Control on utilization --
they have to bill.

- Small volume threshhold exemption
- Set up → Mark, Alison
- Ask Alison → med. nec.

American Medical Association
Physicians dedicated to the health of America

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

Call Nancy Ann

April 20, 1995

Ms. Nancy-Ann Min
Associate Director for Health
Office of Management and Budget
New Executive Office Building
725 17th Street, N.W.
Washington, DC 20503

Dear Ms. Min:

It is our understanding that the final regulations implementing the OBRA '89 self-referral prohibition are awaiting final approval. The American Medical Association (AMA) believes it is essential that the final rule provide an exception from the ban for in-office ancillary services that are shared by physicians. Physicians often share clinical laboratories, x-ray machines and other in-office diagnostic services with other physicians in their office building so they can provide their patients with on-site health services. Patient access to appropriate treatment will be impacted if an exemption for shared facilities is not implemented.

These practical arrangements of sharing equipment provides economic efficiencies that can bring down the costs of health care services by the federal government and private payors. Without an exception, physicians and their patients are left with two poor choices: (1) to continue to provide access to necessary diagnostic services, physicians may have to purchase duplicative equipment, driving up practice overhead costs; or (2) discontinue diagnostic services provided through shared arrangements, resulting in patient loss of easy access to these services.

We urge the Office of Management and Budget to revise this final regulation to provide an exception for the in-office facilities shared by physicians. We believe that the statute gives clear authority to the Secretary of Health and Human Services to grant such an exception. I have included a copy of the statute and highlighted those sections which would give this authority to the Secretary of Health and Human Services.

The AMA believes that including such an exception makes good economic sense and would

be a significant step in meeting the Administration's goal of providing regulatory relief for physicians and their patients. If you have any questions about the AMA's recommendations, please contact Richard Deem in our Washington office at (202) 789-7413.

Sincerely,

James S. Todd, MD
Executive Vice President

cc: Marilyn Yager
Jennifer Klein

American Medical Association
Physicians dedicated to the health of America

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

April 20, 1995

Ms. Sally Katzen
Administrator, Office of Information
and Regulatory Affairs
Office of Management and Budget
Old Executive Office Building
17th Street and Pennslyvania Ave., N.W.
Washington, DC 20503

Dear Ms. Katzen:

It is our understanding that the final regulations implementing the OBRA '89 self-referral prohibition are awaiting final approval. The American Medical Association (AMA) believes it is essential that the final rule provide an exception from the ban for in-office ancillary services that are shared by physicians. Physicians often share clinical laboratories, x-ray machines and other in-office diagnostic services with other physicians in their office building so they can provide their patients with on-site health services. Patient access to appropriate treatment will be impacted if an exemption for shared facilities is not implemented.

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Sincerely,

James S. Todd, MD
Executive Vice President

cc: Marilyn Yager
Jennifer Klein

organization after the date the Secretary notifies the organization that the organization is not in compliance with the requirements of section 1876(c)(6) of such Act [subsec. (c)(6) of this section]."

Revisions in the Payment Methodology for Risk Contractors

Section 4204(b) of Pub.L. 101–508, as amended Pub.L. 103–432, Title I, § 157(a), Oct. 31, 1994, 108 Stat. 4441, provided that:

"(b) **Revisions in the Payment Methodology for Risk Contractors.**—(1)(A) Not later than October 1, 1995, the Secretary of Health and Human Services (in this subsection [this note] referred to as the 'Secretary') shall submit a proposal to the Congress that provides for revisions to the payment method to be applied in years beginning with 1997 for organizations with a risk-sharing contract under section 1876(g) of the Social Security Act [subsec. (g) of this section].

"(B) In proposing the revisions required under subparagraph (A), the Secretary shall consider—

"(i) the difference in costs associated with medicare beneficiaries with differing health status and demographic characteristics; and

"(ii) the effects of using alternative geographic classifications on the determinations of costs associated with beneficiaries residing in different areas.

