SPECIAL

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OFFICE OF MANAGEMENT AND BUDGET
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LEGISLATIVE REFERRAL MEMORANDUM

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SUBJECT: HHS Proposed Testimony on Medicare and Medicaid fraud and abuse prevention.

DEADLINE: NOON Tuesday, September 03,1996

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

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

COMMENTS: Hearing is scheduled for Thursday, September 5th.

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RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

LRM NO: **5431**

FILE NO: **794**

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet.
If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.
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); or
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Please include the LRM number shown above, and the subject shown below.

TO: Robert PELLICCI 395-4871
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FROM: _____ (Date)

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SUBJECT: HHS Proposed Testimony on Medicare and Medicaid fraud and abuse prevention.

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

INTRODUCTION

Mr. Chairman and members of the Subcommittee, it is a pleasure to appear before you today to discuss the very important topic of the exclusion of fraudulent providers from Medicare and Medicaid. We are seriously committed to acting aggressively to respond against all forms of fraud, waste and abuse. Excluding fraudulent providers is essential in protecting the Treasury, the Medicare Trust Funds, the state governments, and the beneficiaries.

As Senior Advisor to HCFA's Administrator, I am personally committed to controlling and eliminating health care fraud and have the full support of HCFA's Administrator Bruce Vladeck in my anti-fraud efforts. We have assumed a pro-active approach in the fight against fraud and abuse by attempting to end costly pay and chase methods. Our goal is to pay right the first time. The exclusion of fraudulent providers is an integral part of HCFA's strategy.

Until several years ago, there was little coordination between Medicare, Medicaid, the enforcement agencies, and other entities interested in curbing health care fraud and abuse. However, I am pleased to report that now significant progress is being made in our war on fraud and abuse. During this Administration, HCFA has substantially increased its efforts, forged new partnerships, and developed new strategies to ensure the integrity of the Medicare and Medicaid programs. HCFA has pioneered fraud and abuse initiatives and financed state-of-the-art information technologies to detect and deter fraud and abuse. Although we still face significant

challenges and have much work before us, we are achieving many successes in our efforts to strengthen, preserve, and protect the Medicare and Medicaid programs.

I would like to explain the process by which a provider or supplier is excluded from either the Medicare or Medicaid programs.

PROVIDER EXCLUSION PROCESS

When HCFA discovers a potentially fraudulent situation, it takes immediate action to protect the Medicare Trust Fund and the beneficiary by suspending or denying payment and recovering overpayments. HCFA does not have independent authority to remove fraudulent or abusive providers from the Medicare or Medicaid programs. It is the HHS-Office of the Inspector General (OIG) that has this authority to impose exclusions. HCFA refers cases to the OIG and assists in the investigations. Further, we cooperate with other enforcement agencies such as the Medicaid Fraud Control Units, the Department of Justice, the Federal Bureau of Investigation, and the U.S. Attorney's office.

Once a provider has been excluded from either Medicare or Medicaid, the OIG informs HCFA, its contractors, state Medicaid and licensure agencies, and others. The OIG also publishes a list of excluded providers quarterly in the *Federal Register*. All Medicare claims processors and states work to ensure that providers being paid or applying for billing numbers are not currently under an exclusion.

HCFA is currently using technology in new ways as well as strengthening the enrollment process so that excluded providers remain excluded and do not attempt to re-enter Medicare or Medicaid by moving to a new state or setting up a new business under a new provider or tax identification number.

EXCLUSION TOOLS and INITIATIVES

1. Fraud Investigation Database (FID)

One of HCFA's most promising initiatives in assisting in the exclusion of fraudulent providers is the Fraud Investigation Database (FID). We began implementing the FID in May, and expect to have complete up-to-date information by December. The FID is a case-tracking system to record and disseminate information regarding exclusions. It will contain extensive national Medicare and Medicaid fraud data as well as comprehensive information on all excluded providers. The FID is intended to assist HCFA and our partners in the identification of excluded providers as well as those who are allegedly defrauding the programs. For example, a Medicare contractor in one area can use this information to ensure that the providers it is reimbursing have not been excluded through the actions of another contractor.

In an effort to enhance coordination of the exclusion process, the FID is also accessible to the Medicaid anti-fraud agencies such as the Medicaid Fraud Control Units and the Surveillance and Utilization Review Systems. We expect to soon be able to obtain data from these Medicaid entities on cases and information related to the providers that they suspect to be fraudulent.

The FID is also designed to ensure the coordination of anti-fraud activities undertaken by our law enforcement partners and to facilitate the monitoring of cases referred to the OIG, the FBI or the U.S. Attorneys. We are pleased to report that several other federal government entities, including the OIGs of the Postal Service, Office of Personnel Management, and the Department of Labor, are in the process of acquiring access to the FID. It is our goal to make sure that a provider who defrauds Medicare or Medicaid cannot defraud other Federal programs.

2. National Provider Identifier System

HCFA is currently leading a joint Federal and State initiative to establish and maintain a comprehensive, unified system of provider identifiers. This system will build upon the success we have achieved in the issuance of unique billing numbers for medical equipment suppliers. With unique provider identifiers we will have the enhanced ability to verify information for each provider seeking to bill Medicare. In the past, this verification and the issuance of billing numbers has been independently done by each of the 70 Medicare contractors, leading to different numbering methodologies and an inability to create a central Medicare database for the verification of provider eligibility. In general, a provider will have only one billing number regardless of the number of Medicare contractors that it bills. Under the National Provider Identifier System, one number (i.e. the National Provider Identifier - NPI) can be used for ALL Medicare billing.

The use of the National Provider Identifier System will help to ensure that only legitimate health care providers are enrolled in the Medicare program. This will occur through the identification of

providers that have been excluded from Medicare reimbursement. Further, as Medicaid and other government programs adopt the NPIs, providers can no longer hide from their Medicare exclusions and other adverse actions through the use of a separate Medicaid or other Federal health care program number.

The Health Insurance Portability and Accountability Act of 1996, which I will discuss later, expands upon HCFA's efforts to create a standard system of provider billing numbers, by requiring the Secretary of HHS to adopt standards for providing a unique identifier for every provider for all health care programs. We are in the process of making sure that the requirements of this Act are consistent with our plans to have the National Provider Identifier System operational. We are also working to encourage states and private payers to also adopt the NPIs.

3. How the Medicare Transaction System Will Assist in Fraud Detection and Provider Exclusion

HCFA is in the process of developing an automated Medicare claims processing and information system, which will, among other things, assist in our provider exclusion efforts. The Medicare Transaction System (MTS) has been designed to consolidate the currently fragmented Medicare claims processing into one standardized system. MTS will greatly improve HCFA's ability to profile data on a national or regional basis by type of service. We plan to use these profiles to identify and review aberrant billing patterns and to prevent inappropriate claims from being paid in the first place, thus avoiding the need to chase down those fraudulent claims that have already been paid. The MTS will integrate data from Medicare Part A, Part B, and managed care and

provide the opportunity to build on best practices in information systems and to incorporate new technology to facilitate innovative investigative techniques.

One of the many benefits of the MTS will be its enhanced ability to keep out fraudulent providers. The MTS is designed to use the National Provider Identifier System. This system, as I mentioned previously, will be a record of all providers and suppliers who are certified to bill Medicare for medical services or equipment provided to our beneficiaries. If a provider is excluded from the Medicare program, or has been identified as fraudulent, that provider will be flagged in the database. This database will be accessed before the claim is paid.

The MTS will improve our ability to coordinate claims processing with medical and fraud review. When a bill or claim is entered into the MTS from an excluded provider or supplier, payment will be denied. Additionally, the OIG can levy a civil monetary penalty on any excluded provider who continues to bill Medicare or Medicaid. We have a civil monetary penalty case tracking system, which will use the claim submission information from MTS to assist in identifying excluded providers and ensuring that they do not continue to bill.

4. The National Supplier Clearinghouse

HCFA established the National Supplier Clearinghouse (NSC) to enroll suppliers of durable medical equipment and supplies in Medicare. The NSC verifies supplier data on all applications and matches suppliers, owners, and managing employees listed on new applications to a file of all

equipment suppliers to ensure that there has been no previous history of fraudulent or abusive practices by any of the listed individuals. If a previous history is noted, the application is denied.

The NSC also verifies that medical equipment suppliers meet Medicare standards. If the NSC determines that the standards are not met, then it will not issue a Medicare billing number. Further, any supplier found to be out of compliance with these standards will have its Medicare billing number revoked. Additionally, there is a re-enrollment process every three years, which prohibits suppliers no longer in compliance with standards to retain their Medicare billing numbers and provides the NSC with updated information. The NSC has recently revoked approximately 1,300 supplier numbers during the latest round of re-enrollment.

The NSC is also investigating oxygen licensure requirements. This would help to ensure that a supplier is legitimate before claims for oxygen or related services are paid by Medicare. As a result of this effort, the NSC has revoked almost 600 oxygen supplier numbers for improper, invalid, non-existent, or otherwise incorrect licensure information.

To date, the NSC system has saved the Medicare program millions of dollars and was instrumental in our response to fraud in the South Florida area which I will address shortly.

5. New Enrollment Application

Presently, HCFA is very limited in its ability to deny providers entry into the program and, more importantly, to make the Medicare provider enrollment process a fraud and abuse prevention tool.

We are in the process of using our administrative authority to expand our efforts at preventing fraudulent providers from continuing to bill Medicare.

We are currently drafting a regulation that would establish new supplier standards and make it more difficult to abuse the use of a Medicare billing number. This will help to ensure that legitimate suppliers' information will not be used by fraudulent suppliers to obtain Medicare billing numbers, thereby protecting both the beneficiary and the legitimate suppliers from fraudulent and unprincipled suppliers. The proposed regulation is scheduled to be out for comment later this year.

HCFA is also implementing improved, standard Medicare provider and supplier enrollment procedures which increase the standards for enrollment in the Medicare program. And, for the first time all Medicare contractors will use the same provider enrollment form. I am pleased to report that in May, HCFA received approval from the Office of Management and Budget to use the new Medicare Provider/Supplier Enrollment application for providers and suppliers not certified through state survey and certification procedures.

The best way to fight fraud is to allow only honest players into the game. By improving the provider enrollment process and raising the standards for participation in both Medicare and Medicaid, HCFA hopes to avoid fraud in the first place.

6. Boston Provider Exclusion Project

HCFA's Boston regional office is currently conducting a review of state policy and procedures involving excluded Medicaid providers in Massachusetts. This review is designed to identify the best practices and make recommendations to other regions about provider exclusion practices that they use. HCFA believes that the Boston review may prove to have national applicability and we will encourage other regions to conduct similar reviews.

7. National Practitioner Data Bank

In addition to the above mentioned tools, HCFA is facilitating the dissemination of information on physicians, and other licensed health care providers concerning malpractice payments, licensure actions, and clinical privilege actions through the National Practitioner Data Bank (NPDB) which is maintained by the Public Health Service. The NPDB assists state licensing boards, hospitals and managed care organizations in conducting investigations of the qualifications of the health care practitioners they seek to license, to hire, or to whom they wish to grant membership or clinical privileges. To perform a thorough investigation of a practitioner's qualifications, these entities also need to know whether or not a practitioner has been excluded from Medicare or Medicaid. HCFA is entering into an agreement with the Public Health Service whereby we will provide a list of excluded providers to be posted on the NPDB. Having the NPDB identify excluded providers will help to prevent prohibited employment arrangements as well as inappropriate Medicare and Medicaid payments. Further, it will reduce the level of effort and redundancy for both the health care industry and the Federal government by having the NPDB distribute the exclusion reports to authorized health care entities, in addition to their own reports.

ADDITIONAL ANTI-FRAUD INITIATIVES

1. The South Florida Task Force

As I mentioned earlier, the NSC's monitoring system became instrumental in HCFA's response to fraud in the South Florida area. South Florida has consistently proven to be a problem area for health care fraud.

In 1994, HCFA launched a task force to attack fraud and abuse in South Florida. Medicare contractors, Medicaid state agencies, U.S. Attorneys, and Medicaid Fraud Control Units worked together to detect fraudulent billing practices in Medicare and Medicaid. In one of the joint activities, the group matched Medicare and Medicaid data, thereby making it easier to identify patterns of aberrant billing. For instance, when the South Florida task force identified medical equipment suppliers as a source of fraud, HCFA met with the NSC, the Medicare contractor, the Florida Medicaid program, and the Florida state licensing agency to obtain their input in developing improved supplier applications.

Building on the success of the South Florida Task Force, similar workgroups have now formed in a dozen states. Further, HCFA also opened an office in Miami in September 1995, to focus on minimizing fraud and abuse. This office supports the investigative and law enforcement efforts of several of our partners, including the FBI, the U.S. Attorney's office, and the contractors. It also conducts outreach and educational activities. The NSC is also establishing on-site representation in the South Florida area to conduct extensive site visits of Medicare supplier billing number applicants to ensure legitimacy.

2. Operation Restore Trust

Based upon HCFA's successful experience in South Florida, the Secretary launched a two-year demonstration in which HCFA, the OIG and the Administration on Aging formed a partnership with federal and state law enforcement agencies. This partnership, known as Operation Restore Trust (ORT), has been aggressively cracking down on Medicare and Medicaid fraud and abuse. The ORT demonstration targets the five states which together account for 40 percent of all Medicare and Medicaid beneficiaries -- New York, Florida, Illinois, Texas, and California.

With a first-year budget of about $4 million dollars, ORT has identified approximately $39 million dollars that should be returned to the Medicare Trust funds due to restitutions, settlements and recovery of overpayments. Under the Health Insurance Portability and Accountability Act, additional funds may be available to expand this demonstration project nationwide.

3. Attacking Medicaid Fraud

The Medicaid programs are run by the states, with guidance and technical assistance from HCFA. HCFA's role in attacking Medicaid fraud is therefore primarily to provide resources and technical assistance that facilitates the exchange of information.

In recent years, HCFA has devoted greater attention to cooperating with states and other entities to attack Medicaid fraud and abuse. HCFA is providing increased technical assistance and encouragement for Medicaid anti-fraud programs. We are working to improve the exchange of information between Medicare and the nation's 54 Medicaid programs, including federal and state

law enforcement agencies. Since states administer Medicaid, states cooperate with Medicaid Fraud Control Units, which are federal-state funded entities devoted to investigate Medicaid fraud. The OIG, FBI, U.S. Attorney, and state Attorney Generals are also involved in Medicaid investigation and prosecution.

Medicaid Fraud and Abuse Network

In conjunction with Medicaid anti-fraud efforts, HCFA has recently established the Medicaid Fraud and Abuse Network which is comprised of employees from HCFA's central and regional offices. This Medicaid Network serves as a forum to coordinate anti-fraud activities, provide an information clearinghouse, and initiate Medicaid anti-fraud prevention projects. HCFA also has developed partnerships with states' Surveillance and Utilization Review Systems (SURs) Units and states' Medicaid Fraud Control Units (MFCUs) to facilitate the detection, referral, and ultimate prosecution of Medicaid fraud and abuse cases.

Medicaid Fraud and Abuse Coordinating Council

As a result of the SURs/MFCUs joint effort, HCFA has established the Medicaid Fraud and Abuse Coordinating Council (Medicaid Council). It provides a forum to exchange ideas; to discuss and resolve problems which may arise between SURs and MFCUs; and to sponsor workshops, conferences, and seminars involving anti-fraud issues.

HCFA is currently conducting training sessions sponsored by the Medicaid Council to ensure that all states, along with the OIG and the FBI, have an opportunity to participate in anti-fraud

managed care workshops. National associations on behalf of SURs and MFCUs have also agreed to jointly develop a cross-training program designed to enhance their communications and to ensure that the two entities work together more closely.

LEGISLATIVE ANTI-FRAUD AND ABUSE INITIATIVES

As the Subcommittee has requested, I would now like to address the potential impact of recently enacted legislation.

Health Insurance Portability and Accountability Act of 1996 **(P. L. 104 - 191)**

As a result of Congress reaching a bipartisan agreement on health insurance reform, President Clinton was able to sign into law the Health Insurance Portability and Accountability Act of 1996. We wish to thank Subcommittee members and all of the many members of Congress who worked to successfully pass this legislation. This new law is designed to ensure that workers changing their jobs can keep their health insurance. It also includes strong anti-fraud and abuse measures. Passage of this Act is most encouraging to this Administration. At this time, I would like to share with you a brief description of these anti-fraud provisions and HCFA's recommendations for further improvements.

The new health insurance law creates the Health Care Fraud and Abuse Control Program to be coordinated by HCFA, OIG, and the Attorney General. The program, which will fight fraud in Medicare, Medicaid and private health plans, is funded by mandatory appropriations from the Medicare Hospital Insurance Trust Fund and the general fund of the Treasury. Under the auspices of the Control Program, HHS may have the resources to implement Operation Restore Trust

nationwide. Building upon the successes of the five-state demonstration project, HCFA will be able to coordinate with the OIG, the state agencies, as well as law enforcement to fight fraud in both Medicare and Medicaid, and to ensure that a provider that defrauds one program is not able to defraud the other.

The new health insurance law also adds new mandatory exclusions from Medicare and Medicaid for felony convictions related to health care fraud or controlled substances. It allows the Secretary to exclude providers convicted of misdemeanors related to health care fraud from the Medicare and Medicaid programs for a minimum of three years. It also adds new permissive exclusions from Medicare and Medicaid for individuals whose health care licenses have been revoked or suspended, or for individuals controlling a sanctioned entity. Further, where a practitioner has failed to successfully complete a Peer Review Organization corrective action plan, or has grossly failed to meet quality standards, the Secretary may exclude them from Medicare for a minimum of one year.

