospital Association, the American Medical Association, and a variety of other interested and knowledgeable parties have been invaluable.

We have also instituted an expedited procedure to supplement the general antitrust guidance set forth in the Statements of Antitrust Enforcement Policy in the Health Care Area with more specific guidance on specific proposed conduct. We have committed to respond to requests for Department business reviews of specific health care activities within 90 or 120 days, depending on the nature of the conduct. The Federal Trade Commission has made the same commitment with respect to its advisory opinion procedure. Health care providers are taking advantage of these procedures, and we anticipate that they will result in significant further clarification of antitrust rules and guideposts to the advantage of all.

5-8

Proposals for Antitrust Immunities

Several of the bills that have been introduced to bring about health care reform contain

proposals for broad antitrust immunities in the health care area. We strongly believe that such immunities are potentially harmful and unnecessary. They are harmful in that they could seriously undercut an important goal of health care reform – to bring to bear for the first time truly effective forces of competition in health care markets to improve health care quality and availability and control health care costs. They are unnecessary in that there are no actual antitrust barriers to individual or collective activities among members of the health care community that would foster improved service quality, cost-saving efficiencies, or procompetitive diversity and opportunity in the provision of health care. Antitrust uncertainty, to the extent it exists, can be and is being vigorously addressed by an unprecedented effort among the Department, the FTC, and interested members of the health care community. In short, our antitrust laws are sound as applied to health care: There is no need for special, broad antitrust immunities that could defeat the basic goals of health care reform.

A discussion of all of the specific provisions in all of the bills that contain proposed health care antitrust immunities is beyond the scope of this statement, but I would offer general comments on three types of broad immunities that would be provided by S. 1658 and its companion bill, H.R. 3486. The Department previously has commented extensively on these provisions in response to requests from the Judiciary Committees. I attach a copy of our comments, and I would request that those comments be included in full in the record of this hearing.

S. 1658 and H.R. 3486 provide several types of broad immunities from the operation of the antitrust laws to the health care industry. The bills would provide antitrust immunity

for any health care activity that (i) falls within one of the "safe harbors" described in the bills, (ii) falls within any additional safe harbor established by the Attorney General, after seeking suggestions for further safe harbors through the Federal Register, or (iii) is covered by a "certificate of review" issued by the Attorney General with the concurrence of the Secretary of Health and Human Services. Additionally, the bills provide 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 that would be created across the health care industry by S. 1658 and H.R. 3486 are not needed and could do substantial harm. 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. The regulatory tasks it imposes as a substitute for straightforward antitrust enforcement could well overwhelm the Justice Department, seriously impeding its ability to focus on any activities that actually would have anticompetitive effects. Moreover, administering such a program would require a massive and costly new bureaucracy. Attempts to guard against anticompetitive effects through regulation have proved to be no substitute for effective antitrust enforcement, and entrusting the guarding of competition in the nations's largest industry -- an industry desperately needing a competitive transfusion -- to such a scheme would be a tragic mistake.

The notification-based antitrust protections in S. 1658 and H.R. 3486 present comparable concerns. These provisions could undercut sound antitrust legal standards that protect consumers against clearly anticompetitive conduct. They could also undermine antitrust damage remedies that appropriately deter conduct that would raise prices and reduce the availability and quality of health care services. And the "safe harbor" provisions in the bills, based as they would be on hard-to-amend statutory language and legislative history, could have unintended anticompetitive effects, whereas enforcement policy statements based on common-sense, basic competitive principles would not.

For these reasons, the Department strongly opposes antitrust immunities in the health care sector such as those that would be provided by S. 1658 and H.R. 3486.

Antitrust Provisions in the Health Security Act

The Health Security Act contains two antitrust-related provisions. First, section 5501 of the Act repeals the broad antitrust immunity in the McCarran-Ferguson Act for the business of insurance to the extent that such business relates to the provision of health benefits. The current, broad immunity could allow health insurers to act anticompetitively and thereby interfere with the Health Security Act's goal of relying on competition between insurers to control health care costs.