"(2) Not later than 8 months after the date of submittal of the proposal under paragraph (1), the Comptroller General shall review the proposal and shall report to Congress on the appropriateness of the proposed modifications."

[Amendment by section 157(a) of Pub.L. 103–432 effective as if included in the enactment of Pub.L. 101–508, 104 Stat. 1388, which was approved Nov. 5, 1990, see section 157(b)(8) of Pub.L. 103– set out as a note under section 1395y of this title.]

Study of Chiropractic Services

Section 4204(f) of Pub.L. 101–508, as amended Pub.L. 103–432, Title I, § 157(b)(6), Oct. 31, 1994, 108 Stat. 4442, provided that:

"(1) The Secretary shall conduct a study of the extent to which health maintenance organizations with contracts under section 1876 of the Social Security Act [this section] make available to enrollees entitled to benefits under title XVIII of such Act [this subchapter] chiropractic services that are covered under such title [this subchapter].

"(2) The study shall examine the arrangements under which such services are made available and the types of practitioners furnishing such services to such enrollees.

"(3) The study shall be based on contracts entered into or renewed on or after January 1, 1991, and before January 1, 1993.

"(4) The Secretary shall issue a report to the Committees on Ways and Means and Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate on the results of the study not later than January 1, 1993. The report shall include recommendations with respect to any legislative and regulatory changes that the Secretary determines are necessary to ensure access to such services."

[Amendment by section 157(b)(6) of Pub.L. 103–432 effective as if included in the enactment of Pub.L. 101–508, 104 Stat. 1388, which was approved Nov. 5, 1990, see section 157(b)(8) of Pub.L. 103–432, set out as a note under section 1395y of this title.]

LIBRARY REFERENCES

Encyclopedias

Health and hospital insurance generally, see C.J.S. Insurance §§ 923 to 930, 1122 to 1124.

NOTES OF DECISIONS

State regulation or control 1

1. State regulation or control

Federal statute regulating Medicare-qualified health maintenance organizations (HMOs) did not preempt field and deprive states of jurisdiction to grant injunctive relief under state unfair trade and deceptive practices law to parties dissatisfied with manner in which HMO solicited and enrolled Medicare recipients. Solorzano v. Superior Court (Family Health Plan, Inc.), Cal. App. 2 Dist.1992, 13 Cal.Rptr.2d 161, 10 Cal. App.4th 1135, 11 Cal.App.4th 443D.

§ 1395nn. Limitation on certain physician referrals

(a) Prohibition of certain referrals

(1) In general

Except as provided in subsection (b) of this section, if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then—

(A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and

(B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for

designated health services furnished pur t to a referral prohibited under subparagraph (A).

(2) Financial relationship specified

For purposes of this section, a financial relationship of a physician (or an immediate family member of such physician) with an entity specified in this paragraph is—

(A) except as provided in subsections (c) and (d) of this section, an ownership or investment interest in the entity, or

(B) except as provided in subsection (e) of this section, a compensation arrangement (as defined in subsection (h)(1) of this section) between the physician (or an immediate family member of such physician) and the entity.

An ownership or investment interest described in subparagraph (A) may be through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service.

(b) General exceptions to both ownership and compensation arrangement prohibitions

Subsection (a)(1) of this section shall not apply in the following cases:

(1) Physicians' services

In the case of physicians' services (as defined in section 1395x(q) of this title) provided personally by (or under the personal supervision of) another physician in the same group practice (as defined in subsection (h)(4) of this section) as the referring physician.

