REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 1-I-08

Subject: Physicians' Self-Referral
(Resolution 17, A-07)

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Referred to: Reference Committee on Amendments to Constitution and Bylaws
(Sandra F. Olson, MD, Chair)

Resolutions 12 (A-07), introduced by the American College of Cardiology and 17 (A-07), introduced by the American College of Radiation Oncology ask the Council on Ethical and Judicial Affairs to examine ethical issues relating to leasing arrangements in medical imaging and misuse of the in-office ancillary services exception, respectively. In addition, the Council has been consulted by AMA's Litigation Center on issues relating to conflicts of interest in physician ownership of health facilities. In view of the fact that these three topics all involve underlying ethical issues in physician self-referral, the Council combines analysis of these topics in the present report.

The Council has issued guidance on a variety of aspects of self-referral over the years, most recently on physician ownership of health care facilities[1] or home care services[2] and prescribing and dispensing practices.[3] Other Council Opinions, such as those on capitation,[4] discounts for specialty care,[5] financial incentives in medicine,[6] and even retainer practices[7] have touched on ethically similar concerns.

At the heart of the Council's analyses and Opinions regarding self-referral have been questions about (financial) conflicts of interest in the practice of medicine. Physicians must be able to ensure their own livelihood, of course, if they are to devote their attention to others. Concerns arise when practice arrangements create conditions that exacerbate the challenge of sustaining that ethical balance. Changes in reimbursement rates or use of financial incentives by third-party payers that affect physician income can play a role in creating tension between physicians' interests and the interests of their patients. So too can physicians' decisions to acquire an ownership or investment interest in a facility or service to which they are in a position to refer patients.

The ethical issues that can arise in the latter situations of self-referral are the focus of this report, which provides guidance for physicians as they seek to balance competing interests in their clinical practice.

THE ETHICAL CHALLENGES OF SELF-REFERRAL

Physicians may lawfully enter into a variety of commercial and other relationships that can benefit both their patients and their own financial situation,[8,9] including ownership or investment interests

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in specialty facilities or services. However, such arrangements inevitably create secondary interests that compete with the physician's primary responsibility to promote the best interests of his or her patient.

Secondary interests, financial or otherwise, are present to some degree in virtually every treatment recommendation a physician makes, of course. Such interests are not necessarily illegitimate themselves and may even be desirable—provided that professional duties remain the primary consideration. Because it can be difficult to recognize when secondary interests become inappropriate, both ethics and the law provide guidance.

ETHICS & MEDICAL PROFESSIONALISM IN SELF-REFERRAL

The values at stake in self-referral lie at the ethical core of medicine as a professional activity: fidelity to the patient, clinical objectivity, professional integrity, trustworthiness, and patient advocacy.[8,10]

As members of the medical profession physicians owe a duty of fidelity to their patients and are expected to put patients' interests ahead of their own.[8,11,12,13,14,15] This responsibility is rooted in patients' need to trust their physicians. Patients are dependent on physicians' expert clinical knowledge, skills, and compassion;[8,16] they must be confident that their physicians will make treatment recommendations in the patient's best interest, based on objective clinical judgment and relevant professional guidelines.[3,6,7,9,17]

Opportunities for self-referral put physicians' primary commitment to patient well-being at risk by creating incentives to provide additional or alternative services not dictated solely by the patient's medical situation. There is evidence that the existence of a financial relationship subtly and unintentionally biases judgment, even when the individual is alert to the possibility of bias.[18, 19] Ordering unnecessary tests or other services can have adverse consequences for patients, including medical risks, cost, and inequitable access to care.[20] Self-referral can also undermine patient autonomy by limiting referral options.[21] Moreover, self-referral can compromise patient trust if the patient senses that the physician's judgment is being influenced by circumstances irrelevant to the individual's medical condition.

In addition, there is concern that the entrepreneurialism inherent in self-referral arrangements can undermine medical professionalism more broadly. Physicians are healers, not simply businessmen.[8] Practices of self-referral can reflect—or just as important, *appear* to reflect—a physician's lack of commitment to the ethos of professionalism. The result can be erosion of trust among patients, fellow professionals, and the public.[17] Trust is widely held to be essential to the therapeutic relationship between patient and physician.[17] Uncertainty or lack of trust can make patients reluctant to disclose private/sensitive information or adhere to recommended treatment;[17,22] in the extreme, it can lead individuals to avoid seeking care altogether.[17]

At the same time, physicians, more than any other members of society, may be aware of deficiencies in existing facilities and the need to bring new technologies and methods into the health care marketplace. The physician's ethical obligations to advance health care (*Principles of Medical Ethics* VI, VII and IX) must be weighed against the need to maintain public trust in the profession.