The new law also expands all Medicare and Medicaid criminal provisions to all federal health programs and establishes new civil money penalties and extends many current Medicaid and Medicare civil money penalties to all federal health care programs.

We view the Health Insurance Portability and Accountability Act of 1996 as a major breakthrough, and note that it contains many of the anti-fraud provisions that the Administration has been seeking. However, there are three major differences in this bill from the President's bill.

Recommendations for Improvement:

The Act creates the Adverse Action Data Base to identify providers that have either been sanctioned or excluded, i.e. those providers that have been subject to a final adverse action. However, the provision prohibits the inclusion of data on "settlements in which no findings of liability have been made." Many final adverse actions are the product of settlements of cases, and characteristically, no findings of liability are made. This provision may encourage many other providers that would currently admit liability to challenge HHS's determinations of their behavior with the goal of entering into a settlement which avoids being listed in the data bank. If significantly larger number of providers do this, the data bank will then list only a fraction of fraudulent providers thereby becoming much less effective. The President's bill had proposed to include final adverse actions resulting from settlements, providing the Administration with comprehensive data on adverse actions.

Second, the new law weakens the penalties for fraudulent claims. Under the new law, the government now has to prove that providers acted with "deliberate ignorance" or "reckless disregard." Previously, we could levy penalties on providers for submitting fraudulent claims if we could prove that they "should have known" the claim was fraudulent.

Third, the new law, unlike the President's bill, requires advisory opinions. The OIG has stated that advisory opinions on intent-based statutes (such as the anti-kickback statute) are impractical if not impossible. Because of the inherently subjective, factual nature of intent, it would be

impossible for HHS to determine intent based solely upon a written submission from the requestor.

Debt Collection Improvement Act of 1996 - P. L. 104 - 134

This past April, President Clinton signed into law the Omnibus Consolidated Rescissions and Appropriations Act of 1996, which includes a provision known as the Debt Collection Improvement Act. The Debt Collection Improvement Act is intended to facilitate collections by the Federal Government and encourage the coordination of information within and among Federal agencies and streamline procedures. This Act permits HCFA to require that its providers and suppliers indicate their tax identification number when submitting a Medicare enrollment application. However, at this time it is unclear how this provision will provide an additional tool to improve our ability to deny entry into Medicare to fraudulent and unscrupulous providers and suppliers. We believe that additional legislation that would allow us to collect Social Security Numbers would be helpful.

CONCLUSION

Since Medicare and Medicaid first began three decades ago, millions of Americans have been helped in paying their medical bills. It is most appropriate that as the 30th Anniversary of Medicare and Medicaid is celebrated, HCFA is even more committed to ensuring that 70 million of our most vulnerable Americans continue to have access to high quality and cost-effective health care. HCFA is committed to act aggressively to pursue all forms of waste, fraud, and abuse.

As we enter the 21st century, HCFA is actively transforming its computer technology to keep pace with the many rapid changes occurring in the health care field. The implementation of information technology is essential in combating and preventing fraud and abuse. Further, we are forging new partnerships to increase cooperation among the federal agencies, state entities, and private industry, to protect the Medicare and Medicaid programs from fraud, waste, and abuse. HCFA and I look forward to working with this Subcommittee and other interested members of Congress in implementing its health care fraud and abuse initiatives.

U.S. Department of Justice
Office of Legislative Affairs

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

FAX COVER SHEET

DATE: 6/18/96

TO: Jennifer Klein

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NO. OF PAGES: 2 (EXCLUDING COVER)

COMMENTS: I will call you shortly to discuss the Senate provision for enhanced anti-kickback guidance that is marked on the attached sheets (§ 505).

"(i) No payment may be made for carrying out any activity pursuant to an agreement under this section to the extent that the activity is carried out pursuant to a contract under the Medicare Integrity Program under section 1893.".

(2) RESPONSIBILITIES OF CARRIERS UNDER PART B.—Section 1842(c) (42 U.S.C. 1395u(c)) is amended by adding at the end the following new paragraph:

"(6) No payment may be made for carrying out any activity pursuant to a contract under this subsection to the extent that the activity is carried out pursuant to a contract under the Medicare Integrity Program under section 1893. The previous sentence shall not apply with respect to the activity described in section 1893(b)(5) (relating to prior authorization of certain items of durable medical equipment under section 1834(a)(15)).".

SEC. 503. BENEFICIARY INCENTIVE PROGRAMS.

(a) CLARIFICATION OF REQUIREMENT TO PROVIDE EXPLANATION OF MEDICARE BENEFITS.—The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall provide an explanation of benefits under the medicare program under title XVIII of the Social Security Act with respect to each item or service for which payment may be made under the program which is furnished to an individual, without regard to whether or not a deductible or coinsurance may be imposed against the individual with respect to the item or service.

(b) PROGRAM TO COLLECT INFORMATION ON FRAUD AND ABUSE.—

(1) ESTABLISHMENT OF PROGRAM.—Not later than 3 months after the date of the enactment of this Act, the Secretary shall establish a program under which the Secretary shall encourage individuals to report to the Secretary information on individuals and entities who are engaging or who have engaged in acts or omissions which constitute grounds for the imposition of a sanction under section 1128, section 1128A, or section 1128B of the Social Security Act, or who have otherwise engaged in fraud and abuse against the medicare program for which there is a sanction provided under law. The program shall discourage provision of, and not consider, information which is frivolous or otherwise not relevant or material to the imposition of such a sanction.

(2) PAYMENT OF PORTION OF AMOUNTS COLLECTED.—If an individual reports information to the Secretary under the program established under paragraph (1) which serves as the basis for the collection by the Secretary or the Attorney General of any amount of at least $100 (other than any amount paid as a penalty under section 1128B of the Social Security Act), the Secretary may pay a portion of the amount collected to the individual (under procedures similar to those applicable under section 7623 of the Internal Revenue Code of 1986 to payments to individuals providing information on violations of such Code).

(c) PROGRAM TO COLLECT INFORMATION ON PROGRAM EFFICIENCY.—

(1) ESTABLISHMENT OF PROGRAM.—Not later than 3 months after the date of the enactment of this Act, the Secretary shall establish a program under which the Secretary shall encourage individuals to submit to the Secretary suggestions on methods to improve the efficiency of the medicare program.

(2) PAYMENT OF PORTION OF PROGRAM SAVINGS.—If an individual submits a suggestion to the Secretary under the program established under paragraph (1) which is adopted by the Secretary and which results in savings to the program, the Secretary may make a payment to the individual of such amount as the Secretary considers appropriate.

SEC. 504. APPLICATION OF CERTAIN HEALTH ANTI-FRAUD AND ABUSE SANCTIONS TO FRAUD AND ABUSE AGAINST FEDERAL HEALTH CARE PROGRAMS.

(a) IN GENERAL.—Section 1128B (42 U.S.C. 1320a-7b) is amended as follows:

(1) In the heading, by striking "MEDICARE OR STATE HEALTH CARE PROGRAMS" and inserting "FEDERAL HEALTH CARE PROGRAMS".

(2) In subsection (a)(1), by striking "a program under title XVIII or a State health care program (as defined in section 1128(h))" and inserting "a Federal health care program".

(3) In subsection (a)(5), by striking "a program under title XVIII or a State health care program" and inserting "a Federal health care program".

(4) In the second sentence of subsection (a)—

(A) by striking "a State plan approved under title XIX" and inserting "a Federal health care program", and

(B) by striking "the State may at its option (notwithstanding any other provision of that title or of such plan)" and inserting "the administrator of such program may at its option (notwithstanding any other provision of such program)".

(5) In subsection (b), by striking "title XVIII or a State health care program" each place it appears and inserting "a Federal health care program".

(6) In subsection (c), by inserting "(as defined in section 1128(h))" after "a State health care program".

(7) By adding at the end the following new subsection:

"(f) For purposes of this section, the term 'Federal health care program' means—

"(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of title 5, United States Code); or

"(2) any State health care program, as defined in section 1128(h).".

(b) EFFECTIVE DATE.—The amendments made by this section shall take effect on January 1, 1997.

SEC. 505. GUIDANCE REGARDING APPLICATION OF HEALTH CARE FRAUD AND ABUSE SANCTIONS.

Title XI (42 U.S.C. 1301 et seq.), as amended by section 501, is amended by inserting after section 1128C the following new section:

"GUIDANCE REGARDING APPLICATION OF HEALTH CARE FRAUD AND ABUSE SANCTIONS

"SEC. 1128D. (a) SOLICITATION AND PUBLICATION OF MODIFICATIONS TO EXISTING SAFE HARBORS AND NEW SAFE HARBORS.—

"(1) IN GENERAL.—

"(A) SOLICITATION OF PROPOSALS FOR SAFE HARBORS. Not later than January 1, 1997, and not less than annually thereafter, the Secretary shall publish a notice in the Federal Register soliciting proposals, which will be accepted during a 60-day period, for—

"(i) modifications to existing safe harbors issued pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 (42 U.S.C. 1320a-7b note);

"(ii) additional safe harbors specifying payment practices that shall not be treated as a criminal offense under section 1128B(b) and shall not serve as the basis for an exclusion under section 1128(b)(7);

"(iii) interpretive rulings to be issued pursuant to subsection (b); and

"(iv) special fraud alerts to be issued pursuant to subsection (c).

"(B) PUBLICATION OF PROPOSED MODIFICATIONS AND PROPOSED ADDITIONAL SAFE HARBORS.—After considering the proposals described in clauses (i) and (ii) of subparagraph (A), the Secretary, in consultation with the Attorney General, shall publish in the Federal Register proposed modifications to existing safe harbors and proposed additional safe harbors, if appropriate, with a 60-day comment period. After considering any public comments received during this period, the Secretary shall issue final rules modifying the existing safe harbors and establishing new safe harbors as appropriate.

"(C) REPORT.—The Inspector General of the Department of Health and Human Services (in this section referred to as the 'Inspector General') shall, in an annual report to Congress or as part of the year-end semiannual report required by section 5 of the Inspector General Act of 1978 (5 U.S.C. App.), describe the proposals received under clauses (i) and (ii) of subparagraph (A) and explain which proposals were included in the publication described in subparagraph (B), which proposals were not included in that publication, and the reasons for the rejection of the proposals that were not included.

"(2) CRITERIA FOR MODIFYING AND ESTABLISHING SAFE HARBORS.—In modifying and establishing safe harbors under paragraph (1)(B), the Secretary may consider the extent to which providing a safe harbor for the specified payment practice may result in any of the following:

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

"(B) An increase or decrease in the quality of health care services.

"(C) An increase or decrease in patient freedom of choice among health care providers.

"(D) An increase or decrease in competition among health care providers.

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

"(F) An increase or decrease in the cost to Federal health care programs (as defined in section 1128B(f)).

"(G) An increase or decrease in the potential overutilization of health care services.

"(H) The existence or nonexistence of any potential financial benefit to a health care professional or provider, which may vary based on their decisions of—

"(i) whether to order a health care item or service; or

"(ii) whether to arrange for a referral of health care items or services to a particular practitioner or provider.

"(I) Any other factors the Secretary deems appropriate in the interest of preventing fraud and abuse in Federal health care programs (as so defined).

"(b) INTERPRETIVE RULINGS.—

"(1) IN GENERAL.—

"(A) REQUEST FOR INTERPRETIVE RULING.—Any person may present, at any time, a request to the Inspector General for a statement of the Inspector General's current interpretation of the meaning of a specific aspect of the application of sections 1128A and 1128B (in this section referred to as an 'interpretive ruling').

"(B) ISSUANCE AND EFFECT OF INTERPRETIVE RULING.—

"(i) IN GENERAL.—If appropriate, the Inspector General shall in consultation with the Attorney General, issue an interpretive ruling not later than 90 days after receiving a request described in subparagraph (A). Interpretive rulings shall not have the force of law and shall be treated as an interpretive rule within the meaning of section 553(b) of title 5, United States Code. All interpretive rulings issued pursuant to this clause shall be published in the Federal Register or otherwise made available for public inspection.

"(ii) REASONS FOR DENIAL.—If the Inspector General does not issue an interpretive ruling in response to a request described in subparagraph (A), the Inspector General shall notify the requesting party of such decision not later than 60 days after receiving such a request and shall identify the reasons for such decision.

"(2) CRITERIA FOR INTERPRETIVE RULINGS.—

"(A) IN GENERAL.—In determining whether to issue an interpretive ruling under paragraph (1)(B), the Inspector General may consider—

"(i) whether and to what extent the request identifies an ambiguity within the language of the statute, the existing safe harbors, or previous interpretive rulings; and

"(ii) whether the subject of the requested interpretive ruling can be adequately addressed by

interpretation of the language of the statute, the existing safe harbor rules, or previous interpretive rulings, or whether the request would require a substantive ruling (as defined in section 552 of title 5, United States Code) not authorized under this subsection.

"(B) NO RULINGS ON FACTUAL ISSUES.—The Inspector General shall not give an interpretive ruling on any factual issue, including the intent of the parties or the fair market value of particular leased space or equipment.

"(c) SPECIAL FRAUD ALERTS.—

"(1) IN GENERAL.—

"(A) REQUEST FOR SPECIAL FRAUD ALERTS.—Any person may present, at any time, a request to the Inspector General for a notice which informs the public of practices which the Inspector General considers to be suspect or of particular concern under the medicare program or a State health care program, as defined in section 1128(h) (in this subsection referred to as a 'special fraud alert').

"(B) ISSUANCE AND PUBLICATION OF SPECIAL FRAUD ALERTS.—Upon receipt of a request described in subparagraph (A), the Inspector General shall investigate the subject matter of the request to determine whether a special fraud alert should be issued. If appropriate, the Inspector General shall issue a special fraud alert in response to the request. All special fraud alerts issued pursuant to this subparagraph shall be published in the Federal Register.

"(2) CRITERIA FOR SPECIAL FRAUD ALERTS.—In determining whether to issue a special fraud alert upon a request described in paragraph (1), the Inspector General may consider—

"(A) whether and to what extent the practices that would be identified in the special fraud alert may result in any of the consequences described in subsection (a)(2); and

"(B) the volume and frequency of the conduct that would be identified in the special fraud alert."

Subtitle B—Revisions to Current Sanctions for Fraud and Abuse

SEC. 511. MANDATORY EXCLUSION FROM PARTICIPATION IN MEDICARE AND STATE HEALTH CARE PROGRAMS.

(a) INDIVIDUAL CONVICTED OF FELONY RELATING TO HEALTH CARE FRAUD.—

(1) IN GENERAL.—Section 1128(a) (42 U.S.C. 1320a–7(a)) is amended by adding at the end the following new paragraph:

"(3) FELONY CONVICTION RELATING TO HEALTH CARE FRAUD.—Any individual or entity that has been convicted after the date of the enactment of the Health Insurance Reform Act of 1996, under Federal or State law, in connection with the delivery of a health care item or service or with respect to any act or omission in a health care program (other than those specifically described in paragraph (1)) operated by or financed in whole or in part by any Federal, State, or local government agency, of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.".

(2) CONFORMING AMENDMENT.—Paragraph (1) of section 1128(b) (42 U.S.C. 1320a–7(b)) is amended to read as follows:

"(1) CONVICTION RELATING TO FRAUD.—Any individual or entity that has been convicted after the date of the enactment of the Health Insurance Reform Act of 1996, under Federal or State law—

"(A) of a criminal offense consisting of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

"(i) in connection with the delivery of a health care item or service, or

"(ii) with respect to any act or omission in a health care program (other than those specifically described in subsection (a)(1)) operated by or financed in whole or in part by any Federal, State, or local government agency; or

"(B) of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct with respect to any act or omission in a program (other than a health care program) operated by or financed in whole or in part by any Federal, State, or local government agency.".

(b) INDIVIDUAL CONVICTED OF FELONY RELATING TO CONTROLLED SUBSTANCE.—

(1) IN GENERAL.—Section 1128(a) (42 U.S.C. 1320a–7(a)), as amended by subsection (a), is amended by adding at the end the following new paragraph:

"(4) FELONY CONVICTION RELATING TO CONTROLLED SUBSTANCE.—Any individual or entity that has been convicted after the date of the enactment of the Health Insurance Reform Act of 1996, under Federal or State law, of a criminal offense consisting of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.".

(2) CONFORMING AMENDMENT.—Section 1128(b)(3) (42 U.S.C. 1320a–7(b)(3)) is amended—

(A) in the heading, by striking "CONVICTION" and inserting "MISDEMEANOR CONVICTION"; and

(B) by striking "criminal offense" and inserting "criminal offense consisting of a misdemeanor".

SEC. 512. ESTABLISHMENT OF MINIMUM PERIOD OF EXCLUSION FOR CERTAIN INDIVIDUALS AND ENTITIES SUBJECT TO PERMISSIVE EXCLUSION FROM MEDICARE AND STATE HEALTH CARE PROGRAMS.

Section 1128(c)(3) (42 U.S.C. 1320a–7(c)(3)) is amended by adding at the end the following new subparagraphs:

"(D) In the case of an exclusion of an individual or entity under paragraph (1), (2), or (3) of subsection (b), the period of the exclusion shall be 3 years, unless the Secretary determines in accordance with published regulations that a shorter period is appropriate because of mitigating circumstances or that a longer period is appropriate because of aggravating circumstances.

"(E) In the case of an exclusion of an individual or entity under subsection (b)(4) or (b)(5), the period of the exclusion shall not be less than the period during which the individual's or entity's license to provide health care is revoked, suspended, or surrendered, or the individual or the entity is excluded or suspended from a Federal or State health care program.

"(F) In the case of an exclusion of an individual or entity under subsection (b)(6)(B), the period of the exclusion shall be not less than 1 year.".