(2) In-office ancillary services

In the case of services (other than durable medical equipment (excluding infusion pumps) and parenteral and enteral nutrients, equipment, and supplies)—

(A) that are furnished—

(i) personally by the referring physician, personally by a physician who is a member of the same group practice as the referring physician, or personally by individuals who are directly supervised by the physician or by another physician in the group practice, and

(ii)(I) in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of designated health services, or

(II) in the case of a referring physician who is a member of a group practice, in another building which is used by the group practice—

(aa) for the provision of some or all of the group's clinical laboratory services, or

(bb) for the centralized provision of the group's designated health services (other than clinical laboratory services),

unless the Secretary determines other terms and conditions under which the provision of such services does not present a risk of program or patient abuse, and

(B) that are billed by the physician performing or supervising the services, by a group practice of which such physician is a member under a billing number assigned to the group practice, or by an entity that is wholly owned by such physician or such group practice,

if the ownership or investment interest in such services meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(3) Prepaid plans

In the case of services furnished by an organization—

(A) with a contract under section 1395mm of this title to an individual enrolled with the organization,

(B) descr in section 1395l(a)(1)(A) of this title to an individual enrolled with the organization,

(C) receiving payments on a prepaid basis, under a demonstration project under section 1395b-1(a) of this title or under section 222(a) of the Social Security Amendments of 1972, to an individual enrolled with the organization, or

(D) that is a qualified health maintenance organization (within the meaning of section 300e-9(d) of this title) to an individual enrolled with the organization.

(4) Other permissible exceptions

In the case of any other financial relationship which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse.

(c) General exception related only to ownership or investment prohibition for ownership in publicly traded securities and mutual funds

Ownership of the following shall not be considered to be an ownership or investment interest described in subsection (a)(2)(A) of this section:

(1) Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) which may be purchased on terms generally available to the public and which are—

(A)(i) securities listed on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis, or

(ii) traded under an automated interdealer quotation system operated by the National Association of Securities Dealers, and

(B) in a corporation that had, at the end of the corporation's most recent fiscal year, or on average during the previous 3 fiscal years, stockholder equity exceeding $75,000,000.

(2) Ownership of shares in a regulated investment company as defined in section 851(a) of Title 26, if such company had, at the end of the company's most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding $75,000,000.

(d) Additional exceptions related only to ownership or investment prohibition

The following, if not otherwise excepted under subsection (b) of this section, shall not be considered to be an ownership or investment interest described in subsection (a)(2)(A) of this section:

(1) Hospitals in Puerto Rico

In the case of designated health services provided by a hospital located in Puerto Rico.

(2) Rural provider

In the case of designated health services furnished in a rural area (as defined in section 1395ww(d)(2)(D) of this title) by an entity, if substantially all of the designated health services furnished by such entity are furnished to individuals residing in such a rural area.

(3) Hospital ownership

In the case of designated health services provided by a hospital (other than a hospital described in paragraph (1)) if—

(A) the referring physician is authorized to perform services at the hospital, and

(B) the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).

(e) Exceptions relating to other compensation arrangements

The following shall not be considered to be a compensation arrangement described in subsection (a)(2)(B) of this section:

(1) Re of office rental of equ

(A) Office space

Payments made by a lessee to a lessor for the use of premises if—

(i) the lease is set out in writing, signed by the parties, and specifies the premises covered by the lease,

(ii) the space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee, except that the lessee may make payments for the use of space consisting of common areas if such payments do not exceed the lessee's pro rata share of expenses for such space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using such common areas,

(iii) the lease provides for a term of rental or lease for at least 1 year,

(iv) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,

(v) the lease would be commercially reasonable even if no referrals were made between the parties, and

(vi) the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(B) Equipment

Payments made by a lessee of equipment to the lessor of the equipment for the use of the equipment if—

(i) the lease is set out in writing, signed by the parties, and specifies the equipment covered by the lease,

(ii) the equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee,

(iii) the lease provides for a term of rental or lease of at least 1 year,

(iv) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,

(v) the lease would be commercially reasonable even if no referrals were made between the parties, and

(vi) the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(2) Bona fide employment relationships

Any amount paid by an employer to a physician (or an immediate family member of such physician) who has a bona fide employment relationship with the employer for the provision of services if—