The Health Security Act also provides that, in connection with the establishment by a regional alliance of a fee schedule for use in regional alliance fee-for-service health plans, health care providers may collectively negotiate the fee schedule with the regional alliance (section 1322(c)). This section recognizes that the establishment of such fee schedules by the

alliances is basically a governmental function under the Act, and provides that the actions of the alliances in this regard and their negotiations with providers collectively shall be accorded the antitrust treatment due to government actions and efforts by private parties to influence those actions (section 1322(c)(5)). Such actions and efforts generally are not subject to the antitrust laws, but under section 1322, as is the case generally, there are important limits on what actions providers may take to influence an alliance's fee-for-service schedule decisions. The principal limitation is that providers may not threaten or engage in any boycott to force an alliance to adopt their suggestions or recommendations (section 1322(c)(6)). As used in section 1322, the term "boycott" is intended to include any threat or action through which providers collectively would decline initially to participate, or departicipate, in fee-for-service health care delivery unless fees were set at certain levels.

* * *

Before concluding, I would like to underscore the one point I think is vital to keep in mind as antitrust issues are considered during health care reform. Among the primary goals of such reform is to bring the forces of competition effectively to bear in health care markets as never before. To accomplish this goal the efficacy of the antitrust laws must be preserved, and we seek the Committee's support in this effort. The Department of Justice must also continue to work with the FTC and the health care community to reduce unwarranted antitrust uncertainty in the health care area, which we have pledged to do.

Thank you again for the opportunity to submit to the Committee the views of the Department of Justice on these important issues.

Antitrust Division

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

APR 14 1994

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.

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

---

[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.[4]

---

[4]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

---

[6](...continued)
may protect anticompetitive conduct that significantly harms consumers.

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.

American Medical Association
Physicians dedicated to the health of America

Memo to: Lynn Margherio
Bob Potter

From: Richard A. Deem

Date: April 1, 1994

Subject: 4/6 Antitrust Meeting

Below are suggested topics for the antitrust discussion scheduled for April 6 at 9:30 a.m. in Mr. Magaziner's office:

I. Administration's position on the Hatch-Archer bill.

II. Size of health care provider joint venture networks (exclusive/non-exclusive).

III. Expansion of current DOJ Safe Harbors to allow physicians to share price information.

IV. Expanded authority for physician negotiations (not just fee for service networks).

V. Process for resolving physician negotiations.

As background information, enclosed are copies of the Hatch-Archer bill, a section by section analysis developed by minority staff of the Senate Judiciary Committee, and a white paper on antitrust relief for physician groups.

cc: Lee J. Stillwell
Ron Szabat
Scott Wilber
Janice Pieper
Karin Bierstein
Mary Jo Malone
Ed Hirshfeld
Mike Ile

II

103D CONGRESS
1ST SESSION

S. 1658

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

IN THE SENATE OF THE UNITED STATES

NOVEMBER 10 (legislative day, NOVEMBER 2), 1993

Mr. HATCH (for himself and Mr. THURMOND) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

---

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

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

SEC. 2. 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 section 3;

(2) the activity is within an additional safe harbor designated by the Attorney General under section 4; or

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

(A) while the certificate is in effect, or

(B) in the case of a certificate issued during the 2-year period beginning on the date of the enactment of this Act, at any time on or after the first day of the 2-year period that ends on the date the certificate takes effect.

(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 exempt 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. 3. SAFE HARBORS.

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

(1) COMBINATIONS WITH MARKET SHARE BELOW THRESHOLD.—Activities relating to health care services of any combination of health care providers if the number of each type or specialty of provider in question does not exceed 20 percent of the total number of such type or specialty of provider in the relevant market area.

(2) 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 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.

(3) 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.

(4) 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. Other providers may be included in the ven-

ture, but only if such other providers could not purchase, operate, or market such equipment or provide a competing service either alone or through the formation of a competing venture.

(5) 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 150 or fewer operational beds and an average daily inpatient census of less than 50 percent of such beds.

(6) 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 or service purchased in the relevant market; and

(B) the cost of the products and services purchased jointly accounts for less than 20 percent of the total revenues from all products or services sold by each participant in the joint purchasing arrangement.