SEC. 513. PERMISSIVE EXCLUSION OF INDIVIDUALS WITH OWNERSHIP OR CONTROL INTEREST IN SANCTIONED ENTITIES.

Section 1128(b) (42 U.S.C. 1320a–7(b)) is amended by adding at the end the following new paragraph:

"(15) INDIVIDUALS CONTROLLING A SANCTIONED ENTITY.—(A) Any individual—

"(i) who has a direct or indirect ownership or control interest in a sanctioned entity and who knows or should know (as defined in section 1128A(i)(6)) of the action constituting the basis for the conviction or exclusion described in subparagraph (B); or

"(ii) who is an officer or managing employee (as defined in section 1126(b)) of such an entity.

"(B) For purposes of subparagraph (A), the term 'sanctioned entity' means an entity—

"(i) that has been convicted of any offense described in subsection (a) or in paragraph (1), (2), or (3) of this subsection; or

"(ii) that has been excluded from participation under a program under title XVIII or under a State health care program.".

SEC. 514. SANCTIONS AGAINST PRACTITIONERS AND PERSONS FOR FAILURE TO COMPLY WITH STATUTORY OBLIGATIONS.

(a) MINIMUM PERIOD OF EXCLUSION FOR PRACTITIONERS AND PERSONS FAILING TO MEET STATUTORY OBLIGATIONS.—

(1) IN GENERAL.—The second sentence of section 1156(b)(1) (42 U.S.C. 1320c–5(b)(1)) is amended by striking "may prescribe)" and inserting "may prescribe, except that such period may not be less than 1 year)".

(2) CONFORMING AMENDMENT.—Section 1156(b)(2) (42 U.S.C. 1320c–5(b)(2)) is amended by striking "shall remain" and inserting "shall (subject to the minimum period specified in the second sentence of paragraph (1)) remain".

(b) REPEAL OF "UNWILLING OR UNABLE" CONDITION FOR IMPOSITION OF SANCTION.—Section 1156(b)(1) (42 U.S.C. 1320c–5(b)(1)) is amended—

(1) in the second sentence, by striking "and determines" and all that follows through "such obligations,"; and

(2) by striking the third sentence.

SEC. 515. INTERMEDIATE SANCTIONS FOR MEDICARE HEALTH MAINTENANCE ORGANIZATIONS.

(a) APPLICATION OF INTERMEDIATE SANCTIONS FOR ANY PROGRAM VIOLATIONS.—

(1) IN GENERAL.—Section 1876(i)(1) (42 U.S.C. 1395mm(i)(1)) is amended by striking "(the Secretary may terminate" and all that follows and inserting "in accordance with procedures established under paragraph (9), the Secretary may at any time terminate any such contract or may impose the intermediate sanctions described in paragraph (6)(B) or (6)(C) (whichever is applicable) on the eligible organization if the Secretary determines that the organization—

"(A) has failed substantially to carry out the contract;

"(B) is carrying out the contract in a manner substantially inconsistent with the efficient and effective administration of this section; or

"(C) no longer substantially meets the applicable conditions of subsections (b), (c), (e), and (f).".

(2) OTHER INTERMEDIATE SANCTIONS FOR MISCELLANEOUS PROGRAM VIOLATIONS.—Section 1876(i)(6) (42 U.S.C. 1395mm(i)(6)) is amended by adding at the end the following new subparagraph:

"(C) In the case of an eligible organization for which the Secretary makes a determination under paragraph (1) the basis of which is not described in subparagraph (A), the Secretary may apply the following intermediate sanctions:

"(i) Civil money penalties of not more than $25,000 for each determination under paragraph (1) if the deficiency that is the basis of the determination has directly adversely affected (or has the substantial likelihood of adversely affecting) an individual covered under the organization's contract.

"(ii) Civil money penalties of not more than $10,000 for each week beginning after the initiation of procedures by the Secretary under paragraph (9) during which the deficiency that is the basis of a determination under paragraph (1) exists.

"(iii) Suspension of enrollment of individuals under this section after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the deficiency that is the basis for the determination has been corrected and is not likely to recur.".

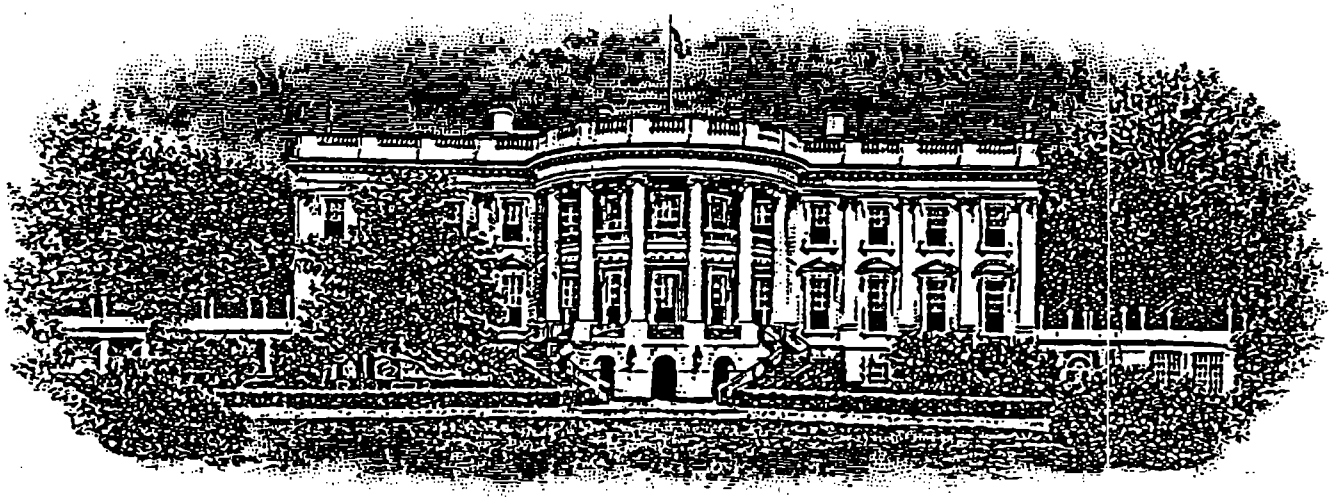
(3) PROCEDURES FOR IMPOSING SANCTIONS.—Section 1876(i) (42 U.S.C. 1395mm(i)) is amended by adding at the end the following new paragraph:

"(9) The Secretary may terminate a contract with an eligible organization under this section or may impose the intermediate sanctions described in paragraph (6) on the organization in accordance with formal investigation and compliance procedures established by the Secretary under which—

"(A) the Secretary first provides the organization with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the Secretary's determination under paragraph (1) and the organization fails to develop or implement such a plan;

"(B) in deciding whether to impose sanctions, the Secretary considers aggravating factors such

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Jennifer Klein

FAX NUMBER: 6-2878

TELEPHONE NUMBER:

FROM: Chris G

TELEPHONE NUMBER:

PAGES (INCLUDING COVER):

COMMENTS:

TO: John

FROM: Andy

DATE: June 17

RE: Health Care Insurance Bill

You mentioned today that there may be movement soon on the health insurance bill and we have been hearing that you may be closing a deal with Lott any minute now. HERE'S SOMETHING THAT YOU HAVE TO KNOW!!

I just wanted to make very sure that you were aware of how strongly DOJ feels about he advisory opinions issue. This is something in the House bill only that would allow a medical provider to seek an "advisory opinion" about whether certain activity they plan to undertake would constitute a violation of the law. This would effectively eliminate health care fraud investigation and prosecution as all available resources would go into developing these opinions. Defense counsel have told us that it would constitute malpractice not to get one so we would get gazillions. And it is unprecedented in criminal law - imagine a crook asking if robbing the bank would constitute a violation of law!

Anyway, the AG has written the attached letter and she and the Deputy have made calls to Hatch, Hyde and others. FBI Director has also written. This is big deal here. If it's in the bill, expect possible DOJ veto recommendation.

Senate - can ask for interpretive rulings on subject matters not specific actions

DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF THE GENERAL COUNSEL
INSPECTOR GENERAL DIVISION
330 INDEPENDENCE AVENUE, SW
ROOM 5541, COHEN BLDG.
WASHINGTON, D.C. 20201

FACSIMILE TRANSMISSION RECORD

DATE_____

TOTAL NUMBER OF PAGES (including this cover page): _____

Please deliver this transmission immediately:

TO: Jennifer Klein

ADDRESS: _____

_____

TELEPHONE: _____

FAX: 456 2878

FROM: Mac Thornton

TELEPHONE: _____

Return Fax #: (202) 205-0604

REMARKS Re: advisory opinions

_____

REQUEST FOR ADDITION TO ADVISORY OPINION SUBSECTION:

(6) Authorized Use of Fees

The Secretary is authorized to accept and retain user fees generated under this section, and expend them, without fiscal year limitation, on providing guidance regarding the application of health care fraud and abuse sanctions under this section.

Reason for this amendment: Under the latest draft bill, advisory opinions would be required of the Secretary under the criminal sections of the Social Security Act, the Civil Monetary Penalty Law and the program exclusion statute. This is potentially an enormous new workload, depending on the volume of requests for advisory opinions received. While the bill contains authority to charge a user fee, the fees would NOT go to the Department of HHS, but rather to the Treasury as Miscellaneous Receipts. The amendment above would allow the user fees to be used to provide the service for which a charge was made. Without this change, the Department may be forced to reprogram a significant part of its anti-fraud investigative and auditing efforts in order to provide advisory opinions.

CREATING AN UNPRECEDENTED MECHANISM FOR ADVISORY OPINIONS ON THE ANTI-KICKBACK STATUTE

Background: The Government already offers more advice on the anti-kickback statute than is provided regarding any other criminal provision in the United States Code.

Industry groups have been seeking advisory opinions under the anti-kickback statute for many years, with vigorous opposition by the Department of Justice (DOJ), and the HHS Office of Inspector General (OIG) under the last three administrations, as well as the National Association of Attorneys General. In 1987, Congress rejected calls to require advisory opinions under this statute. As a compromise, Congress required HHS, in consultation with the Attorney General, to issue "safe harbor" regulations describing conduct which would not be subject to criminal prosecution or exclusion. See Section 14 of Public Law 100-93.

To date, the OIG has issued 13 final anti-kickback "safe harbor" rules and solicited comment on 8 additional proposed safe harbor rules, for a total of 21 and proposed safe harbors. Over 50 pages of explanatory material have been published in the Federal Register regarding these proposed and final rules. In addition, the OIG has issued six general "fraud alerts" describing activity which is suspect under the anti-kickback statute. Thus, the Government gives providers guidance on what is clearly permissible (safe harbors) under the anti-kickback statute and what we consider illegal (fraud alerts).

H.R. 3103 Proposal. HHS would be required to issue advisory opinions to the public on the Medicare/Medicaid anti-kickback statute (section 1128B(b) of the Social Security Act), as well as civil monetary penalty and exclusion authorities pertaining to Medicare and Medicaid. HHS would be required to respond to requests for advisory opinions within 30 days.

HHS would be authorized to charge requestors a user fee, but there is no provision for this fee to be credited to HHS. Fees would therefore be deposited in the Treasury as miscellaneous receipts.

Major problems with anti-kickback advisory opinions include:

- o Advisory opinions on intent-based statutes (such as the anti-kickback statute) are impractical if not impossible. Because of the inherently subjective, factual nature of intent, it would be impossible for HHS to determine intent based solely upon a written submission from the requestor. Indeed, it does not make sense for a requestor to ask the

Government to determine the requestor's own intent. Obviously, the requester already knows what his or her intent is.

- o None of the 11 existing advisory opinion processes in the Federal Government provide advisory opinions regarding the issue of the requestor's intent. An advisory opinion process for an intent-based statute is without precedent in U.S. law.

- o The advisory opinion process in H.R. 3103 would severely hamper the Government's ability to prosecute health care fraud. Even with appropriate written caveats, defense counsel will hold up a stack of advisory opinions before the jury and claim that the defendant read them and honestly believed (however irrationally) that he or she was not violating the law. The prosecution would have to disprove this defense beyond a reasonable doubt. This will seriously affect the likelihood of conviction of those offering kickbacks.

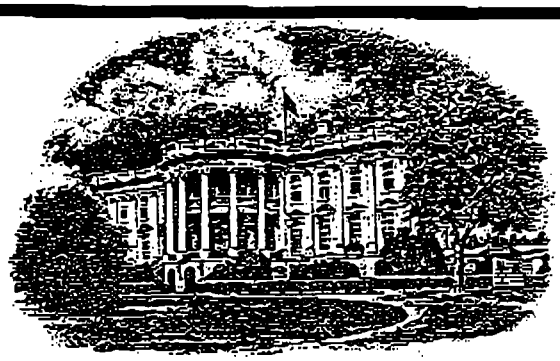
- o Advisory opinions would likely require enormous resources and many full time equivalents (FTE) at HHS. The user fees in the bill would go to the Treasury, not to HHS. Even if they did go to HHS, appropriations committees tend to view them as offsets to appropriations. There are no estimates of number of likely requests, number of FTE required, etc. Also, HHS is permanently downsizing, even as it faces massive structural and program changes. The possible result of the bill is a diversion of hundreds of anti-fraud workers to handle the advisory opinions.

For the above reasons, DOJ, HHS/OIG and the National Association of Attorneys General strongly oppose advisory opinions under the anti-kickback statute, and all other intent-based statutes. The CBO has scored a very significant cost to this provision due to lower recoveries in kickback cases due to the inappropriate exploitation of advisory opinions by defense attorneys.

FAX COVER

Health and Personnel Division

Executive Office of the President
Office of Management and Budget
OEOB, Room 262
Washington, D.C. 20503



DATE: _____

TO: Jen Klein

AGENCY: _____

FAX NO: 6-2878

FROM: Nancy-Ann Min
Associate Director for Health and Personnel

Phone Number (202) 395-5178
Fax number (202) 395-9119

Number of pages (including cover) _____

COMMENTS:

FAX TRANSMISSION SHEET

American Medical Association
Physicians dedicated to the health of America

1101 Vermont Avenue, NW
Washington, DC 20005

Date: 7/24/96

From: Rich Deem

Division of Federal Affairs

Phone number: _____

To: Nancy Ann-Min
Marilyn Yager
Chris Jennings

Message: This is being mailed out today.

Total Pages including cover sheet: 3

Reply Fax Number: 202-789-4581

July 24, 1996

The President of the United States
The White House
Washington, DC 20500

Dear Mr. President:

As health insurance reform legislation moves toward final passage in Congress, the American Medical Association (AMA) and the American Hospital Association (AHA) are writing to alert you to an issue of great importance to physicians and hospitals. The pending legislation devotes an entire title to eliminating fraud and abuse in our health care marketplace. Both the AMA and the AHA support efforts to rid our health care system of these abhorrent practices that drain limited health care resources and threaten quality health care for all Americans.

We firmly believe, however, that physicians and hospitals deserve to be governed by fraud and abuse laws that are clear and provide useful guidance as to what conduct is prohibited. Key provisions such as intent standards and advisory opinions are essential to protect honest physicians and hospitals from what has become an exceedingly complex and vast web of fraud and abuse laws and regulations.

The antikickback laws, for example, are full of overly broad and inexact language. As HHS Inspector General, June Gibbs Brown, recognized in a March 22, 1994 letter to Representative Pete Stark, "the [antikickback] statute is broad and encompasses many arrangements between health care providers, many of which may not be abusive." As a result, a number of physicians and hospitals avoid activities that in many cases would benefit patients, precisely because they fear these activities might be in violation of the antikickback statute.

The variety and complexity of financial relationships in today's health care market make it impossible for physicians and hospitals to depend solely upon statutes and regulations of general applicability. In addition, the regulatory process simply cannot keep pace with developing new and innovative, integrated delivery systems. Without advisory opinions to guide physicians and hospitals, many beneficial arrangements that would provide high quality health care more efficiently will never see the light of day.

Contrary to what many have argued, the advisory opinion process contemplated in the House version of the health insurance reform bill, would not require the Office of the Inspector General (OIG) to make a finding of a provider's intent. Rather, the opinion would be based solely on the factual circumstances presented. A physician or hospital would be required to make an accurate presentation to the OIG of all relevant facts. The opinion would not be valid if significant facts were omitted or changed.

Moreover, an advisory opinion would not shield a physician or provider acting in bad faith. Thus, despite the issuance of an advisory opinion, the OIG would be free to prosecute physicians or hospitals that exhibited an intent to commit fraudulent acts.

Providing physicians and hospitals with guidance on what factual arrangements violate the fraud and abuse laws would not overwhelm the OIG with frivolous requests. More than 11 federal agencies successfully provide similar guidance.

We hope that we have alleviated some of the concerns surrounding the issue of advisory opinions, and we thank you for your consideration of our arguments. If the health care field is to be subjected to new federal criminal and civil penalties, physicians and hospitals must be assured they will be assisted, rather than hampered, in their number one goal of treating patients.

Sincerely,

P. John Seward M.D.

P. John Seward, MD
Executive Vice President
American Medical Association

Richard J. Davidson

Richard J. Davidson
President
American Hospital Association

cc: Leon E. Panetta, Chief of Staff to the President
Donna E. Shalala, Secretary of Health and Human Services
Janet Reno, Attorney General
June Gibbs Brown, HHS Inspector General

American Medical Association
Physicians dedicated to the health of America

Richard A. Deem
Director
Division of
Federal Affairs

1101 Vermont Avenue, NW
Washington, DC 20005

202 789-7400
202 789-7485 Fax

July 19, 1996

Nancy-Ann Min

Dear Nancy—

We understand that DOJ is really pushing the Administration to fight advisory opinions. The argument that we are seeking special treatment does not hold water. Attached is a chart of existing federal advisory opinion programs. I can't put a good spin on Admin. opposition to advisory opinions.