(A) the employment is for identifiable services,

(B) the amount of the remuneration under the employment—

(i) is consistent with the fair market value of the services, and

(ii) is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician,

(C) the remuneration is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer, and

(D) the employment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

OFFICE OF MANAGEMENT AND BUDGET

Legislative Reference Division
Labor-Welfare-Personnel Branch

Telecopier Transmittal Sheet

SPECIAL

FROM: Bob Pellicci -- 395-4871

DATE: 5/2 **TIME:** _____

Pages sent (including transmittal sheet): 8

COMMENTS:

Markup of Physician Referral Statutory -

TO:

Jennifer Klein

PLEASE CALL THE PERSON(S) NAMED ABOVE FOR IMMEDIATE PICK-UP.

File

DRAFT as of 9:27am April 28, 1995

Mr. Chairman and members of this Subcommittee, I am here this morning to discuss HCFA's implementation of the physician self-referral prohibitions that are found in section 1877 of the Social Security Act.

The Clinton Administration has been working on a number of initiatives to control fraud and abuse in the Medicare and Medicaid programs, which we will be announcing shortly as part of our Reinventing Government efforts. ~~In fact, later today the President will be announcing our comprehensive proposal for program integrity.~~

Preventing inappropriate utilization through a prohibition on self-referrals is one part of our coordinated effort to fight fraud and abuse. Today I will be focusing on the self-referral provisions, as you requested, and not the anti-kickback provisions, which are frequently confused with self-referral.

I would like to recognize the interest and responsibility of this Subcommittee in the development and passage of these provisions. I will begin by presenting a bit of background information and discussing the research and related ethical issues; following this, I'll briefly summarize the law and our regulatory activity.

BACKGROUND AND RESEARCH

First, ~~While I realize that many members here today were involved in the development of these provisions,~~ I would like to ~~review~~ explain briefly why we believe there is a need for provisions like these. Self-referral is the term used to describe a patient referral made by a physician to an entity with which the physician or a family member has a financial relationship; the relationship may be an ownership or investment interest or a compensation arrangement.

Physicians who invest in health care entities are likely to have ownership or investment interests in magnetic resonance imaging (MRI) centers, other diagnostic imaging facilities, clinical laboratories, ambulatory surgical centers, or physical therapy facilities. Hospital-physician joint ventures are also a common form of financial relationship; the General Accounting Office (GAO) estimates that 18 percent of non-profit hospitals were participating in joint ventures with physicians in 1991.

The American Medical Association (AMA) estimates the number of physicians with financial interests in health facilities at about seven percent, although others cite higher numbers. For example, a 1991 study that examined the prevalence and scope of physician joint ventures in Florida found that at least 40 percent of Florida physicians involved in direct patient care had an investment in a health care business to which they could--in the absence of prohibiting legislation--refer patients for services.[1] However, some have suggested that increased examination of self-referral arrangements and enactment of both Federal and State laws prohibiting such arrangements has led to a decline in self-referral activity and financial relationships between physicians and entities.

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[1] "Joint Ventures Among Health Care Providers in Florida: State of Florida Cost Containment Board," (September, 1991)

Cleared NOB o/a
Carl Taylor on 5/2/95
BPellicci

In 1989, a study from the Office of Inspector General (OIG) of the Department of Health and Human Services found that Medicare patients of referring physicians who owned or invested in independent clinical laboratories received 45 percent more lab services than Medicare patients in general.[2] OIG estimated that this increased utilization cost Medicare $26 million in 1987. While this report does not examine medical necessity, it clearly shows a significant deviation from general medical practice. More importantly, it illustrates the need for provisions that limit the acceptability of unnecessarily costly referral patterns.