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

(A) described in this section,

(B) within an additional safe harbor designated by the Attorney General under section 4,

(C) that is the subject of an application for a certificate of review under section 5, or

(D) that is deemed a submission of a notification under section 6(a)(2)(B),

without regard to whether such an activity is carried out.

SEC. 4. DESIGNATION OF ADDITIONAL SAFE HARBORS.

(a) IN GENERAL.—

(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 additional safe harbors.

(2) 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 Secretary of Health and Human Services and the Chair of the Federal Trade Commission) shall—

(A) review the proposed safe harbors submitted under paragraph (1); and

(B) submit a report to Congress describing the proposals to be included in the publication of additional safe harbors described in paragraph (3) and the proposals that are not to be so included, together with explanations therefore.

(3) 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 Secretary of Health and Human Services and the Chair of the Federal Trade Commission) shall publish in the Federal Register proposed additional safe harbors for purposes of section 2(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.

(b) CRITERIA FOR SAFE HARBORS.—In establishing safe harbors under subsection (a), 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 under subsection (a) 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. 5. 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) FORM; CONTENT.—To apply for a certificate of review, a person shall submit to the Attorney General a written application which—

(A) specifies the activities relating to the provision of health care services which satisfy

the criteria described in section 4(b) and which will be included in the certificate; and

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

(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 title. Under such procedures the Attorney General 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 4(b) for additional 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.

(4) TIMING FOR DECISION ON APPLICATION.—

(A) IN GENERAL.—Within 90 days after the Attorney General receives an application for a certificate of review, the Attorney General shall determine whether the applicant's health care market activities are in accordance with the procedures described in paragraph (3). If the Attorney General, with the concurrence of the Secretary, determines that such procedures 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 necessary to assure compliance with the appli-

cable procedures described in paragraph (3).

(B) APPLICATIONS DEEMED APPROVED.—If the Attorney General does not reject an application before the expiration of the 90-day period beginning on the date the Attorney General receives the application, the Attorney General shall be deemed to have approved the application and to have issued a certificate of review relating to the applicant's health care market activities covered under the application.

(5) EXPEDITED ACTION.—If the applicant indicates a special need for prompt disposition, the Attorney General and the Secretary may expedite action on the application, except that no certificate of review may be issued within 30 days of publication of notice in the Federal Register under subsection (b)(2).

(6) ACTIONS UPON DENIAL.—

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

(B) REQUEST FOR RECONSIDERATION.—An applicant may, within 30 days of receipt of notification that the application has been denied in whole or in part, request the Attorney General to reconsider the determination. The Attorney General, with the concurrence of the Secretary, shall notify the applicant of the determination upon reconsideration within 30 days of receipt of the request.

(C) RETURN OF DOCUMENTS.—If the Attorney General denies an application for the issuance of a certificate of review and thereafter receives from the applicant a request for the return of documents submitted by the applicant in connection with the application for the certificate, the Attorney General and the Secretary shall return to the applicant, not later than 30 days after receipt of the request, the documents and all copies of the documents available to the Attorney General and the Secretary, except to the extent that the information has been made public under an exception to the rule against public disclosure described in subsection (g)(2)(B).

(7) 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 reflect 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 submitted to the Attorney General.

(3) REVOCATION.—

(A) GROUNDS FOR REVOCATION.—In accordance with this paragraph, the Attorney General may revoke in whole or in part a cer-

tificate of review issued under this section. The following shall be considered grounds for the revocation of a certificate:

(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 4(b).

(B) REQUEST FOR COMPLIANCE INFORMATION.—If the Attorney General or 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 Sec-

retary 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 procedures for the issuance of certificates described in subsection (b)(2).

(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 any appropriate district court of the United States to set aside the determination on the ground that such determination is erroneous based on the preponderance of the evidence.

(2) NO OTHER REVIEW PERMITTED.—Except as provided in paragraph (1), no action by the Attorney General or the Secretary pursuant to this title 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.—Infor-

mation 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 privileged or confidential and 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 es-

tablishing that a person is entitled to the protections provided by such a certificate.