SELF-REFERRAL IN THE LAW

In 1972, Congress passed the Anti-Kickback Statute, which prohibits physicians from receiving or paying anything of value to influence the referral of business from federal health care programs;[23] states have passed their own general anti-kickback laws that apply to private insurance as well.[24] While the Anti-Kickback Statute does apply to self-referral arrangements such as lease arrangements or physician ownership in specialty hospitals, participants may structure the arrangements to comply with one or more of the regulatory exceptions to the Anti-Kickback Statute, commonly referred to as safe harbors. Safe harbors that may apply to physician investments include the investment interest safe harbor[25] and the ambulatory surgical center safe harbor.[26] Although arrangements that do not fall within the requirements of a particular safe harbor are not *per se* illegal, parties to self-referral arrangements should structure the arrangements within a safe harbor.

The rise of physician ownership interests in clinical laboratories, ambulatory surgical centers, specialty hospitals, and outpatient diagnostic and imaging centers created additional concerns that health services were being influenced by financial, and not solely medical, considerations. Thus in 1989 the federal government enacted the Ethics in Patient Referrals Act of 1989, commonly referred to as the Stark Law, to prohibit physicians from referring Medicare beneficiaries to facilities in which they held a financial relationship such as an ownership or investment interest.

There are many exceptions to Stark Law's general prohibition on referrals. One exception to the Stark Law is for in-office ancillary services,[27] which in part protects services ancillary to the referring physician's professional services which meet certain billing, supervision, and location requirements, including services performed by a physician in the same group practice at certain of the group's offices. This exception recognizes that referral within a group practice can promote quality, create efficiency, and advance continuity of care and thus offer sufficient benefits to offset the risk created by financial incentives. Certain leasing arrangements in medical imaging and certain referrals among members of multi-specialty group practices have been found to satisfy the requirements of the in-office ancillary services exception.

If the relationship is structured appropriately, physicians are also legally permitted under the Stark Law to refer patients to certain facilities in which they have an ownership interest, such as ambulatory surgery centers[28] and specialty hospitals.[29] The latter exception, the "whole hospital" exception, allows referral of patients to hospitals in which the referring physician has an ownership interest if the referring physician is authorized to provide services at the hospital and if the ownership interest is in the entire hospital rather than a particular segment.[30]

Currently, legislatures, courts, and regulatory agencies are addressing additional aspects of self-referral practices. The regulations accompanying the Stark Law were recently modified and will likely continue to be modified periodically as new issues arise. Courts are tackling the issue of ownership and self-referral, evidenced by numerous cases that address the ability of physicians to refer to facilities they own or lease or in which they have a financial interest.[31,32,33]

Clearly, physicians must avoid arrangements that violate legal prohibitions and should consult with experienced counsel regarding compliance with the Anti-Kickback Statute and the Stark Law. But the core ethical issues that self-referral raises for physicians go beyond legal requirements.[14] Setting a floor for acceptable conduct that is based solely on the law leaves salient ethical considerations out of account. Importantly, law fails to provide guidance for how physicians should respond when an arrangement that may be legally permissible is nonetheless ethically problematic.

MANAGING CONFLICT-CREATING SITUATIONS

Arrangements in which physicians maintain ownership or investment interests in a facility or service, or equity interest in a device or other health product to which they refer or that they recommend to patients can create a conflict between physicians' responsibilities to the investment and their responsibilities to the patient. In some situations it may be ethically justifiable to permit such conflicts of interest and take steps to manage their effects on professional judgment and the patient-physician relationship.