In past hearings on this topic, this Subcommittee has heard testimony from academic researchers in Florida and from the GAO and the OIG, among others, that consistently cited problems in referral patterns for physicians who have financial relationships with the entities to which they refer patients. The problems include increased utilization, increased use of costly services, and, in some cases, higher charges per procedure, decreased access, and lower quality (e.g., less time spent with the patient or patient care is provided by health care personnel with less training). Broadly stated, beneficiaries caught in these referral patterns may be subject to unnecessary medical procedures and/or high-cost, lower quality care.

Aside from the cost-containment issues posed by self-referral patterns, inappropriate utilization ~~can~~ result in ~~significant~~ health hazards. Each time a medical procedure is performed, patients ~~are~~ exposed to an increased risk of injury ~~which varies according to the procedure; thus, unnecessary testing or treatment exposes beneficiaries to health hazards to which they would not otherwise be exposed~~. One study actually showed that the frequency and costs of radiation therapy treatments at free-standing centers were 40 to 60 percent higher in Florida than in the rest of the United States, yet Florida did not have higher cancer rates and the hospitals in the study did not have below-average use of radiation therapy to explain the higher use or higher costs.[3]

ETHICAL ISSUES

~~We feel strongly that we should help insure that our beneficiaries are not placed in potentially dangerous situations~~. Ethicists and legal scholars have argued that self-referral creates an unnecessary conflict of interest without providing any significant benefits. Physicians are members of a profession that is characterized by binding ethical obligations and a unique responsibility to care for patients who are presented to them. Indeed, AMA has stated that physicians "have different and higher duties than even the most ethical businessperson."[4] Physicians direct the

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[2] "Financial Arrangements Between Physicians and Health Care Businesses: Office of the Inspector General," OAI-12-88-01410 (May 1989)

[3] Mitchell JM, Sunshine JH; New England Journal of Medicine, 1992; 327:1497-1501

[4] "Conflicts of Interest: Physician Ownership of Medical Facilities," Council on Ethical and Judicial Affairs, American Medical Association, JAMA, May 6, 1992:2358-2360.

purchase of health care services. Patients depend on their providers to guide them in making health care decisions. Yet, ~~when~~ physicians ~~are~~ invested in health care services that they refer to, ~~there is always a question about~~ whether the referral is being made because of medical necessity or financial interest.

As early as 1986, the Institute of Medicine condemned physician self-referral in its examination on for-profit enterprise in health care. Describing the patients' vulnerability in health care decision making, Brock and Buchanon[5] state that patients are especially vulnerable for two reasons: first, they lack the special knowledge required to judge the necessity of the recommended or provided service; second, the presence of illness or injury may make it difficult for the patient to engage in the type of self-protective bargaining behavior typically expressed in the admonition "caveat emptor," or "let the buyer beware." The report stressed that "Only if one believes that medical training renders physicians impervious to the effects of economic incentives or that patients can adequately cope with physicians' conflicts of interest can one be indifferent to economic conflicts of interests resulting from physicians' investments." ~~It also recommended that the trend toward setting up arrangements in which the physician has economic inducements to make referrals should be deplored and rejected in strong terms by professional associations, State laws, and third-party payers.~~

In December 1992, after considerable debate, the AMA ~~also~~ voted to declare self-referral unethical, with few exceptions. One year earlier, the AMA's Council on Ethical and Judicial Affairs had concluded that physicians should not refer patients to a health care facility outside their office at which they do not directly provide services when they have an investment interest in the facility. Exceptions are allowed if there is a demonstrated need in the community and alternative financing is not available. The Council stated that physicians have a special fiduciary responsibility to their patients and that "there are some activities involving their patients that physicians should avoid whether or not there is evidence of abuse."

SELF-REFERRAL AND MANAGED CARE

Prohibitions on self-referrals were created in the context of a traditional fee-for-service system, where there are no incentives for providers to control utilization. In a managed care arrangement that uses capitated payments, the implications of self-referral practices change considerably. It is highly unlikely that physicians who are receiving a capitated payment would actually refer for unnecessary services.