The President of the United States has the ability to seek advisory opinions on campaign activities from the Federal Election Commission? Why should there be a double standard for physicians seeking clarification of complex Medicare rules?

Please urge reconsideration of the Administration's position.

Sincerely

Richard Deem

Comparison of Existing Advisory Opinion Procedures
Health Industry Initiative

Agency/Statutes	Time from Request to Issuance of Advisory Opinions	Precedential Effect of Opinion	Agency Discretion to Decline to Provide	Public Availability of Request	Can Party Request Advisory Opinion of Another's Conduct?	Applicant Cost	Authority: Authorizing Statute/Regulation	
Department of Justice (Criminal Division) Foreign Corrupt Practices Act of 1977	30 days-§ 80.8	(a) applying to requesting party only—§ 80.5 (b) binding on DOJ only—§ 80.11	No, if request meets information requirements in § 80.6	(a) documents submitted to support request not disclosed in § 80.14(a) (b) DOJ can issue press release re: request and response—§80.14(b)	No, requesting party must be part of transaction which is subject of request § 80.4	Not specified	15 U.S.C. §§ 78dd-1 & 78dd-2; 28 C.F.R. Part 80	S
Department of Justice (Antitrust Division) Antitrust Laws	Not specified	Yes, to the extent written business review letter is signed by Assistant Attorney General in charge of Antitrust Division—§ 50.6(b)	Yes—§ 50.6(3)	Request, supporting documents and response placed in public index; can request delay in indexing—§ 50.6(10)(c)	Not specified	Not specified	5 U.S.C. § 552; 28 C.F.R. § 50.6	I
Federal Election Commission (Office of General Counsel) Federal Election Campaign Act of 1971	60 days-§ 437f(a)(1)	Opinions may be relied on by person specifically involved in addressed activity or who relies in good faith—§ 437f(c)	No—§ 437(a)(1)	All requests are made public—§ 437f(d)	No, limited to specific transaction or activity by requesting party—§ 437f(a)(1)	Not specified	2 U.S.C. § 437f; 11 C.F.R. Part 112	S
Federal Trade Commission Federal Trade Laws	Not specified	No action against requesting party if in good faith relies on advice and Commission had all facts prior to its advice—§ 1.3(b)	Yes—§ 1.1(a)	Yes, but can separately request information submitted be held confidential—§ 1.4	No, request limited to course of action requesting party proposes to pursue—§ 1.1(a)	Not specified	15 U.S.C. § 46; 16 C.F.R. Part 1	I
Internal Revenue Service Internal Revenue Code	Not specified	Binding as to requesting party only; ruling can be revoked at any time—§ 601.201(l)	Yes—§ 601.201(a) & (d)	Requesting party may request that portions of material likely to appear in ruling be deleted prior to publication—§ 601.201(e)(11)	No, limited to requesting party's tax status or to tax effects of its acts or transactions—§ 601.201(a)	Not specified	5 U.S.C. § 552; 26 C.F.R. § 601.201	In
Office of Government Ethics Ethics in Government Act of 1978	Not specified	Opinion may be relied on by person specifically involved in addressed activity or who relies in good faith—§ 2638.309	Yes, based on criteria in § 2638.303	Yes, but name of all persons deleted to extent possible—§ 2638.310 Opinion will be published—§ 2638.310(c)	No, limited to situation in which person is directly involved—§ 2638.302	Not specified	5 U.S.C. app. § 402(b)(8); 5 C.F.R. § 2638.301	Sp

Type of Statutory Authority	Effective Date of Implementing Regulations
pecific	New regulations effective September 1, 1992
nplicit	Regulations effective March 1, 1977
pecific	Statute effective January 8, 1980
nplicit	Regulations effective April 11, 1979
iplicit	Regulations effective November 22, 1967
ecific	Regulations effective December 5, 1989

Agency/Statutes	Time from Request to Issuance of Advisory Opinions	Precedential Effect of Opinion	Agency Discretion to Decline to Provide	Public Availability of Request	Can Party Request Advisory Opinion of Another's Conduct?	Applicant Cost	Authorizing Statute/Regulatio
Department of Labor, Pension and Welfare Benefit Programs ERISA	Not specified, but Department will normally process requests "in regular order and as expeditiously as possible" - ERISA Proc. 76-1, § 6.06.	Binding on parties described in request so long as the request fully disclosed all necessary facts - ERISA Proc. 76-1, § 10	Yes - ERISA Proc. 76-1, § 5	(a) documents filed in support of request available for three years after receipt of opinion unless they contain proprietary information - ERISA Proc. 76-1, § 12 (b) Opinions are available for public inspection - ERISA Proc. 76-1, § 12	Not specified	Not specified	29 U.S.C. § 1135; ERI Proc. 76-1 (41 Fed. R 36281)
Food and Drug Administration Matters within FDA Commissioner's authority	180 Days - 21 C.F.R. §§ 10.30(e)(2), 10.85(b)	Absent an "immediate and significant danger to health," binding on Commissioner of FDA, until revoked, as to "action taken in conformity with an advisory opinion" - 21 C.F.R. § 10.85	Yes—21 C.F.R. § 10.85(a)(2)	Generally available but see exclusions at 21 C.F.R. §§ 10.85(b), 10.20 (j); public index of opinions maintained— 21 C.F.R. § 10.90(g)	Not specified	Not specified	21 U.S.C. § 371(a); 21 C.F.R. § 10.85
Housing and Urban Development Real Estate Settlement Procedures Act	Not specified	Not binding - no formal protection from liability	Yes - 24 C.F.R. § 3500.4(c)	Not specified	Not specified	Not specified	12 U.S.C. § 2617(a); 2 C.F.R. § 3500.4
International Trade Commission International Trade Statutes	Not specified	So long as Commission has not rescinded or revoked its advice, party may rely if it disclosed all relevant facts at time of opinion - 19 C.F.R. § 211.54(c)	Yes—19 C.F.R. § 211.54(b)	Yes—under FOIA but FOIA exemptions may apply—19 C.F.R. § 201.19	No, advisory opinions limited to respondent's conduct—19 C.F.R. § 211.54(b)	Not specified	19 U.S.C. §§ 1333, 133 1337; 19 C.F.R. § 211.5
Securities and Exchange Commission Securities Laws	Not specified	Technically not-binding on Commission even as to requesting party	Not specified	Yes—but can separately request information submitted be held confidential—17 C.F.R., §§ 200.81(b), 200.83	Not specified	Not specified	15 U.S.C. §§ 77s, 77sss, 78d-1, 78w, 79t, 80a-37, 80b-11; 17 C.F.R. §§ 200.81, 202.1(d), 202.2

thority	Type of Statutory Authority	Effective Date of Implementing Regulations
SA g.	Implicit	August 27, 1976
	Implicit	April 13, 1979
	Implicit	New regulation effective November 2, 1992
i, t	Implicit	New regulations effective August 29, 1988
	mplicit	Regulations effective November 11, 1970 (17 C.F.R. § 200.81), July 15, 1960 (17 C.F.R. § 202.2)

Letter sent to all Senate and House Republicans.
Prepared by Elizabeth Seifert x412.

American Medical Association
Physicians dedicated to the health of America

P. John Seward, MD
Executive Vice President

515 North State Street
Chicago, Illinois 60610

312 464-5000
312 464-4184 Fax

July 22, 1996

The Honorable Trent Lott
Majority Leader
United States Senate
S-230 Capitol Building
Washington, DC 20510

Dear Mr. Leader:

As you continue to work toward resolving issues in H.R. 3103, the Health Insurance Reform bill, including medical savings accounts, the American Medical Association (AMA) is writing to restate our position regarding the legislation's fraud and abuse provisions. As the attached "Dear Colleague" letter from House Committee Chairmen Archer, Hyde and Bliley states, language acceptable to the medical community has been agreed upon after lengthy negotiations.

First, the agreement would ensure that physicians would not be penalized for inadvertent behavior or errors. This is because the new federal crimes of "health care fraud" and "false statements" would require that a provider possess the specific intent to violate the Act. In short, he or she must act with knowing and willful intent. Second, the agreement includes the House language on the level of intent required for the imposition of civil monetary penalties under Federal health care programs. We strongly request that legitimate disagreements regarding medical treatment decisions, and variations in coding without an intent to fraudulently bill for services not be cause for imposing the substantial legal penalties contemplated by the bill. Finally, the agreement would provide for binding advisory opinions, which would give providers the necessary guidance as to whether anticipated factual arrangements violate the fraud and abuse laws.

The AMA strongly encourages Congress to uphold these critical agreements when the formal conference convenes. Altering the existing language at this stage of the debate would seriously jeopardize support for the underlying bill.

We remain committed to pursuing the principles of incremental health insurance reform, and we urge you to protect the significant improvements that have been made thus far to the fraud and abuse provisions in H.R. 3103.

Sincerely,

P. John Seward, M.D.

P. John Seward, MD

cc: House and Senate Republicans

American Medical Association
Physicians dedicated to the health of America

Kirk B. Johnson, JD
Group Vice President
Health Policy and
General Counsel

515 North State Street
Chicago, Illinois 60610

312 464-4600
312 464-5599 Fax

July 3, 1996

Robert Pitofsky
Chairman
Federal Trade Commission
Pennsylvania Ave. at 6th St., N.W.
Washington, D.C. 20580

Ann K. Bingaman
Assistant Attorney General
United States Department of Justice
Constitution Avenue and Tenth St., N.W.
Washington, D.C. 20530

Re: Draft Revisions to "Statements of Enforcement Policy and Analytical Principles Relating to Health Care and Antitrust"

Dear Mr. Pitofsky and Ms. Bingaman:

Thank you for the opportunity to review the draft revisions to your "Statements of Enforcement Policy and Analytical Principles Relating to Health Care and Antitrust" (hereinafter the "Statements"). We very much appreciate the opportunity to review the draft revisions and comment on them prior to their release in final form. We also appreciate the courtesy and professionalism of your talented staffs.

This letter sets forth our comments on the draft revisions. In summary, we were pleased with certain aspects of the draft revisions, but we still have major concerns that we believe need to be addressed before the Statements will be accepted by the profession. This letter summarizes the aspects of the draft revision that we believe to be improvements and the issues that we are still concerned about.

Aspects of the draft revisions that the AMA is pleased with are as follows:

- *Networks Without Insurance Risk.* There is progress made towards recognition of the legality of physician networks where the physicians agree upon fees or charges to payers but do not share insurance risk (hereinafter "alternative networks"). As you know, the prevailing belief among antitrust attorneys and physicians has been that the Federal Trade Commission (FTC) and the (DOJ) considered such networks to be per se illegal. The draft revisions would allow alternative networks that use certain kinds of financial incentives to control utilization, such as bonuses for reducing hospital days, to qualify for a safety zone. They would also allow alternative networks that have sufficient clinical and functional integration to qualify for review under the rule of reason. We recognize that this is a step forward in the antitrust analysis of physician and multiprovider networks.

- *Network Size.* Enhanced references to the fact that networks substantially larger than those qualifying for the safety zones may be legal under a rule of reason analysis. As you know, one of the most significant problems with the Statements has been their interpretation by attorneys and physicians not familiar with the antitrust laws. This audience is unfamiliar with rule of reason analysis, and prefers the certainty of the safety zones. Therefore, they tend to believe that networks too large to be in the safety zones are at too much risk of being

considered illegal, even when that is not the case. The more definite statement that networks larger than the safety zone limits can be legal is helpful.

- *Truncated Rule of Reason.* One problem that physicians have experienced in network organization is the complexity and expense of antitrust review by private attorneys for networks that are not in the safety zones. The reference to the truncated rule of reason will help reduce the depth of review necessary and reduce its expense.

- *Messenger Model.* The modifications to the messenger model, including the so called "power of attorney" and "assumed acceptance" variations will help messenger model networks operate more efficiently. In addition, clarification that messenger model networks can engage in joint negotiations over non-fee related matters will also contribute to efficient operation.

- *Competitive Markets.* There is a reference in the draft revisions that networks formed in competitive markets for health care delivery and finance are less likely to have an anticompetitive affect than networks formed in markets that are not competitive. The AMA believes that competitiveness of a market is a major factor in whether a new network could adversely affect competition, and it is helpful that it is recognized in the draft revision.

- *Clarifications.* There are other clarifications in the draft revisions that clear up problems of interpretation.

We have two major concerns about the draft guidelines. Our concerns about these two issues are substantial enough that, in spite of the progress made in the draft guidelines listed above, we believe that the bulk of the medical profession will be disappointed in them. Our concerns center on the tone of the section that describes rule of reason analysis for networks that do not fall within the safety zones, and the lack of expansion of the size limits in the safety zones or adoption of a quick look test for networks too large to be in the safety zones. These issues are critical to the medical profession. Each concern is described in more detail below.

Tone. The draft revisions state that, under a rule of reason analysis, networks that do not share the kinds of substantial financial risk necessary to qualify for a safety zone may be legal under a rule of reason analysis if it achieves efficiencies associated with clinical and functional integration. However, the draft revision emphasizes that the efficiencies most likely to be recognized by the FTC and the DOJ in the evaluation of networks pursuant to the rule of reason are those that involve the sharing of substantial financial risk or the use of other financial incentives to control utilization. In the past, this has been interpreted as a signal that it would be very difficult to persuade the agencies that a network that does not assume insurance risk would be legal. We are concerned that the draft revisions continue to communicate skepticism about the

merit and legality of alternative networks. As Professor Havighurst has stated, "A marketplace lacking health plans designed by physicians alone (and not by antitrust authorities) could easily fail to serve consumers well or to be fully reliable, from the standpoint of a society as a whole, as a place for working out the difficult trade-offs with which health care necessarily abounds." (Havighurst, Clark C., Are the Antitrust Agencies Overregulating Physician Networks? Nov. 1995 "Draft," p. 21).

There is no question that the assumption of insurance risk and the use of other financial incentives can be associated with reducing costs. However, as is discussed in detail in the white paper that we submitted to you, there is still controversy about how to assure that the use of these incentives does not result in the withholding of necessary care. As a result, there is a very substantial market for networks that do not rely on insurance risk or financial incentives to control utilization, and there is evidence that these kinds of networks can reduce costs. We want to be sure that physicians and other providers will be able to participate in this market and to experiment with the development of this kind of network.

As we emphasized in our white paper, experience has shown that when physicians are allowed to experiment with networks and to learn how to manage them, they have been successful in spite of the predictions of experts. These successes have been achieved primarily by independent practice organizations (IPAs) that accept insurance risk as opposed to alternative networks. However, it was legal for IPAs to operate, experiment, gain experience, during the period when they learned how to achieve success. It has not been legal for alternative networks to operate. We believe that in competitive markets, physicians allowed to experiment with alternative networks will be able to develop products that are appealing to purchasers. However, they need the latitude necessary to engage in this experimentation. Therefore, we had hoped for a stronger commitment to rule of reason analysis than appeared in the draft revisions.

Size Limits. Our second major concern is that no changes were made in the size limits for networks in the safety zones, and our suggestion for a "quick look" test that would focus on the market power of large networks size was not adopted. Your staff indicated surprise that we are concerned about size limits because the antitrust reform legislation that we support in Congress does not address size limits. That is the case because we concluded, after lobbying for legislatively set size limits in safety zones in prior years, that it was too difficult to arrive at legislatively set size thresholds and that the issue should be addressed in enforcement policies. As you know, the legislation that we support calls for the development of guidelines to implement it, and we expected the size limit issue to be addressed in those proceedings in the event of passage. We have consistently raised the issue of size limits in our position papers on this issue, including all of our written submissions to the FTC and the DOJ. Our presentation at the meeting of AMA and FTC staff on March 6, 1996 was primarily devoted to describing examples of procompetitive IPAs that were substantially larger than the safety zone thresholds.

We have raised concerns about the size limits for two reasons. First, the size limits are set at low levels. Networks that are truly nonexclusive pose little threat of anticompetitive activity. We recommend that the safety zone for nonexclusive networks be increased to 50% of any specialty in a market, a figure that we feel is conservative for nonexclusive networks and what

may be the minimum size necessary to compete with many nonphysician directed plans. Again Professor Havighurst would agree with us: "Such nonexculsivity should, in fact, save any network (whatever its size) that exists in a market where large employers and other payers have, and exercise, real opportunities either to organize their own networks or to patronize other existing physician groups." Havighurst, p. 14.

We also recommended that at "quick look" test be developed for fee for service networks that would qualify for the safety zones but for their size (we recommended that fee for service networks with certain characteristics be included in the safety zones). The quick look test would focus on one factor, whether the network was so large that it had an impermissible amount of market power. The focus would be on market power because every other aspect of the network can be assumed procompetitive, since it has the characteristics necessary to be within a safety zone. We have recommended several criteria for evaluating whether the network would have too much market power to included in Statements. They are listed in the June 21, 1996 letter and white paper. The criteria would include:

- the extent of managed care penetration in the market;
- the kinds of managed care plans that are dominant in the market;
- the number of managed care plans that serve the market;
- the number of networks organized by managed care plans, including those organized by insurers acting in an administrative services only capacity and by third party administrators;
- the number of independent physician networks designed to serve managed care plans, and the percentage of physicians in the market that participate in these networks; and
- the approximate percentage of physician revenues attributable to different networks.

A quick review of this information would indicate whether there is any concern that networks larger than the safety zone limits but within the larger limits could exercise market power.