Law and ethics offer three approaches to conflict of interest: avoidance, disclosure, and management. For instance, the *Code of Medical Ethics* categorically prohibits compensation to physicians for referral of patients (including compensation from health care facilities) in Opinions condemning "fee splitting."[34,35] Disclosure is addressed in Opinions on physician ownership of health facilities and on compensation arrangements, which instruct physicians to disclose conflicts to patients (and other stakeholders).[1,6] It should be noted, however, that while disclosing competing interests to patients is an ethically important step, disclosure by itself cannot ensure that patients' interests are adequately protected.[10,36]

In yet other circumstances, the Council has offered guidance for managing conflicts. The *Code* identifies several ethical criteria and corresponding mechanisms to guide physicians facing conflict-creating situations. Broadly, these include transparency, proportionality, fairness, and what we might refer to as criteria of "mitigation" and "engagement" that should inform physicians' relationships with both patients and fellow professionals. The *Code* also requires physicians to deal fairly with professional peers in establishing and managing facilities and services in which the individual has an ownership or other significant financial interest.[1]

The *Code* further directs physicians to consider the expected levels of financial reward involved and to avoid "large" incentives[6] and situations that impose inordinate financial risk in any given arrangement.[4,6] These Opinions have not attempted to define specific thresholds beyond which the physician's interests would be considered to have "undue influence" on his or her recommendations for patient care. The *Code* also calls for physicians to be sensitive to referral arrangements that have a financial impact on the physician through his or her treatment decisions or recommendations.[6] Finally, the *Code* stresses the importance of physicians' direct engagement in care when services are provided through arrangements involving self-referral.[1,2]

PUTTING PATIENTS FIRST

Ensuring that self-referral arrangements offer the prospect of real benefit to patients is an essential condition for ethical practice. Without confidence that patients' interests are being well served by such arrangements, it is not possible to successfully balance the competing interests they create.

The recent rapid growth of physician-owned specialty hospitals, ambulatory surgical centers, and new arrangements for providing diagnostic imaging services has raised questions about whether these emerging health care models are ethically appropriate.[23,35,37,38,39] In light of the ethical and policy questions they raise, the Robert Wood Johnson Foundation comprehensively reviewed existing data about these self-referral arrangements and analyzed their implications.[20]

The Foundation's report looked at the patients whom physicians tend to self-refer and explored questions about the impact of self-referral on quality, cost, and access to health care services. Overall, the report found evidence that self-referral increases utilization of health care services. But

the data currently available indicate that the benefits and costs of self-referral can differ significantly depending on the type of referral arrangement.

In looking at the factors that drive self-referral, the report found that multiple financial, regulatory, and clinical incentives influence the development and utilization of self-referral arrangements. Financially, ownership interest—for example, in a specialty hospital—can enable a physician to be paid a fee for his or her service as a professional, to receive a facility fee, and to share in any overall profits the enterprise may generate, helping to maintain income in the face of cost containment measures implemented by third-party payers.

The regulatory environment, including not only Stark regulations and anti-kickback laws but also certificate of need laws and certification requirements, also influences opportunities for self-referral. Finally, clinical incentives are at play as well. When a specialty facility is able to provide highly focused services, it may generate higher quality care for appropriately identified patient populations. Specialty facilities also have the potential to offer benefits for patients in the form of greater convenience, timely care, and enhanced amenities, all of which contribute to patient satisfaction.

Yet the report found that it is difficult to determine how well self-referral arrangements live up to the potential to provide benefits for patients on the basis of the data currently available. There is no national census of specialty hospitals and information about physician ownership is not publicly available. As a result, different studies have used slightly different methods to identify specialty hospitals and to attempt to categorize physicians as owners, making comparisons difficult. Some studies of specialty hospitals include both physician-owned and non-physician-owned facilities, limiting what they can say specifically about self-referral. There are likewise few data available about self-referral within physician offices, e.g., for imaging services. Finally, most studies to date have used Medicare claims data, which cannot provide evidence about patient outcomes or offer insight into the effects of self-referral for non-Medicare patients.

Thus while the available data do show that physician ownership is related to referral patterns, at present they cannot unequivocally answer the question that is of most interest ethically: i.e., whether these referrals were or were not clinically appropriate.

The Robert Wood Johnson Foundation's review of available data on self-referral addresses the specific topics the Council has been asked to consider as follows:

Physician-Owned Specialty Hospitals. The limited evidence currently available suggests that overall there is relatively little difference between the quality of clinical care provided by specialty hospitals and that provided by general hospitals. Cardiac hospitals tend to care for healthier patients and to have lower risk-adjusted mortality, but they have similar rates of complication. They also seem to transfer patients out at the same rate as competing general hospitals.[20] The general findings are similar for orthopaedic hospitals, although there have been fewer studies of these facilities.