Accordingly, there is an exception for prepaid health plans under Medicare, including risk- and cost-based Medicare contractors. Therefore, we do not see these provisions as an impediment to the development of legitimate Medicare managed care arrangements.

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[5]Brock D, Buchanon A, "Ethics of For-Profit Health Care," For-Profit Enterprise in Health Care, Gray BH, ed., National Academy Press, 1986.

LEGISLATIVE HISTORY AND SUMMARY OF LAW

Prohibitions on physician self-referrals were first enacted in the Omnibus Budget Reconciliation Act of 1989 (OBRA 89), when Congress amended Title XVIII of the Social Security Act to prohibit the referral of Medicare patients to clinical laboratories by physicians who have a financial relationship with those laboratories (or whose immediate family members have such a relationship), unless they qualified for one of the many exceptions.

The law has subsequently been modified in every piece of major Medicare legislation that has passed since its creation: OBRA 90, OBRA 93, and the Social Security Act Amendments of 1994 (SSAA 94). OBRA 90 and SSAA 94 included technical corrections and other changes, while OBRA 93 expanded the scope of the law by adding a list of ten additional designated health services, expanding and clarifying the exceptions, and applying certain aspects of the law to referrals for Medicaid services.

Health care reform deliberations during the 103rd Congress also re-evaluated the self-referral provisions. Proposals to create different exceptions, modify the list of covered services and even extend the self-referral provisions to all payers were among the changes that were considered in various bills.

Because of its exceptions, the current law is complicated. However, the essence of the prohibition is clear: if a physician or a family member has a financial relationship with an entity that furnishes items or services on the list, then he or she cannot refer Medicare or Medicaid patients to that entity. Unlike the anti-kickback statute, the law is triggered by the mere fact that a financial relationship exists; the intention of the referring physician is not taken into consideration.

The provisions state that the relationship may be through an ownership or investment interest or a compensation arrangement. The ownership or investment interest may be through debt, equity or other means, or an interest in an entity that holds such an interest; the compensation arrangement is defined as any remuneration that does not fit within certain narrow exceptions between the physician (or immediate family member) and the entity. OBRA 89 provisions became effective for referrals occurring on or after January 1, 1992; many of the OBRA 93 provisions that applied to the exceptions for clinical labs were retroactive to January 1, 1992. OBRA 93 provisions that apply to referrals for designated health services became effective January 1, 1995.

Following is the list of designated health services that are covered under the self-referral ban:

-clinical laboratory services;
-physical therapy services;
-occupational therapy services;

-radiology services (including MRI, CAT scans and ultrasound);
-radiation therapy services and supplies;
-durable medical equipment and supplies;
-parenteral and enteral nutrients, equipment and supplies;
-prosthetics, orthotics, and prosthetic devices and supplies;
-home health services;
-outpatient prescriptions drugs; and
-inpatient and outpatient hospital services.

Although some inappropriate utilization may exist, Congress created a number of exceptions in recognition of existing business practices. While the Secretary has authority under Section 1877 to create new exceptions, we must first determine, and specify in regulations, that any new exception will not pose a risk of program or patient abuse. ~~This is an extremely difficult test to meet.~~

The in-office ancillary services exception is perhaps the most important exception. It exempts physicians (both group practices and solo practitioners) with ownership and/or compensation arrangements from the self-referral ban for most services provided in their offices if they meet a set of requirements. There are 14 additional exceptions, including ones for prepaid health plans, rural providers, and isolated financial transactions.

The statute also prohibits an entity from billing Medicare, Medicaid, the beneficiary or anyone else for a designated health service resulting from a prohibited referral. Under the Medicaid program, the Federal government cannot pay Federal financial participation to a State for medical assistance that is furnished as the result of a referral that would be prohibited under Medicare, if Medicare covered the service in the same way as the State Medicaid program. If a person collects any amount for services billed in violation of the law, he or she must make a timely refund. A person can be subject to civil money penalties or exclusion from Medicare, Medicaid and other programs if that person: (1) presents or causes to be presented a claim to any payer for a service that the person knows or should know is a result of a prohibited referral, or (2) fails to make a timely refund. The maximum penalty is $15,000 for each service.