We believe that the reference to the truncated rule of reason analysis in the draft revisions is a step forward in the evaluation of physician and multiprovider networks. Our quick look test recommendation is based on the concept of the truncated rule of reason analysis, but is different. Under the truncated rule of reason, the reviewer is able to categorize networks that do not fall within the safety zones as obviously illegal or obviously legal due to the presence of various factors that make a full blown rule of reason analysis unnecessary. Under our quick look test, the reviewer focuses on a specific factor, market power, because it is unnecessary to inquire into other factors given that the network has the characteristics (but for size) to fall within a safety zone. There is enough that is uncertain about antitrust analysis without exposing unnecesary issues to the ardently protective, good faith and inevitably subjective view of agency staff.

Another way to address the size issue would be to incorporate the concept of adverse financial interests among physicians in a network that was developed in the final judgements and competitive impact statements in DOJ consent orders in U.S. v Health Choice of Northwest Missouri, Inc., Civil Action No. 95-6171-CVSJ6, U.S.D.C, W.D. Mo., and U.S. v. Healthcare Partners, Inc., Civil Action No. 395-CV-01946RNC, U.S.D.C., D. Conn. In those consent orders, it was recognized that a core of physicians may invest in and organize a network, and then contract with other physicians to provide the geographic and specialty coverage necessary to be competitive. The interests of the owner physicians who want the network to be a financial success and gain a return on their investment are adverse to contracting physicians who simply want to be paid for treating patients assigned to them by the network. Similarly, when a core of primary care physicians in a network have capitated arrangements which reward them for conserving on specialty and hospital care, their interests are adverse to the specialist physicians in the network. These adverse interests make it less likely that a large network would engage in a price-fixing conspiracy. These criteria could be included in the discussion of the rule of reason analysis in the draft revisions.

In conclusion, the AMA appreciates the progress that has been made in resolving the concerns that we have raised. However, we feel that there is more progress to be made before the profession will be enthusiastic about the draft revisions.

Very truly yours,

Kirk B. Johnson

American Medical Association
Physicians dedicated to the health of America

1101 Vermont Avenue, NW
Washington, DC 20005
(202) 789-7400

Date: 7/18/96

To: Chris Jennings
Nancy-Ann Min

From: Rich Deem
phone 789-7413

Message: We are hearing some troubling rumblings regarding WH efforts to remove advisory opinions from the K/K bill. Attached is a recent coalition letter signed by all the large state and national medical specialty societies.

We want a bill to move forward w/ advisory opinions + the F/K changes agreed to by Hyde, Archer, + Bliley.

[redacted]

Physicians will not accept the arguments being made by DOJ. It is a mistake to stir this issue up again.

Total pages (Including cover sheet) 4 Reply Fax Number: (202) 789-7485

Fax Transmission

Sent to all Members of Congress.
Prepared by Kristen Morris x408.

June 7, 1996

The Honorable Spencer Abraham
United States Senate
245 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Abraham:

The undersigned medical societies are writing to apprise you of our members' strong opposition regarding the extensive fraud and abuse provisions contained in HR 3103. **We are hearing from thousands of physicians each day across the country who are outraged that Congress would consider imposing such excessive sanctions against physicians making inadvertent administrative mistakes.** Although we support efforts to curb fraud and abuse in the health care sector, we believe that the provisions currently contained in HR 3103 go far beyond merely tightening laws to prosecute wrongdoers. The extensive new health care offenses would dramatically increase civil monetary penalties and threaten physicians who are dedicated to doing what's best for their patients.

Since we learned that fraud and abuse provisions would be added to the health insurance reform bill, we have repeatedly made our positions known to Congress. We are concerned, however, that our requested reasonable modifications are being ignored. Accordingly, we would like to take this opportunity to reemphasize our key requests for revisions to the fraud and abuse provisions.

- Legitimate disagreements regarding medical treatment decisions, and variations in coding without an intent to fraudulently bill for services, should not be cause for imposing legal penalties (especially since inappropriate payments are already recouped by the government.) A determination of whether services are "medically necessary" is by nature a subjective judgment and must be made by a professional. Unless there is a specific intent to defraud the system, **the legal system should not have the right to question what a physician believes to be medically necessary.** Likewise, coding of health care services for Medicare billing often is subjective. A physician may have to choose between several codes to describe a procedure. **Such innocent coding decisions could trigger huge civil monetary penalties if later determined to be inappropriate.** We urge you to drop provisions which apply penalties for medical necessity or uncoding.

- **We strongly encourage you to add the word "willfully" to the new federal health care offenses (House sections 242 -- Health Care Fraud and 244 -- False Statements).** These criminal provisions would create new law, and it is important that

this new law not be ambiguous. We request that the House recede to the Senate language which ensures that offenders who intentionally break the law are punished, but those with no intent to do wrong are not treated as criminals. It is unconscionable that physicians could be subjected to criminal sanctions for unintentional coding errors.

- We agree that civil monetary penalties (CMPs) can be appropriate to deter fraudulent behavior. We strongly believe, however, that an individual should be able to know that his or her conduct is prohibited, and that the penalties should be commensurate with the offense committed. Toward this end, **we support the House provision which would establish a "knowledge" standard for CMPs. In addition, we support tying the amount of the penalty to the amount of the inappropriate claim to avoid unnecessarily and unreasonably excessive fines.** Without these two safeguards, physicians may find themselves subject to enormous and disproportionate penalties for activities they did not know were prohibited.

- **In any fraud and abuse program, physicians and other providers should be able to obtain binding written advisory opinions from the appropriate enforcement agencies as to whether anticipated conduct violates the law.** Advisory opinions that apprise the medical community of which factual circumstances are illegal would allow enforcement agencies to fight fraud and abuse, but would reduce the unintended chilling of activities that do not violate the law. We therefore urge you to accept the House provisions providing for advisory opinions.

- Both the House and Senate bills contain fraud and abuse provisions that would make changes in the existing Medicare Integrity Program. These provisions would mandate the use of new commercial software technologies. **Our concern is that the content of these new commercial products would not be disclosed based on the claim that such information should be private, thereby creating "black box" review screens.** At a time when patients are demanding more information on benefit coverage, it is wrong to permit such closed, "black box" edits. We urge you to amend these provisions to reflect the public nature of the Medicare program and allow for the appropriate review of these commercial products.

To effectively combat fraud, the laws must be balanced and clear so that the real wrongdoers are brought to justice. But it is beyond reason to treat physicians as if they are worse than violent criminals. Innocent physicians and health care providers should not be put in jail or subjected to excessive fines for unintended mistakes while trying to decipher complex administrative rules or regulations.

As you move to finalize the conference report to HR 3103, we urge you to consider seriously the concerns raised above.

Sincerely,

Alaska State Medical Association
American Academy of Allergy Asthma and Immunology
American Academy of Child and Adolescent Psychiatry
American Academy of Dermatology
American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Family Physicians
American Academy of Hematology
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Orthopaedic Surgeons
American Academy of Otolaryngology - Head and Neck Surgery
American Academy of Pain Medicine
American Academy of Pediatrics
American Academy of Physical Medicine and Rehabilitation
American Association of Clinical Endocrinologists
American Association of Clinical Urologists
American Association of Neurological Surgeons
American Association of Plastic Surgeons
American College of Cardiology
American College of Emergency Physicians
American College of Nuclear Physicians
American College of Obstetricians and Gynecologists
American College of Occupational and Environmental Medicine
American College of Osteopathic Surgeons
American College of Physicians
American College of Rheumatology
American College of Surgeons
American Group Practice Association
American Medical Association
American Medical Directors Association
American Orthopaedic Foot and Ankle Society
American Osteopathic Association
American Psychiatric Association
American Society for Dermatologic Surgery
American Society for Gastrointestinal Endoscopy
American Society for Reproductive Medicine
American Society of Abdominal Surgeons
American Society of Anesthesiologists
American Society of Cataract and Refractive Surgery
American Society of Clinical Oncology
American Society of Clinical Pathologists
American Society of Hematology
American Society of Internal Medicine
American Society of Maxillofacial Surgeons
American Society of Plastic and Reconstructive Surgeons
American Urological Association
Arkansas Medical Society
College of American Pathologists
Colorado Medical Society
Congress of Neurological Surgeons
Connecticut State Medical Society
Florida Medical Association

Greater Albuquerque Medical Association
Hawaii Medical Association
Idaho Medical Association
Illinois State Medical Society
Indiana State Medical Association
Iowa Medical Society
Kansas Medical Society
Kentucky Medical Association
Maine Medical Association
Massachusetts Medical Society
Medical and Chirurgical Faculty of Maryland
Medical Association of Georgia
Medical Association of the State of Alabama
Medical Group Management Association
Medical Society of Delaware
Medical Society of New Jersey
Medical Society of the State of New York
Medical Society of Virginia
Michigan State Medical Society
Minnesota Medical Association
Mississippi State Medical Association
Missouri State Medical Association
Montana Medical Association
Nebraska Medical Association
New Hampshire Medical Society
New Mexico Medical Society
North Carolina Medical Society
North Dakota Medical Association
Ohio State Medical Association
Oklahoma State Medical Association
Oregon Medical Association
Pennsylvania Medical Society
Renal Physicians Association
Rhode Island Medical Society
Society of Cardiovascular and Interventional Radiology
Society of Nuclear Medicine
Society of Thoracic Surgeons
South Carolina Medical Association
South Dakota State Medical Society
State Medical Society of Wisconsin
Tennessee Medical Association
Texas Medical Association
US and Canadian Academy of Pathology
Walnut Hill OB/Gyn Associates
Utah Medical Association
Vermont State Medical Society
Washington State Medical Association
West Virginia State Medical Association
Women's Association for Obstetrics and Gynecology
Wyoming Medical Society

U.S. Department of Justice
Office of Legislative Affairs

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

FAX COVER SHEET

DATE: 7/11/96

TO: JENNIFER KLEIN

PHONE NO. 456-2599

FAX NO. 456-2878

FROM: **JAMES CASTELLO**

PHONE NO. 305-0091

FAX NO. 514-9149

NO. OF PAGES: 5 (EXCLUDING COVER)

COMMENTS: THIS IS A COPY OF THE PREPARED REMARKS THAT THE DEPUTY ATTORNEY DELIVERED THIS MORNING AT THE ATTORNEY GENERAL'S PRESS MEETING (THE AG IS OUT OF TOWN)

STATEMENT OF DEPUTY ATTORNEY GENERAL GORELICK
ADVISORY OPINIONS AND
HEALTH CARE FRAUD LEGISLATION
July 11, 1996

Good morning.

For some time, Congress has been considering important health care fraud legislation, and we have very worked closely with Congress on a variety of measures designed to help curb health care fraud and abuse. Both the Senate and the House have passed separate versions, and the legislation is headed toward conference.

We are pleased that the Congress has included health care fraud and abuse provisions in the Health Coverage Availability Act which is H.R. 3103. The fight against white collar crime, and health care fraud in particular, is one of the Department's highest priorities, and we support many of the fraud and abuse provisions in the bill. But this morning, I want to take a minute to raise a very serious concern about the House version of that legislation -- one that has not received very much attention and certainly far less attention than it deserves and which would make it more difficult for us to prosecute those who pay or receive bribes for the referral of Medicare patients. That is the requirement in the House bill that the HHS Inspector General issue advisory opinions concerning what constitutes a crime under the Medicare anti-kickback statute.

It is a crime to pay someone for referring health care business which is to be paid for by Medicare/Medicaid. Decisions that physicians make day in and day out -- such as whether to and where to hospitalize a patient, what tests to order, what drugs to prescribe -- affect the health and well being of our elderly parents and of our children. Allowing those decisions to be made under the influence of a kickback would be wrong.

The House bill would make it more difficult for the government to enforce the anti-kickback statute by prosecuting those who pay or receive kickbacks. It would require the HHS Inspector General to issue written advisory opinions on whether certain arrangements violate the criminal statute. These opinions could be, would be construed to bless conduct based on the provider's own description of it. Yet, the determination about whether conduct violates a criminal law is and always must be based upon evidence that is gathered through an independent investigation, not on information provided by a potential defendant.

Now our concern is that defendants will argue that they relied on these opinions in concluding that their conduct was permissible; the government will find itself mired in endless litigation over the application of these opinions; and the end result will be that our efforts will be undermined.

The provision of these opinions also will consume significant law enforcement resources and trigger other costs to the federal government.

Those who claim they need advisory opinions to know whether they are violating the anti-kickback statute are being straightforward. The HHS IG already offers guidance on the statute (in the form of safe harbor regulations and fraud alerts). And, the Senate bill would offer even more guidance, in the form of interpretive rulings.

The key point here is, we do not prosecute people for mistakes. Our efforts are aimed at those who commit intentional misconduct and unscrupulous providers who defraud their patients and the health care system, the government can not afford that additional burden. Our prosecutions are directed at those who intentionally lie, or file false claims, or steal money from health plans, or pay bribes to corrupt the professional judgment of medicare providers. Our goals are to protect the Medicare system and the other government and private health care payers

and the people who rely on them.

So, on behalf of the Administration, I want to urge that the House protect the integrity of our fraud fighting efforts and accede to the Senate's version of this legislation.

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

June 8, 1996

The Honorable Newt Gingrich
Speaker of the House of
Representatives
Washington, D. C. 20515

Dear Mr. Speaker:

This is to advise you that although the Department strongly supports many of the health care fraud and abuse provisions of H.R. 3103, the Health Coverage Availability and Affordability Act, we strongly object to the requirement for advisory opinions, contained in the bill as passed by the House of Representatives. As this legislation moves toward conference, we urge removal of the advisory opinion provision from the final bill. We also urge you to adopt the provision in the Senate bill that authorizes an investigative demand provision in both civil and criminal investigations.

The House bill would require the Department of Health and Human Services (HHS) to issue written advisory opinions with respect to whether certain provider arrangements violate the anti-kickback statute, 42 U.S.C. 1128B. This is an unprecedented and unwise requirement that would severely undermine our law enforcement efforts relating to health care fraud.

The Department of Justice has the exclusive authority to enforce all federal criminal laws, including the anti-kickback statute, and we do not issue advisory opinions with regard to any criminal statute. One important reason is that judgments about whether conduct violates a federal criminal law should be based only on evidentiary facts that have been corroborated through independent investigations conducted under the supervision of prosecutors. They are never based upon information provided by the actor, and potential defendant. This is particularly important because the actor's intent is an element of the criminal offense.

Under these circumstances, the imposition of the advisory opinion requirement on HHS, or this Department, would serve only to generate countless complexities in our health care fraud prosecutions. Indeed, it may be used by wrongdoers as a shield for fraudulent activities that rob the Medicare system and cause real harm to patients. There is already more governmental guidance provided with regard to the anti-kickback statute than other white collar crime laws. Under current law, the HHS IG

issues safe harbor regulations as well as fraud alerts and the Senate bill would provide new interpretive rulings about the statutory language, which would add even greater guidance.

We are pleased that both the House and Senate bills have included an authorized investigative demand provision. We urge you to eliminate language that would limit the issuance of such demands to criminal investigations and to clarify that these demands are authorized for civil as well as criminal investigative purposes. The demands would be an important investigative tool in our civil fraud efforts under the False Claims Act, which return losses to Medicare and other federal programs. It is essential that we give equal consideration to the civil aspects of health care fraud in order to recover those losses where criminal prosecution is not appropriate. The investigative demand provision should be available in civil as well as criminal investigations.

I appreciate your support for our efforts to protect the Medicare system and other health care programs from fraud and abuse. Please demonstrate that support by ensuring that there is no advisory opinion provision in the final insurance portability legislation and providing a complete authorized investigative demand.

The Office of Management and Budget has advised that there is no objection to this report from the standpoint of the Administration's program.

Sincerely,

Janet Reno

cc: The Honorable Richard Gephardt
Minority Leader

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

June 8, 1996

The Honorable Newt Gingrich
Speaker of the House of
Representatives
Washington, D. C. 20515

Dear Mr. Speaker:

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I appreciate your support for our efforts to protect the Medicare system and other health care programs from fraud and abuse. Please demonstrate that support by ensuring that there is no advisory opinion provision in the final insurance portability legislation and providing a complete authorized investigative demand.

The Office of Management and Budget has advised that there is no objection to this report from the standpoint of the Administration's program.