Data about the impact of specialty hospitals on general hospitals in the same community are limited.[20] General hospitals do lose some profitable patients to specialty hospitals, but to date there is no evidence to indicate that total profit margins of general hospitals have been affected.

Leasing of Medical Imaging. The Robert Wood Johnson Foundation report also found that there are few data about the quality of imaging services in nonhospital facilities.[20] From an ethics perspective, however, leasing arrangements for medical imaging can be problematic. Either of the two common forms of leasing arrangements, per click or time block, can create incentives for the

leasing physician to refer for other than strictly medical reasons. In "per-click" (fee-for-use) leases, physicians bill on behalf of the imaging facility each time the facility is used. Per-click leases carry almost no financial risk to the physician, who pays the facility based only on the number of patients referred, but there is reward with every referral. Such arrangements thus create an incentive for physicians to self-refer. Concerns about the potential for abuse in these arrangements recently led the Centers for Medicare and Medicaid to issue new rules for self-referral, to take effect in October 2009, that prohibit "per click" payments for services provided to patients referred by a physician who has an interest in the imaging service.[40]

In time block leases, physicians lease an amount of time, during which the leasing physician is able to bill for use of the imaging equipment. In contrast to per click leases, time block leases impose a measure of financial risk, since failure to utilize all leased time slots means less income to the physician who must still pay the facility for the full amount of time leased.

In-Office Ancillary Services Exception. The Robert Wood Johnson Foundation report did not specifically examine in-office ancillary services. The in-office ancillary services exception to the Stark Law was intended to encourage the creation of multi-specialty group practices that would better serve patients' needs. Where multi-specialty group practices are formed to improve the quality of services provided to patients, they are ethically acceptable. However, arrangements that are designed to support referral within the practice primarily for the purpose of generating revenue rather than to meet patient needs are prohibited under the *Code of Medical Ethics*.[31,32]

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that Opinion E-8.032 "Conflict of Interest: Health Facility Ownership by a Physician and Clarification," Opinion E-8.035 "Conflict of Interest in Home Health Care," and Policy D-140.970 "Legal and Ethical Guidelines for Leasing Arrangements in Medical Imaging" be rescinded; that the following be adopted in lieu of Resolution 17 (A-07); and that the remainder of this report be filed.

> Business arrangements among physicians in the health care marketplace have the potential to benefit patients by enhancing quality of care and access to health care services. However, these arrangements can also be ethically challenging when they create opportunities for self-referral in which patients' medical interests can be in tension with physicians' financial interests. Such arrangements can undermine a robust commitment to professionalism in medicine as well as trust in the profession.
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> In general, physicians should not refer patients to a health care facility that is outside their office practice and at which they do not directly provide care or services when they have a financial interest in that facility. Physicians who enter into legally permissible contractual relationships—including acquisition of ownership or investment interests in health facilities, products, or equipment; or contracts for service in group practices—are expected to uphold their responsibilities to patients first. When physicians enter into arrangements that provide opportunities for self-referral they must:
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> (1) Ensure that referrals are based on objective, medically relevant criteria.
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> (2) Ensure that the arrangement:
>
> (a) is structured to enhance access to appropriate, high quality health care services or products; and

(b) within the constraints of applicable law:

(i) does not require physician-owners/investors to make referrals to the entity or otherwise generate revenues as a condition of participation;

(ii) does not prohibit physician-owners/investors from participating in or referring patients to competing facilities or services; and

(iii) adheres to fair business practices vis-à-vis the medical professional community—for example, by ensuring that the arrangement does not prohibit investment by nonreferring physicians.

(3) Take steps to mitigate conflicts of interest, including:

(a) ensuring that financial benefit is not dependent on the physician-owner/investor's volume of referrals for services or sales of products;

(b) establishing mechanisms for utilization review to monitor referral practices; and

(c) identifying or if possible making alternate arrangements for care of the patient when conflicts cannot be appropriately managed/mitigated.

(4) Disclose their financial interest in the facility, product, or equipment to patients; inform them of available alternatives for referral; and assure them that their ongoing care is not conditioned on accepting the recommended referral.

(New HOD/CEJA Policy)

Fiscal Note: Staff cost estimated at less than $500 to implement.

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