If a physician or entity enters into a circumvention scheme (such as a cross-referral arrangement), which the physician knows or should know has a principal purpose of assuring referrals to a particular entity that would be prohibited if made directly, the participating providers could be subject to civil money penalties of not more than $100,000 for each scheme and exclusion from Medicare, Medicaid and other programs.

As of October 1994, 27 states have enacted legislation that restricts or qualifies self-referral. There is great variation among the states. Some only require disclosure of the financial relationship to the patient, while others ~~actually~~ prohibit such referrals.

DRAFT as of 9:27am April 28, 1995

REGULATIONS

We are faced with twin challenges as we try to implement this law. While the basic concept is simple, the legislative process created complicated exceptions. Adequately defining these exceptions has proven to be a daunting task. The resulting issues have played an important role in the development of the accompanying regulations. In addition, the repeated modifications to the underlying legislation that I mentioned earlier have further delayed and complicated the development of the implementing regulations.

Due to the order in which they were enacted and in which work began on them, we are issuing two separate rules: one for the provisions that are related to referrals for clinical lab services and one for the provision of the designated health services.

The proposed rule for the original legislation was published in the Spring of 1992. We received more than 300 comments on the proposed rule, many of which included multiple, technical questions and each of which needed to be addressed in detail. These comments included descriptions of practical considerations that we needed to weigh in order to achieve an appropriate balance.

In addition, we have spent a significant amount of time meeting with and talking to individual providers, their attorneys and industry associations in an attempt to deal fairly and proactively with issues that are raised by the law and subject to interpretation in the regulations. Many of these discussions have focused on reviewing individual situations that do not fit clearly within one of the stated exceptions, but which have the same or similar situations as those that are provided for in the exceptions.

The final rule for the self-referral provisions for clinical lab services is under review and we hope to be able to publish it shortly.

The final rule on referrals to clinical laboratories will contain many definitions and interpretations that will also apply to referrals for all designated health services. As a result, we expect the rule to answer many questions for situations that are prohibited under the law as it is currently written. In addition, conversations with the provider community have also addressed questions relating to the interpretation of the OBRA 93 expansion; these outreach efforts have helped us prepare for the development of the second set of regulations. Once the first final rule is published, we hope to publish a proposed rule for the remaining provisions that are related to the designated health services within a few months. At this point, we estimate that we will publish the proposed rule for these provisions by the end of Summer.

ENFORCEMENT

As I am sure you know, the provider community is concerned about

enforcement. We do not have discretion to alter the effective dates and, while we recognize that the complexity of the law raises many questions about how it is to be applied, it is nonetheless in effect. We feel that the spirit of the law is clear: physicians who want to continue to refer patients to entities with which they have financial relationships must fit within one of the exceptions. We intend to implement the law using the least burdensome manner that will still allow for effective enforcement. As we stated in a summary that we sent to provider groups, Medicare carriers and fiscal intermediaries, and other interested groups in January, we will begin compliance audits once the final rule for clinical laboratories is published. In addition, we will investigate reported abuses.

CONCLUSION

Appropriate referral guidelines are necessary to preserve the integrity of the programs that we oversee. The provisions I have spoken about this morning are complex, and they have been difficult to interpret. Because the self-referral ban does not apply within the context of Medicare managed care, we do not believe that these provisions hamper the development of managed care in the Medicare program. As I mentioned earlier, we are in the process of implementing a ~~comprehensive~~ cost effective effort to combat fraud and abuse in the Medicare and Medicaid programs, ~~We feel strongly that this is not the time to compromise~~ consistent with the spirit of the self-referral provisions.