Sincerely,

Janet Reno

cc: The Honorable Richard Gephardt
Minority Leader

AMA Position

FAX TRANSMISSION SHEET

American Medical Association
Physicians dedicated to the health of America

1101 Vermont Avenue, NW
Washington, DC 20005

Date: 6/14/96

From: Rich Deem

To: Marilyn Yager

Division of Federal Affairs

Phone number: _____

Message: Opposition to Fraud + Abuse provisions

Total Pages including cover sheet: 11

Reply Fax Number: 202-789-4581

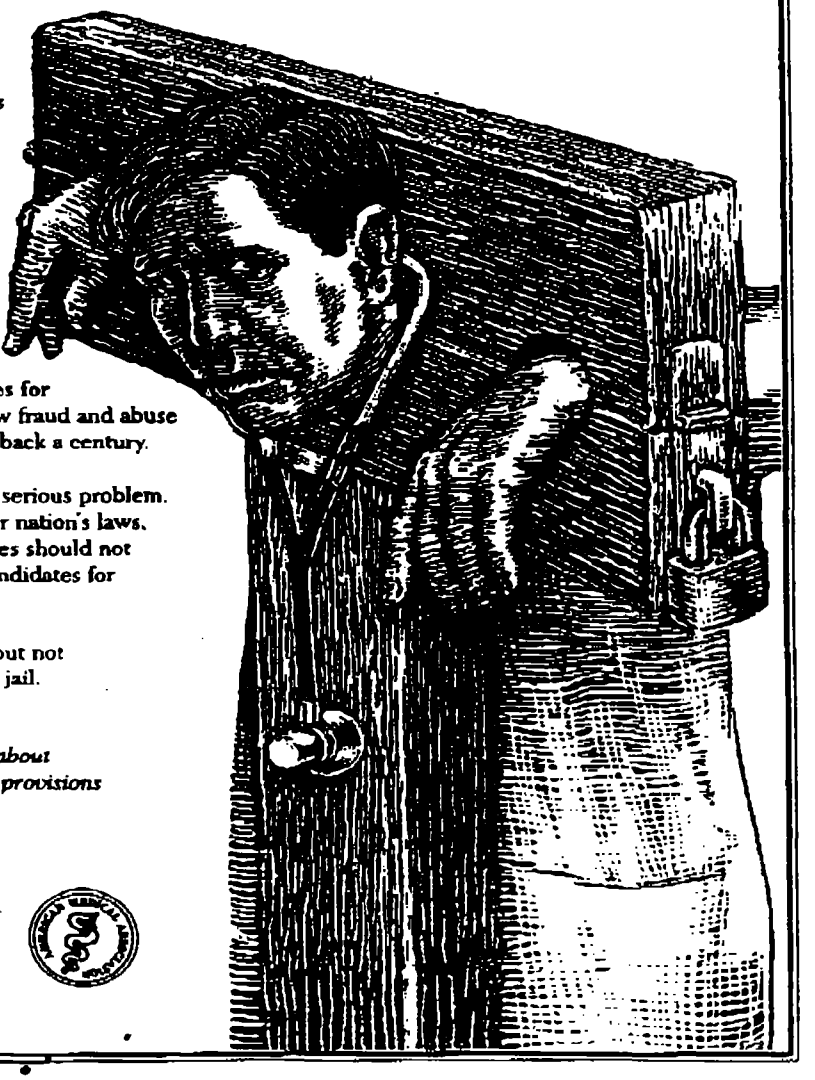
America needs health insurance reform. But unfair fraud and abuse laws need a second opinion.

Congress is moving now to pass long-needed legislation making health insurance portable and ending coverage exclusions due to preexisting medical conditions.

Congress is also considering ways to end the discrimination in health care by providing a greater range of treatment choices for patients through Medical Savings Accounts and enhanced coverage of mental illness.

The nation—and our patients— need these reforms.

HOWEVER...some proposals in the House and Senate go too far. Despite months of negotiations, legislation is now being considered that could put your doctor in jail or exact grossly excessive fines for unintended paperwork mistakes. These new fraud and abuse laws will set basic principles of due process back a century.



Medicine agrees that fraud and abuse is a serious problem. If doctors willfully and knowingly violate our nation's laws, they should be punished. But honest mistakes should not make physicians—or any other citizens—candidates for incarceration.

America needs health insurance reform...but not unfair laws that will put innocent doctors in jail.

Call the AMA's Grassroots Hotline at 1-800-833-6354 to obtain more information about joining the campaign to strike these onerous provisions from the law.

American Medical Association
Physicians dedicated to the health of America

Sent to all Members of Congress.
Prepared by Kristen Morris x408.

June 7, 1996

The Honorable Spencer Abraham
United States Senate
245 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Abraham:

The undersigned medical societies are writing to apprise you of our members' strong opposition regarding the extensive fraud and abuse provisions contained in HR 3103. **We are hearing from thousands of physicians each day across the country who are outraged that Congress would consider imposing such excessive sanctions against physicians making inadvertent administrative mistakes.** Although we support efforts to curb fraud and abuse in the health care sector, we believe that the provisions currently contained in HR 3103 go far beyond merely tightening laws to prosecute wrongdoers. The extensive new health care offenses would dramatically increase civil monetary penalties and threaten physicians who are dedicated to doing what's best for their patients.

Since we learned that fraud and abuse provisions would be added to the health insurance reform bill, we have repeatedly made our positions known to Congress. We are concerned, however, that our requested reasonable modifications are being ignored. Accordingly, we would like to take this opportunity to reemphasize our key requests for revisions to the fraud and abuse provisions.

- Legitimate disagreements regarding medical treatment decisions, and variations in coding without an intent to fraudulently bill for services, should not be cause for imposing legal penalties (especially since inappropriate payments are already recouped by the government.) A determination of whether services are "medically necessary" is by nature a subjective judgment and must be made by a professional. Unless there is a specific intent to defraud the system, **the legal system should not have the right to question what a physician believes to be medically necessary.** Likewise, coding of health care services for Medicare billing often is subjective. A physician may have to choose between several codes to describe a procedure. **Such innocent coding decisions could trigger huge civil monetary penalties if later determined to be inappropriate.** We urge you to drop provisions which apply penalties for medical necessity or upcoding.

- **We strongly encourage you to add the word "willfully" to the new federal health care offenses (House sections 242 – Health Care Fraud and 244 – False Statements).** These criminal provisions would create new law, and it is important that

this new law not be ambiguous. We request that the House recede to the Senate language which ensures that offenders who intentionally break the law are punished, but those with no intent to do wrong are not treated as criminals. It is unconscionable that physicians could be subjected to criminal sanctions for unintentional coding errors.

- We agree that civil monetary penalties (CMPs) can be appropriate to deter fraudulent behavior. We strongly believe, however, that an individual should be able to know that his or her conduct is prohibited, and that the penalties should be commensurate with the offense committed. Toward this end, **we support the House provision which would establish a "knowledge" standard for CMPs. In addition, we support tying the amount of the penalty to the amount of the inappropriate claim to avoid unnecessarily and unreasonably excessive fines.** Without these two safeguards, physicians may find themselves subject to enormous and disproportionate penalties for activities they did not know were prohibited.

- **In any fraud and abuse program, physicians and other providers should be able to obtain binding written advisory opinions from the appropriate enforcement agencies as to whether anticipated conduct violates the law.** Advisory opinions that apprise the medical community of which factual circumstances are illegal would allow enforcement agencies to fight fraud and abuse, but would reduce the unintended chilling of activities that do not violate the law. We therefore urge you to accept the House provisions providing for advisory opinions.

- Both the House and Senate bills contain fraud and abuse provisions that would make changes in the existing Medicare Integrity Program. These provisions would mandate the use of new commercial software technologies. **Our concern is that the content of these new commercial products would not be disclosed based on the claim that such information should be private, thereby creating "black box" review screens.** At a time when patients are demanding more information on benefit coverage, it is wrong to permit such closed, "black box" edits. We urge you to amend these provisions to reflect the public nature of the Medicare program and allow for the appropriate review of these commercial products.

To effectively combat fraud, the laws must be balanced and clear so that the real wrongdoers are brought to justice. But it is beyond reason to treat physicians as if they are worse than violent criminals. Innocent physicians and health care providers should not be put in jail or subjected to excessive fines for unintended mistakes while trying to decipher complex administrative rules or regulations.

As you move to finalize the conference report to HR 3103, we urge you to consider seriously the concerns raised above.

Sincerely,

Alaska State Medical Association
American Academy of Allergy Asthma and Immunology
American Academy of Child and Adolescent Psychiatry
American Academy of Dermatology
American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Family Physicians
American Academy of Hematology
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Orthopaedic Surgeons
American Academy of Otolaryngology - Head and Neck Surgery
American Academy of Pain Medicine
American Academy of Pediatrics
American Academy of Physical Medicine and Rehabilitation
American Association of Clinical Endocrinologists
American Association of Clinical Urologists
American Association of Neurological Surgeons
American Association of Plastic Surgeons
American College of Cardiology
American College of Emergency Physicians
American College of Nuclear Physicians
American College of Obstetricians and Gynecologists
American College of Occupational and Environmental Medicine
American College of Osteopathic Surgeons
American College of Physicians
American College of Rheumatology
American College of Surgeons
American Group Practice Association
American Medical Association
American Medical Directors Association
American Orthopaedic Foot and Ankle Society
American Osteopathic Association
American Psychiatric Association
American Society for Dermatologic Surgery
American Society for Gastrointestinal Endoscopy
American Society for Reproductive Medicine
American Society of Abdominal Surgeons
American Society of Anesthesiologists
American Society of Cataract and Refractive Surgery
American Society of Clinical Oncology
American Society of Clinical Pathologists
American Society of Hematology
American Society of Internal Medicine
American Society of Maxillofacial Surgeons
American Society of Plastic and Reconstructive Surgeons
American Urological Association
Arkansas Medical Society
College of American Pathologists
Colorado Medical Society
Congress of Neurological Surgeons
Connecticut State Medical Society
Florida Medical Association

Greater Albuquerque Medical Association
Hawaii Medical Association
Idaho Medical Association
Illinois State Medical Society
Indiana State Medical Association
Iowa Medical Society
Kansas Medical Society
Kentucky Medical Association
Maine Medical Association
Massachusetts Medical Society
Medical and Chirurgical Faculty of Maryland
Medical Association of Georgia
Medical Association of the State of Alabama
Medical Group Management Association
Medical Society of Delaware
Medical Society of New Jersey
Medical Society of the State of New York
Medical Society of Virginia
Michigan State Medical Society
Minnesota Medical Association
Mississippi State Medical Association
Missouri State Medical Association
Montana Medical Association
Nebraska Medical Association
New Hampshire Medical Society
New Mexico Medical Society
North Carolina Medical Society
North Dakota Medical Association
Ohio State Medical Association
Oklahoma State Medical Association
Oregon Medical Association
Pennsylvania Medical Society
Renal Physicians Association
Rhode Island Medical Society
Society of Cardiovascular and Interventional Radiology
Society of Nuclear Medicine
Society of Thoracic Surgeons
South Carolina Medical Association
South Dakota State Medical Society
State Medical Society of Wisconsin
Tennessee Medical Association
Texas Medical Association
US and Canadian Academy of Pathology
Walnut Hill OB/Gyn Associates
Utah Medical Association
Vermont State Medical Society
Washington State Medical Association
West Virginia State Medical Association
Women's Association for Obstetrics and Gynecology
Wyoming Medical Society

AMENDMENT URGENTLY NEEDED TO PERFECT FRAUD AND ABUSE LANGUAGE IN H.R. 3103

Status: Both the House and Senate have passed incremental health insurance reform bills that dramatically increase fraud and abuse enforcement authority. Physicians may face criminal prosecution and exorbitant fines, unless the fraud and abuse provisions are modified to specifically define the level of intent and precise conduct that is prohibited.

Problem: The proposed House bill would subject physicians to criminal prosecution and fines for conduct which they are not aware is illegal.

With today's health care marketplace constantly changing, there are financial arrangements which may not be black and white. That is why it is critical that fraud and abuse legislation be carefully crafted to avoid punishing unintentional acts by physicians.

1. NEW FEDERAL FRAUD AND FALSE STATEMENT PROVISIONS MUST CONTAIN THE TERM "WILLFULLY"

Any new federal health care offenses in HR 3103 should be specifically defined to include both a "knowing and willful" intent as well as the precise conduct which is prohibited. Legitimate disagreements regarding **medical judgment** and **treatment decisions** should not be cause for imposing legal penalties.

Both the vetoed Balanced Budget Act and Senator Cohen's bill would create new fraud and abuse crimes that require an individual to act with "knowing and willful" intent. However, the House health insurance reform bill (HR 3103) deleted the word "willfully" simply to make it easier for prosecutors to prove that a health provider violated the new crimes.

Today, fraudulent health care providers are prosecuted under Federal mail and wire fraud laws, the False Claims Act, and other related laws. Some of these require "knowing" and some require both "knowing and willful" intent. The fraud and abuse legislation creates fraud and abuse crimes to apply specifically to the health care context.

The addition of "willful," is essential to ensure that inadvertent or accidental conduct is not deemed criminal. The "**willful**" requirement imposes criminal liability upon one who: (1) knows of a legal duty; and (2) intentionally violates that duty.

The "**knowing**" requirement, on the other hand, imposes criminal liability on one who intentionally engages in the proscribed conduct whether or not he knows that act is against the law.

The term "willful" is necessary to separate conduct that is so inherently bad that a person would not engage in the behavior for innocent reasons, from conduct that is inadvertent or accidental. **(See attached examples of why "willful" is necessary in the medical billing context.)**

2. THE NEED FOR PHYSICIAN INPUT IN DEVELOPING COMMERCIAL TECHNOLOGIES

Both the House and Senate versions of HR 3103 contain fraud and abuse provisions that would make changes in the existing Medicare Integrity Program. These provisions would mandate the use of new commercial software technologies. Implementing these commercial technologies would come at the expense of Medicare patients.

The content of today's Medicare coding methodologies is open and available to the public. Patients, as well as physicians, have a right to know which services are covered. Under the bill, the content of these new commercial products, however, would not be disclosed based on the dubious claim that such information should be private.

A 1989 Institute of Medicine report entitled "Controlling Costs and Changing Patient Care?/ The Role of Utilization Management" recognized that the making clinical criteria and standards open to the public outweighed any privacy concerns.

If black box "edits" are to be used, they must be developed and reviewed in consultation with the medical profession. Without physician input, quality patient care could be compromised.

"Black box" review screens, particularly in the Medicare program, often do not reflect the actual practice of medicine. At a time when patients are demanding more information on benefit coverage, it is unthinkable that such closed, black-box edits would be permitted.

3. BINDING ADVISORY OPINIONS SHOULD BE REQUIRED TO PROVIDE GUIDANCE

In any fraud and abuse system, physicians should be able to obtain binding written advisory opinions from the appropriate enforcement agencies as to whether or not anticipated conduct violates the law. Advisory opinions would allow enforcement agencies to fight fraud and abuse but would reduce the unintended chilling of activities that do not amount to a prohibited health care offense.

4. CIVIL MONETARY PENALTIES SHOULD BE COMMENSURATE WITH THE OFFENSE COMMITTED

The AMA supports civil monetary penalties to deter fraudulent behavior. We would request, however, that the penalties be commensurate with the offense committed, and that the language require the individual to know that his or her conduct is prohibited. Without these two safeguards, physicians and other providers may find themselves subject to enormous penalties for activities they did not know were illegal.

5. FRAUD AND ABUSE ACCOUNT SHOULD BE ABOLISHED

The AMA specifically opposes the creation of a Health Care Fraud and Abuse Account that

would consist of fines, civil penalties or damages. Funding a governmental program directly through penalties collected from law enforcement activities would create an inappropriate bounty system. Such a system would provide unlawful incentives that would impair the objective implementation of the program.

6. DATA COLLECTION PROGRAM SHOULD PROTECT PATIENT PRIVACY

Although agencies need access to information regarding those who engage in fraud and abuse, we believe that at this time creating a national data collection program is not the best use of limited enforcement dollars. Maintaining security over the information in the data base would be difficult and inappropriate disclosure and misuse of data base information could irreparably harm patients as well as providers.

We want to avoid the careless disclosure of patient information and "fishing expeditions" which may keep patients from seeking needed medical care.

EXAMPLES OF NECESSARY "KNOWING AND WILLFUL" INTENT

The argument for a knowing and willful standard for health care fraud is particularly powerful due to the complexity of today's health care payment system. Most allegations of health care fraud by physicians involve the billing process in some way, such as billing for services not rendered, billing for a more intensive service than was provided (upcoding), or billing separately for several parts of the same service (unbundling). Most physicians use a coding system, called CPT, to describe their services in submitting bills to Medicare and many private payers.

CPT is updated annually, and it contains thousands of codes which describe discrete physician services. However, due to the complexity of medical practice, the correct code for a particular procedure may not be obvious, and in fact may be difficult to determine. The AMA devotes substantial resources to explaining and interpreting these codes, including distributing a regular newsletter and responding to thousands of telephone inquiries each year. Despite the efforts of the AMA and others, ambiguity remains a part of the application of physician billing codes in many circumstances. (It is worth noting that the AMA consults regularly with health care fraud enforcement agencies to assist them in interpreting and understanding CPT codes).

Thus, it is not uncommon for physicians or their billing staffs to use an incorrect billing code, and to do so on a regular basis. This behavior may be the result of intentional misconduct, but more often it is the result of mistaken coding. Retaining the "knowing and willful" standard is critical in distinguishing between intentional misconduct and honest mistakes. Given the complex environment in which physicians must bill for their services, it would be unfair in the extreme to hold them criminally liable for knowingly using a code that, in retrospect, is incorrect. On the other hand, physicians or anyone else who use an improper code knowing that it is inappropriate for purposes of increasing their reimbursement should be subject to criminal and civil penalties.

Following are two examples of the difficulty of interpreting current billing codes:

1. A common laboratory test is CPT code 84479, Triiodothyronine (T-3), resin uptake method. The T-3 test can also be performed using another method, Chemiluminescent assay. Because this assay can be used for other purposes as well, it has its own CPT code, 82397. A physician performing a T-3 test using the assay method should use code 82397. However, because the test being performed is a T-3 test, the physician may mistakenly use the code 84479, which is described as a T-3 test. Thus, in order to provide a code for both situations, the CPT has an inevitable element of ambiguity.

2. Surgeons often cause and must repair damage in the course of treating a condition. For example, in removing a skin lesion deep within the arm, layers of skin must be removed and then repaired. The CPT description for this process, complex repair of skin, includes the phrase "may include creation of defect", which means that the removal of the lesion and repair of any necessary ancillary damage is included in the code. Physicians should not use this code and bill separately for removing the skin lesion. However, because the physician

has removed the lesion, and a separate code exists for doing so, the physician may bill for the excision of the lesion in addition to the complex repair of the skin. While incorrect, this coding error may reflect a lack of understanding of the coding system rather than an intent to defraud.