SEC. 6. NOTIFICATIONS PROVIDING REDUCTION IN CERTAIN PENALTIES UNDER ANTITRUST LAW FOR HEALTH CARE COOPERATIVE VENTURES.

(a) NOTIFICATIONS DESCRIBED.—

(1) SUBMISSION OF NOTIFICATION BY VENTURE.—Any party to a health care cooperative 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) ACTIVITIES DEEMED SUBMISSION OF NOTIFICATION.—The following health care cooperative ventures shall be deemed to have filed a written noti-

fication with respect to the venture under paragraph (1):

(A) SUBMISSION OF APPLICATION FOR CERTIFICATE OF REVIEW.—Any health care cooperative venture for which an application for a certificate of review is filed with the Attorney General under section 4.

(B) CERTAIN VENTURES.—Any health care cooperative venture meeting the following requirements:

(i) The venture consists of a network of non-institutional providers not greater than—

(I) in the case of a nonexclusive network in which the participating members are permitted to create or join other competing networks, 50 percent of the providers of health care services in the relevant geographic area and 50 percent of the members of the provider specialty group in the relevant market; or

(II) in the case of an exclusive network in which the participating members are not permitted to create

or join other competing networks, 35 percent of the providers of health care services in the relevant geographic area and 35 percent of the members of the provider specialty group in the relevant market.

(ii) Each member of the venture assumes substantial financial risk for the operation of the venture through risk-sharing arrangements, including (but not limited to)—

(I) the acceptance of capitation contracts;

(II) the acceptance of contracts with fee withholding mechanisms relating to the ability to meet established goals for utilization review and management; and

(III) the holding by members of significant ownership or equity interests in the venture, where the capital contributed by the members is used to fund the operational costs of the venture such as administration, marketing, and computer-operated medical

information, if the venture develops and operates comprehensive programs for utilization management and quality assurance that include controls over the use of institutional, specialized, and ancillary medical services.

(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 cooperative venture.

(B) PARTIES TO VENTURE.—Any party to a health care cooperative 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 cooperative venture for which a notification is in effect under this section shall submit information on any change in the membership of the

venture not later than 90 days after such change occurs.

(4) PUBLICATION OF NOTIFICATION.—

(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 cooperative 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). Any person who is deemed to have filed a notification under paragraph (2)(A) shall be deemed to have withdrawn the notification if the certificate of review in question is revoked or withdrawn under section 5.

(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.—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 co-operative 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 that a party to a health care cooperative 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.

SEC. 7. REVIEW AND REPORTS ON SAFE HARBORS AND CERTIFICATES OF REVIEW.

(a) IN GENERAL.—The Attorney General (in consultation with the Secretary and the Chair) shall periodically review the safe harbors described in section 3, the additional safe harbors designated under section 4, and the certificates of review issued under section 5, and—

(1) with respect to the safe harbors described in section 3, submit such recommendations to Congress as the Attorney General considers appropriate for modifications of such safe harbors;

(2) with respect to the additional safe harbors designated under section 4, issue proposed revisions

to such activities and publish the revisions in the Federal Register; and

(3) with respect to the certificates of review, submit a report to Congress on the issuance of such certificates, and shall include in the report a description of the effect of such certificates 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)(3) any recommendations of the Attorney General for legislation to improve the program for the issuance of certificates of review established under this title.

SEC. 8. RULES, REGULATIONS, AND GUIDELINES.

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

(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 additional safe harbors under section 4 and grant certificates of review under section 5, publish guidelines—

(A) to assist providers of health care services in analyzing whether the activities of such providers may be subject to a safe harbor under sections 3 or 4; and

(B) describing specific types of activities which would meet the requirements for a certificate of review under section 5, 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. 9. ESTABLISHMENT OF HHS OFFICE OF HEALTH CARE COMPETITION POLICY.

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

(b) DUTIES.—The Office shall coordinate the responsibilities of the Secretary under this Act and otherwise assist the Secretary in developing policies relating to the competitive and collaborative activities of providers of health care services.

SEC. 10. DEFINITIONS.

In this Act, 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 cooperative venture" means any activities, including attempts to enter into or perform a contract or agreement, carried out by 2 or more persons for the purpose of providing health care 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.