Physicians may be subject to unfair criminal penalties for other types of conduct should the "willful" standard be dropped. These include:

1. Medical Necessity. Physicians are often reviewed to assure that the care they provide is medically necessary. On occasion, allegations of fraud have been made on the grounds that physicians have deliberately provided care, such as lab tests, which is unnecessary. If the "willful" standard is removed, physicians could be liable on fraud grounds any time they knowingly provide care which is later determined to be unnecessary. To be sure, appropriate utilization of health care services is a serious issue, but it ought not be called fraud without some evidence that physicians know that the care they are providing is unnecessary.

2. Referral. Physicians are often asked to attest that a patient is in need of a particular medical device or service, such as DME or home health care. As in many medical decisions, these judgments frequently are not absolute, and require the exercise of some discretion. As the patients usually urge that they should be eligible for the service, physicians may err on the side of providing (or authorizing) it. Admittedly, physicians have an obligation to exercise their professional judgment appropriately, but they should not be subject to fraud charges for making an honest decision which is questioned after the fact.

American Medical Association
Physicians dedicated to the health of America

Richard A. Deem
Director
Division of
Federal Affairs

1101 Vermont Avenue, NW
Washington, DC 20005

202 789-7400
202 789-7485 Fax

July 18, 1996

James Costello
Office of Legislative Affairs
U.S. Department of Justice
10th and Constitution Avenue, NW - Room 1141
Washington, DC 20530

Dear Mr. Costello:

This is in follow-up to our conversation yesterday regarding our concerns with fraud and abuse proposals.

The brief by Sidley and Austin speaks to the "intent" issue, which is our top priority. The article "Rationalizing the Fraud and Abuse Statue" describes provider concerns with expanding an already complex fraud and abuse statute. The attached letter from Rep. Peter Hoagland argues in support of advisory opinions.

Real fraud must be punished. However, innocent mistakes should not trigger criminal or civil penalties.

Please feel free to call me, 202-789-7413, if you would like to discuss this further.

Sincerely,

Richard A. Deem

Attachments
cc: Nancy-Ann Min
Marilyn Yager
Chris Jennings

M E M O R A N D U M

TO: SENATE FINANCE COMMITTEE
The Honorable William V. Roth, Jr., Chair

FROM: SIDLEY & AUSTIN
Jack R. Bierig
David B. Toscano

RE: Intent Requirement in Fraud and Abuse Provisions of Proposed Health Insurance Reform Legislation

DATE: April 18, 1996

The Senate Finance Committee is taking up legislation that would criminalize certain specified conduct relating to the provision of health care services. The proposed legislation would amend current fraud and abuse statutes. The Committee is considering language that would govern the intent required for violations of these criminal provisions. In this connection, the American Medical Association has asked us to advise the Committee on the differences, if any, between a "knowingly" and a "willfully" standard in federal criminal statutes. The AMA has also asked us to determine how common it is for federal criminal statutes to include a requirement of willfulness.

In essence, our conclusions are as follows: Although judicial interpretations are not entirely uniform, there is a significant distinction between a "knowingly" standard on one hand and a "willfully" (or "knowingly and willfully") standard on the other. Specifically, a "willfully" or "knowingly and willfully" requirement (often referred to as one of "specific intent") imposes criminal liability on a person who intentionally engages in the proscribed conduct knowing that the conduct is unlawful. By contrast, a "knowingly" requirement (often referred to as one of "general intent") imposes criminal liability on a person who intentionally engages in the proscribed conduct -- whether or not that person knows that the conduct is unlawful.

The willful intent standard is quite common in federal criminal statutes. A list of statutes incorporating the "knowingly and willfully" standard is attached. We are not aware of any congressional efforts to have this standard deleted from federal criminal statutes. On the contrary, the standard serves a particularly salutary purpose when the proscribed conduct is not obviously evil or inherently bad. In particular, by limiting the stigma of criminality to conduct undertaken with knowledge that it is wrong, it helps to maintain the moral

underpinnings of criminal laws and to assure that these laws are not used simply for routine regulatory purposes.

If the Committee concludes that a willfulness requirement should be incorporated into the fraud and abuse provisions of the proposed legislation, various approaches are set forth at the conclusion of this memorandum.

DISCUSSION

1. The Distinction Between "Willfully" and "Knowingly"

a. "Willfully". Courts have generally interpreted use of the term "willfully" in federal criminal statutes as an indication of congressional intent to require proof that the accused acted with knowledge that his or her conduct was unlawful. Recently, for example, in Ratzlaf v. United States, 114 S. Ct. 655 (1994), the Supreme Court considered the intent requirement of 31 U.S.C. §5322(a), the statute imposing criminality on persons who "willfully violat[e]" the federal law against structuring currency transactions to avoid reporting requirements.[1] The Court held that "[t]o establish that a defendant 'willfully violat[ed]' the antistructuring law, the Government must prove that the defendant acted with knowledge that his conduct was unlawful." 114 S. Ct. at 657. Thus, the Court construed the term "willfully" to define a specific intent crime. See, e.g., United States v. Miranda-Enriquez, 842 F.2d 1211, 1212 (11th Cir.) ("We have often referred to [intent to break the law] as 'specific intent.'"), cert. denied, 488 U.S. 836 (1988).

In interpreting the term "willfully," the Court in Ratzlaf recognized that "willful" is a "'word of many meanings' and 'its construction [is] often . . . influenced by its context.'" 114 S. Ct. at 659 (quoting Spies v. United States, 317 U.S. 492, 497 (1943)). Looking to the lower federal courts' interpretation of "willful" in similar contexts, the Court noted many decisions in which a "willful" standard had been held to require the defendant to know of a legal duty and intentionally violate it. 114 S. Ct. at 659-660 (citing cases). Although the Court concluded that "willfully" was unambiguous in the context

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[1] Federal law requires that financial institutions report to the U.S. Department of the Treasury transactions -- such as bank deposits -- involving more than $10,000 in cash. See 31 U.S.C. §5313; 31 C.F.R. §103.22(a). "Structuring" refers to the act of breaking up a large cash transaction into a number of smaller transactions in order to avoid triggering the financial institution's reporting requirement. See 31 U.S.C. §5324; Ratzlaf, 114 S. Ct. at 657.

at issue, it added that were "willfully" ambiguous, it "would resolve any doubt in favor of the defendant." Id. at 662-663.

In addition to cases cited in Ratzlaf, numerous other decisions have recognized that "willfully," as used in federal criminal statutes, generally defines a specific intent crime. See, e.g., United States v. Hopkins, 53 F.3d 533, 539 (2d Cir. 1995) ("The term 'willfulness' has generally, albeit not uniformly, been interpreted as referring to knowledge that the conduct in question was wrongful or unlawful."); United States v. Wells, 766 F.2d 12, 20 (1st Cir. 1985) ("Willfulness means having the specific intent to do something the law forbids; a general intent to commit the proscribed act is not enough."); United States v. Garcia, 751 F.2d 1033, 1035 (9th Cir. 1985) ("In a criminal statute, 'willfully' generally means a voluntary, intentional violation of a known legal duty in bad faith or with evil purpose.").[2]

b. "Knowingly and willfully". "Willfully" is particularly likely to be construed as an indication of congressional intent to define a specific intent crime where it is used together with "knowingly." As the Ratzlaf Court reasoned, "[j]udges should hesitate . . . to treat statutory terms [as surplusage] in any setting, and resistance should be heightened when the words describe an element of a criminal offense." 114 S. Ct. at 659. Indeed, for well over one hundred years, federal courts have held that the term "knowingly and willfully" defines a specific intent crime. See United States v. Felton, 96 U.S. 699, 703-04 (1877) (holding that the federal criminal statute which proscribed "knowingly and willfully" using a specific method of distilling would be violated only if the defendant had a "purpose to evade the laws"). See also United States v. Forbes, 64 F.3d 928, 933 (4th Cir. 1995)

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[2] To the extent that "willfully" is not always construed to define a specific intent crime, the term is significantly more likely to be so construed where the proscribed conduct is not so obviously evil or inherently bad that a person would not engage in the behavior for innocent reasons. See, Ratzlaf, 114 S. Ct. at 660-62 (currency structuring is not "inevitably nefarious"; person might make cash deposits "in small doses" out of fear that "the bank's reports would increase the likelihood of burglary"). Indeed, in the context of the criminal tax statutes, the federal courts have consistently construed "willfully" to define a specific intent crime, "largely due to the complexity of the tax laws." Cheek v. United States, 498 U.S. 192, 200 (1991); see United States v. Murdock, 290 U.S. 389, 394 (1933); United States v. Bishop, 412 U.S. 346, 360 (1973) ("[T]he word 'willfully' in [the federal criminal tax] statutes generally connotes a voluntary, intentional violation of a known legal duty."); accord United States v. Pomponio, 429 U.S. 10, 12 (1976) (per curiam).

("'[W]illfully,' especially in a statute in which Congress simultaneously uses 'knowingly,' connotes a more deliberate criminal purpose, sometimes to the point of requiring a specific intent to violate the law.") (footnote omitted); United States v. Obiechie, 38 F.3d 309, 315 (7th Cir. 1994) ("[T]he only reasonable distinction between section 924(a)(1)'s 'knowingly' and 'willfully' standards is that the latter requires knowledge of the law.").

c. "Knowingly". Where a statute does not include willfulness as an element of a crime, courts usually conclude that Congress chose to enact a general intent criminal statute. In construing federal statutes requiring that criminal conduct be engaged in "knowingly," courts have required only that the conduct be undertaken intentionally -- as opposed to accidentally or through coercion. They have not required that the defendant specifically intend to violate the law.[3] See, e.g., United States v. Bailey, 444 U.S. 394, 405 (1980) ("In a general sense, . . . 'knowledge' corresponds loosely with the concept of general intent.").

In United States v. International Minerals & Chem. Corp., 402 U.S. 558 (1971), for example, the Supreme Court reviewed a statute imposing criminality on a person who "knowingly violates any . . . regulation" governing the transport of corrosive liquid. Id. at 559. The Court held that, in order to be convicted, a defendant need neither know nor intend that his actions violated the regulations. Id. at 563. Lower courts also tend to interpret "knowingly," when not used in combination with "willfully," to define a general intent crime. See, e.g., United States v. Hayden, 64 F.3d 126, 130 (3d Cir. 1994) ("In defining 'knowingly,' courts have almost uniformly rejected arguments that the term requires the defendant know his conduct was unlawful; rather they have

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[3] Liparota v. United States, 471 U.S. 419 (1985), is not contrary to this conclusion. The statute at issue in Liparota prescribed punishment for "whoever knowingly uses, transfers, acquires, alters, or possesses [food] coupons . . . in any manner not authorized by" statute or regulation. 471 U.S. at 420. This language left unclear whether "knowingly" modified only "uses, transfers, acquires, alters, or possesses," or whether "knowingly" also modified "in any manner not authorized by" law. See id. at 424-25 n.7. There was no question whether the term "knowingly" itself connoted an intent to violate the law. Rather, if "knowingly" modified "in any manner not authorized by" law, a defendant would have to know that his actions were illegal, but if "knowingly" only modified "uses, transfers, acquires, alters, or possesses," a defendant could be convicted without any intent to violate the law. The Liparota Court concluded that "knowingly" modified "in any manner not authorized by" law. See id. at 433.

interpreted 'knowingly' merely to require that the defendant know he was engaging in the prohibited conduct.").

d. Congressional use of these terms. Congress has relied on the distinction between "knowingly" and "willfully." See, e.g., Babbitt v. Sweet Home Chapter of Communities for a Great Oregon, 115 S. Ct. 2407, 2412 n.9 (1995) ("Congress added 'knowingly' in the place of 'willfully' in 1978 to make 'criminal violations of the [Endangered Species Act] a general rather than a specific intent crime.'"). Similarly, the Executive Branch has invoked the distinction when participating in the legislative process. See, e.g., Letter from Patricia M. Wald, Assistant Attorney General, to Morris K. Udall, Chairman, House Committee on Interior and Insular Affairs (undated), reprinted in 1979 U.S.C.C.A.N. 1726, 1728 ("The Department would oppose any efforts to make violations of Section 5 a specific intent crime by adding the phrase 'willfully.' As currently drafted, Section 6(b) makes violation of Section 5 a general intent crime by using the word 'knowingly' alone.").

2. Use of Willfulness Standard in Federal Criminal Statutes

At least thirty-three federal criminal statutes incorporate a "knowingly and willfully" standard. See Attachment. In addition, computerized legal research indicates that approximately 196 sections of Title XVIII include a willfulness requirement. We are not aware that Congress has recently sought to repeal any statute that includes an element of willfulness.

Quite to the contrary, a requirement of willfulness can play an important role in maintaining the moral underpinnings of the criminal law. As the Supreme Court has often noted, some criminal statutes prohibit conduct that is not obviously evil and that a person acting in good faith might not recognize as unlawful. Other statutes are so technical or complex that a reasonable person might not understand that particular conduct amounts to a violation.

In these circumstances, a willfulness requirement helps assure that the stigma of criminality will be reserved for those who engage in "conscious and calculated wrongdoing" and that the criminal laws are not used simply "to regulate business practices regardless of the intent with which they were undertaken." See United States v. United States Gypsum Co., 442 U.S. 422, 442 (1978). Absent a requirement of willfulness in these situations, the criminal law loses its moorings in our Anglo-American system of justice in which notions of criminality are grounded ultimately in our."'belief in freedom of the human will and a consequent ability and duty of the normal individual

to choose between good and evil.'" Id. at 436 (quoting Morissette v. United States 342 U.S. 246, 250 (1952)).

3. Possible Approaches to a Willfulness Requirement

If the Committee concludes that fairness suggests making intent to violate the law a requirement for criminal culpability under the fraud and abuse provisions of the proposed legislation, it could substitute "willfully" for "knowingly" in the language before it. However, because the term "willfully" may be construed differently depending on its context, a more certain approach would be to include the phrase "knowingly and willfully." Another alternative would be to define "knowingly" as follows:

> (1) As used in this Subtitle, the term "knowingly" means that a person ---
>
> (a) is aware of the nature of his or her act; and
>
> (b) intentionally and willfully commits the act, with the specific intent to violate the law.

In any event, the Committee should make clear that an essential element of a criminal violation of the fraud and abuse provisions of the proposed legislation is proof that the accused knew that his or her conduct was wrong or unlawful.

Attachment

FEDERAL CRIMINAL STATUTES WITH "KNOWINGLY AND WILLFULLY" REQUIREMENT

The following statutes appear in Title 18 of the United States Code:

§288 (false claims for postal losses)

§289 (false claims for pensions)

§545 (smuggling)

§550 (false claims for refund of customs duties)

§798 (disclosure of classified information)

§871 (threats against the President)

§878 (threats against and extortion of foreign officials)

§879 (threats against former Presidents)

§954 (false statements influencing foreign government)

§957 (possession of property in aid of foreign government)

§1001 (false statements to federal agencies)

§1115 (owner's liability for neglect of ship officers)

§1165 (hunting, trapping, or fishing on Indian land)

§1366 (destruction of an energy facility)

§1501 (assault on process server)

§1502 (resistance to extradition agent)

§1508 (recording jury deliberations)

§1541 (issuance of passport to person not owing allegiance)

§1542 (false statement in application for passport)

§1543 (use of forged passport)

§1544 (misuse of passport)

§1584 (involuntary servitude)

§1701 (obstruction of mails)

§1720 (use of cancelled stamps)

§1721 (unauthorized sale of stamps)

§1725 (depositing mail without payment of postage)

§1752 (entry into President's temporary residence)

§1920 (false claim for federal employee's compensation)

§1922 (false report on federal employee's compensation)

§2424 (false statement about alien individual)

§3056(d) (obstruction of federal agent protecting President)

The following two statutes appear in Title 26 of the United States Code:

§9012 (presidential campaign financing)

§9042 (kickbacks related to presidential campaign expense)

RATIONALIZING THE FRAUD AND ABUSE STATUTE*

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Under current law, the application of the antikickback provision is broad. While HHS is authorized to establish safe harbors from the broad coverage of the antikickback law, the approach it has taken is to promulgate narrow exceptions to the all-encompassing embrace of the statute and to refuse to establish any formal administrative mechanism for providing advice in advance regarding particular circumstances.[3] As a result, practices that encourage cost-effective care, the formation of MCOs, innovation in the structure of healthcare delivery, and the development of efficient relationships among providers are potentially illegal under the fraud and abuse statute. These practices should be encouraged, not discouraged; yet, the overbroad scope of the existing fraud and abuse law inhibits appropriate, economically-adaptive innovations that are beneficial to both consumers and governmental payors.

The Medicare Payment System

Traditionally, medical care has been paid for on a fee-for-service basis. The fee-for-service system compensates a health care provider for every service provided to a patient. The financial incentives of the fee-for-service system promote the use of medical facilities and services; the effect of these incentives is limited by the professional ethics of the provider, the willingness of the patient to spend the time necessary for the procedures, and the willingness of the patient or

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[3] Through the Office of the Inspector General, HHS does issue alerts from time to time. These can aid lawyers in providing advice to clients about HHS' current thinking -- how it will exercise its prosecutorial discretion. But these alerts do not have the force of law. The conduct is not immunized or made legal by these alerts. Accordingly, these alerts cannot be relied upon without risk; the underlying conduct may still constitute a violation of the law -- even if the enforcement agency is disinclined to enforce the law in certain circumstances. This will become an increasing problem if, as at least one federal district court has now held, private parties are allowed to sue to enforce the antikickback provisions by using the federal False Claims Act. See United States *ex rel.* Pogue v. American Healthcorp, Inc., No. 3-94-0515 (M.D. Tenn., January *5, 1996).*

referring doctor interpret the test was concern about future referrals. The second physician, who owned the testing company, defended his conduct on the ground that the referring physician had competence to perform the task and already had a relationship with the patient. At the same time, the second physician acknowledged his belief that he would not receive future referrals if he did not request interpretations from the referring physician.

The United States Court of Appeals for the Third Circuit upheld the second doctor's felony conviction for fraud and abuse violation. The inducement need not be a dominant or predominant factor, nor must the services provided be in some way inappropriate. Any economic motivation concerning the use of remuneration as an inducement suffices to constitute a violation. Thus, a motivation to develop business among Medicare or Medicaid patients or to assure a flow of such patients is illegal. Yet, such types of arrangements are commonplace in the economic marketplace in general and in the medical care marketplace in particular. And, they can be beneficial. But the merits or demerits of the arrangement are irrelevant. They are all illegal -- case closed.

The breadth of the *Greber* doctrine is truly breathtaking.[5] There are many appropriate payment arrangements that may be considered fraud and abuse violations. Hospitals are purchasing physician practices and are making payments to recruit physicians. Such arrangements may enable a hospital to compete with another hospital with respect to price and quality. Nevertheless such practices may be interpreted as fraud and abuse violations since a goal is to develop a flow of patients for the hospital. Another activity that could be inhibited is the

[5] For example, an emergency room doctor, hired as an independent contractor, cannot refer appropriate cases to the hospital that hires him or her if that emergency room doctor (as just one of many other appropriate motivations) worries that failure to refer to the hospital might result in the termination of his or her contract.

the program beneficiaries. The current environment creates disrespect for law because the legal regime is so out of sync with the realities of the marketplace -- and it is the marketplace, in this case, that is signaling socially and economically appropriate (albeit illegal) behavior. This illegal conduct is occurring; it is occurring routinely; much of that conduct is benign; the pillars of the community are participating; and enforcement officials are typically looking the other way.[8]

Reforming the relevant provisions of the fraud and abuse statute, unfortunately, is surely a politically unappealing task because of the risk of misinterpretation, misunderstanding, and outright demagoguery; surely it is politically unappealing to face headlines suggesting that one is seeking to water down tough federal laws against fraud and abuse. But revising the law as interpreted in *Greber* is quite clearly in the public interest and in the consumer's interest.

Safe Harbor Regulations

The existing antikickback provisions, as interpreted in *Greber*, are excessively broad. Recognition of this led Congress, in the aftermath of *Greber*, to authorize the establishment of "safe harbors" from its coverage. The idea was that appropriate conduct that nevertheless fell within the *Greber* fraud and abuse prohibition could be identified administratively by HHS and shielded from the broad proscriptions established by *Greber*. In response to this authority, HHS has only promulgated narrow exceptions to the all-encompassing embrace of the statute.[9] These

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[8] A recent decision by the United States Court of Appeals for the Ninth Circuit may make proof of a violation more difficult -- and therefore may reduce some of the risks of unjust conviction in the short run. See The Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995). Hanlester, however, really does not change the underlying principles and, in the long run, does not substantially alter the fundamental dilemma.

[9] In July 1991 and November 1992, HHS published as final regulations thirteen safe harbors from the provisions of the fraud and abuse law. In January 1996, HHS adopted revisions to some

HHS has repeatedly declined to provide advice in advance on specific proposals. Recently, HHS opposed proposed legislative revision that would have required that type of in-advance advisory process. The existing regime -- in which so much legitimate conduct is being ignored even though it is technically illegal -- is the antithesis of the rule of law. It invites abuse and misconduct on the part of government by giving enforcement officials vast standardless discretion and virtually a blank enforcement check.

This potential problem is now about to be exacerbated because two federal district courts have held that private citizens can bring an action in federal court without the authorization or approval of federal enforcement officials to enforce the provisions of the antikickback law. This allows the pursuit of a suit for civil liability without the restraining influence of a governmental official's exercise of prosecutorial discretion. Thus, in *United States* ex rel. *Pogue v. American Healthcorp, Inc.*,[10] a United States District Judge allowed a disgruntled former employee to sue on behalf of the federal government to enforce the antikickback provisions. Under the False Claims Act (FCA), a private party, on behalf of the United States, can sue persons who defraud the federal government. The private party who sues under the FCA need not secure government approval; if successful, the private litigant receives a substantial percentage of any recovery generated on behalf of the federal government. This creates a bounty-hunter scenario for public-spirited whistleblowers.

In the *Pogue* case, the court held that the private party bringing the action need not show any harm to the government in order to maintain and prevail on an FCA claim. If a private party can sue to enforce the technical provisions of the fraud and abuse law and need not prove any

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[10] No. 3-94-0515 (M.D. Tenn., January 5, 1996).

services and resources but with insufficient utilization and accompanying doubts about the quality of care.

Millions of Americans are now enrolled in HMOs, and provider risk-bearing through capitation is increasing dramatically. In markets with a high degree of capitation, such as California, costs or the rate of increase in costs have come down. Networks have developed, vertical integration has taken place, and efficiencies have emerged in response to competition and prudent purchasing practices. Clinical uncertainty exists. Procedure rates vary enormously for no apparent reason. It has been demonstrated that incentives matter. DRGs have shifted behavior. Lengths of hospital stay are down, less costly outpatient services are up.

In this new and evolving market -- and as Medicare risk-contracting is receiving greater attention --, the *Greber*-type fraud and abuse law is an overreaching anachronism. There is no accommodation for capitation or other provider-at-risk arrangements, in which the risk of over-utilization is minimal. The law does not provide for the consideration of the economic benefit of an arrangement -- there is just room for prosecutorial discretion without any procedure for advisory opinions to guide good-faith compliance. And there is no requirement for a showing of economic harm to the government from specific activity. On top of this comes the district court's decision in *Pogue* holding that any private citizen can sue to enforce the technical requirements of the fraud and abuse law without any restraint by government and without any showing of financial detriment to the government.

These changes in the marketplace suggest that current rules may be out of place as providers take on financial risk. HHS offers as reassurance to providers that there has never been any action against an HMO or PPO arrangement operating in good faith. This "trust me"

Summary

The antikickback provisions of the fraud and abuse statute were passed when fee-for-service and cost-based reimbursement were the dominant payment mechanisms in the healthcare field. By prohibiting inducements for referrals, the statute attempts to limit the volume-inducing incentives of fee-for-service and cost-based-reimbursement payments and thus to limit costs to Medicare and Medicaid. However, times have changed, but the statute has not. The statute inhibits many efficiency-enhancing arrangements as well as the formation of some MCOs, which have been credited with the apparent slowdown of health care costs in recent years. Legislative modification of the fraud and abuse law would be an important step in eliminating a potentially substantial obstacle for market-adaptive conduct among Medicare and Medicaid providers and in facilitating the development of more risk-contracting in the Medicare program. It would contribute to the further rationalization of the healthcare market.

inferior levels of quality. Rather, this type of "fraud and abuse" violation stems purely from a motivation -- an intent (among many others) to induce future referrals, a concern about developing a flow of patients -- even if the service is medically appropriate, priced favorably, and performed at acceptable levels of quality. The very premise of the law -- that an intent to induce future referrals, by itself, is illicit -- reflects a hostility to a market-oriented health care policy, and these fraud and abuse provisions pose significant barriers to market-oriented attempts to rationalize the medical care marketplace. Existing legal fraud and abuse doctrine discourages vertical integration and other forms of cooperative integration that are socially desirable and essential to improving economic efficiency and consumer welfare in the medical care marketplace. Reexamination of this component of the fraud and abuse laws is necessary if market incentives are to succeed within the medical care system because these provisions criminalize market-adaptive conduct.

BACKGROUND

The antikickback provision was designed to deal with the problems of overutilization in Medicare and Medicaid and overall containment of costs in those programs.[1] In 1977, those programs paid for hospital services on a cost-reimbursement basis and paid for physician services on the basis of usual, customary and reasonable fees. In such a cost-based, fee-for-service healthcare market, payors have a legitimate concern about the use of payments to induce referrals

[1] Other objectives sometimes ascribed to the antikickback provisions are the preservation of patient freedom of choice and the protection of competition. See Richard P. Kusserow, *The Medicare & Medicaid Ant-Kickback Statute and the Safe Harbor Regulations -- What's Next?*, 7 EXEMPT ORGANIZATION TAX REVIEW 419, 420 (March 1993). These would surely seem to be subordinate goals of the antikickback ban and should not be viewed as independent objectives of the fraud and abuse law.

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WAYS AND MEANS

SUBCOMMITTEES:
TRADE
SELECT REVENUE MEASURES

Congress of the United States
House of Representatives

April 21, 1994

The Honorable Fortney Pete Stark
United States House of Representatives
239 Cannon House Office Building
Washington, D.C. 20510

Dear Chairman Stark:

As you are aware, on March 11, 1994, I introduced H.R. 4028, the "Health Care Fraud and Abuse Advisory Opinion Act of 1994". The advisory opinion process proposed in this legislation would give health care providers specific, advance guidance on structuring transactions to comply with the fraud and abuse laws as they apply to the Medicare and Medicaid programs.

Many of the fraud and abuse statutes originated in your Subcommittee and have been refined by the Subcommittee over time. Those statutes have enhanced the government's efforts to ferret out and reduce fraud and abuse in the Medicare and Medicaid programs and have saved the government billions of dollars. I fully support the aim and reach of the statutes as do most of the health care providers in my District. Unless the providers who abuse the system are identified and punished, they will obtain a competitive advantage over the majority of providers who comply with the law and will drain federal and state dollars from the health care providers who properly provide services.

Unfortunately, as the Inspector General of the Department of Health and Human Services ("Department"), June Gibbs Brown, notes in her letter to you dated March 22, 1994, "the [anti-kickback] statute is broad and encompasses many arrangements between health care providers, many of which may not be abusive." This breadth and lack of clarity has long created confusion and uncertainty for health care providers working to develop innovative, lawful arrangements for the delivery of health care. Moreover, this confusion and uncertainty is likely to increase if Congress enacts the dramatic expansion of the fraud and abuse laws contained in the Clinton Administration's health care reform package as amended by your Subcommittee and other health care bills pending in Congress. In fact, the Inspector General's letter itself highlights the need for clarity and certainty in this area when it states "we would anticipate a flood of thousands of voluminous requests for advisory opinions".

Although for a variety of reasons, some of which are set forth below, I do not believe that the Department will be besieged in this fashion, I firmly believe Congress has an obligation to ensure a process that will provide clarity and certainty.

The Inspector General has voiced opposition to advisory opinions, citing utilization of enormous resources, impracticality, and harmful effects on future prosecutions. I believe that the advisory opinion process outlined in H.R. 4028 gives providers the guidance that they need while addressing each of the Inspector General's objections to the process. The advisory opinion process would be funded by the requesters via a user's fee, which is intended to render the process budget neutral. Because the advisory opinion process would make more providers aware of specific practices within the industry that violate the law, the process is intended to be more practical and economical, and may actually be more effective, than the Department's current enforcement approach. Finally, the advisory opinion process should simplify, rather than complicate criminal prosecutions. Each of these points is addressed more fully below.

A number of federal agencies issue advisory opinions pursuant to a process similar to that contained in H.R. 4028. Attached to this correspondence is a schedule which identifies pertinent statutes and regulations requiring eleven federal agencies to issue forms of advisory opinions.

THE ADVISORY OPINION PROCESS WOULD GIVE PROVIDERS MORE GUIDANCE THAN IS CURRENTLY AVAILABLE FROM THE OFFICE OF THE INSPECTOR GENERAL

The Department's Safe Harbor Regulations have not adequately addressed the needs of providers as they attempt to maneuver in the ambiguous waters of the fraud and abuse laws. The Safe Harbors have been widely criticized for describing as legal, activities that no one believed to be illegal. Further, published safe harbors have either been so broad as to be ineffective in giving providers practical guidance in structuring complex relationships or so narrow as to affect only a minuscule number of health care providers and business relationships. In addition, the Department has been slow to issue the Safe Harbor regulations. Although the legislation requiring the Department to issue Safe Harbor regulations was enacted in 1987 (and required the promulgation of final regulations within two years), the first set of regulations was not published until 1991.

The Fraud Alerts issued by the Department, though somewhat helpful, are issued only after an existing practice within the industry has been identified as violative of the law. Further, they have been designed merely to raise issues which the Department believes may be suspect. The advisory opinion process proposed by H.R. 4028 would give providers prospective direction with respect to the propriety of

their proposed transactions. This would allow providers to develop transactions which comply with the law and would give the Department an alternative to its current practice of enforcement by prosecution.

THE ADVISORY OPINION PROCESS WILL BE SELF FUNDING

Although the process of issuing advisory opinions will be resource intensive, the user's fee to be charged to providers seeking opinions will fund the process and is likely to deter providers from bombarding the Department with trivial questions. I anticipate the users fee will be substantial, potentially in the $5,000 to $10,000 range. Moreover, the publication of advisory opinions or of Fraud Alerts based upon questions raised in requests for advisory opinions should reduce the numbers of requests received by the Department each year.

Most importantly, the clarity provided by the advisory opinion process will ensure greater compliance with the law. Greater compliance will in turn reduce the need for costly Departmental investigations and prosecutions. Any estimate of the cost of the advisory opinion process should take into account these savings.

THE ADVISORY OPINION PROCESS WILL NOT REQUIRE THE DEPARTMENT TO MAKE A FINDING WITH RESPECT TO A PROVIDER'S INTENT

The philosophy underlying the Safe Harbor regulations is that there are certain objective standards, which if met, will ensure compliance with the anti-kickback provisions, the provider's intent not withstanding. As was pointed out by the Inspector General, the Medicare and Medicaid Patient and Program Protection Act of 1987 requires the Department to set forth specific payment practices which, although potentially capable of inducing referral of Medicare or Medicaid business, would be immunized from criminal or civil prosecution. The Department's Safe Harbor Regulations outline the requirements that such transactions must satisfy. Via the advisory opinion process, providers would be merely requesting that the Department advise it as to whether the objective elements of a transaction, as described by the provider, would be violative of the anti-kickback provisions. A finding with respect to the Provider's intent is neither requested nor required.

Moreover, H.R. 4028 also mandates the issuance of advisory opinions with respect to the self-referral provisions of the Social Security Act which you sponsored. As you are aware, those provisions do not contain or require an element of intent.

Finally, the provider's protection from prosecution under H.R. 4028 will be contingent upon the provider's good faith reliance upon the Department's advice. Good faith will encompass the full, complete and accurate presentation of all relevant

facts, including the providers intent, to the Department.

The Department of Justice currently provides pre-clearance or advisory opinions on conduct that falls within the reach of criminal statutes. The Criminal Division's Foreign Corrupt Practices Act Review Procedure at 28 C.F.R. Section 50.18 and the Antitrust Division's Business Review Procedure at 28 C.F.R. Section 50.6, both allow parties to submit descriptions of intended conduct to the Department of Justice and to obtain a determination of whether the conduct contravenes the Department's present enforcement policy under criminal statutes.

THE ADVISORY OPINION PROCESS WILL NOT INTERFERE WITH SUBSEQUENT CRIMINAL PROSECUTION OF THE REQUESTER OR OF ANOTHER PERSON WHO HAS READ THE ADVISORY OPINION.

An advisory opinion process will not unduly complicate criminal Medicare or Medicaid prosecutions irrespective of whether an advisory opinion is obtained, the Department of Justice has the burden of proving, beyond a reasonable doubt, that elements of a transaction violate the anti-kickback statute. An advisory opinion would establish the boundaries of permissible activities, thus simplifying, rather than complicating prosecutions.

Moreover, with respect to users requesting advisory opinions, the Department will be in a position of having given its views -- users ignoring such advice will be at risk of prosecution. H.R. 4028 specifically provides that only the parties to the opinion are bound by its terms; providers who have not requested an advisory opinion are not entitled to rely on the opinion as its sole defense in a criminal prosecution.[1]

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[1] The Inspector General cites United States v. Levin, 973 F. 2nd 463 (6th Cir. 1992) for the proposition that providers who have not requested opinions will be able to rely upon issued opinions in a criminal prosecution. Providers may be entitled to rely upon the statements of policy provided in opinions as an element of proof in defending their criminal prosecution under the Medicare and Medicaid statute. To the extent that the opinions reflect the Department's interpretation of the law, however, all providers should be able to rely upon the Department's consistent interpretation of the law. The fact that providers who do not request opinions will know how the Department interprets the law given a specific set of facts, is a benefit, not a drawback of the advisory opinion process contemplated in H.R. 4028. Moreover, the Levin prosecution involved a fact pattern in which the Department apparently issued conflicting guidance over time. H.R. 4028 is intended to avoid such inconsistencies and potential misinterpretations.

In addition, advisory opinions will not act as a absolute limit upon the prosecutorial discretion of the Department. The Department can, as have other agencies, expressly state in their opinions that they do not guarantee that prosecution will not ensue. Second, because the Department will qualify its advice by limiting the opinion to the facts as represented, the Department will not be bound to an opinion based on incomplete information.

In sum, the advisory opinion process will provide the guidance necessary to the health care industry to allow for the development of innovative, legitimate business practices without the risk of uncertain application of the laws. If successful enforcement of the fraud and abuse laws is to be measured in terms of compliance, rather than in numbers of prosecutions, the advisory process outlined in H.R. 4028 is clearly a needed addition to the Medicare and Medicaid fraud and abuse laws. For all of these reasons I introduced and continue to fully support H.R. 4028 and urge you to support the bill as well.

Sincerely,

Peter Hoagland

cc: June Gibbs Brown
Inspector General