

E-8.032 Conflicts of Interest: Health Facility Ownership by a Physician

Physician ownership interests in commercial ventures can provide important benefits in patient care. Physicians are free to enter lawful contractual relationships, including the acquisition of ownership interests in health facilities, products, or equipment. However, when physicians refer patients to facilities in which they have an ownership interest, a potential conflict of interest exists. In general, physicians should not refer patients to a health care facility which is outside their office practice and at which they do not directly provide care or services when they have an investment interest in that facility. The requirement that the physician directly provide the care or services should be interpreted as commonly understood. The physician needs to have personal involvement with the provision of care on site.

There may be situations in which a needed facility would not be built if referring physicians were prohibited from investing in the facility. Physicians may invest in and refer to an outside facility, whether or not they provide direct care or services at the facility, if there is a demonstrated need in the community for the facility and alternative financing is not available. Need might exist when there is no facility of reasonable quality in the community or when use of existing facilities is onerous for patients. Self-referral based on demonstrated need cannot be justified simply if the facility would offer some marginal improvement over the quality of services in the community. The potential benefits of the facility should be substantial. The use of existing facilities may be considered onerous when patients face undue delays in receiving services, delays that compromise the patient's care or affect the curability or reversibility of the patient's condition. The requirement that alternative financing not be available carries a burden of proof. The builder would have to undertake efforts to secure funding from banks, other financial institutions, and venture capitalists before turning to self-referring physicians.

Where there is a true demonstrated need in the community for the facility, the following requirements should also be met:

- (1) physicians should disclose their investment interest to their patients when making a referral, provide a list of effective alternative facilities if they are available, inform their patients that they have free choice to obtain the medical services elsewhere, and assure their patients that they will not be treated differently if they do not choose the physician-owned facility;

- (2) individuals not in a position to refer patients to the facility should be given a bona fide opportunity to invest in the facility on the same terms that are offered to referring physicians;

- (3) the opportunity to invest and the terms of investment should not be related to the past or expected volume of referrals or other business generated by the physician investor or owner;
- (4) there should be no requirement that a physician investor make referrals to the entity or otherwise generate business as a condition for remaining an investor;
- (5) the return on the physician's investment should be tied to the physician's equity in the facility rather than to the volume of referrals;
- (6) the entity should not loan funds or guarantee a loan for physicians in a position to refer to the entity;
- (7) investment contracts should not include "noncompetition clauses" that prevent physicians from investing in other facilities;
- (8) the physician's ownership interest should be disclosed to third party payers upon request;
- (9) an internal utilization review program should be established to ensure that investing physicians do not exploit their patients in any way, as by inappropriate or unnecessary utilization;
- (10) when a physician's commercial interest conflicts to the detriment of the patient, the physician should make alternative arrangements for the care of the patient. (II, III, IV)

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Clarification of Opinion 8.032

(1) If physicians who share office space want to share a clinical lab, may they refer their patients there?

The Council does not view self-referral to a shared clinical lab as inappropriate when the facility is a true extension of the physician's practice. Thus, the Council's guidelines permit two or more solo practicing physicians to share a clinical laboratory to avoid duplication and limit overhead costs, as long as several conditions are met: (a) the physicians have office space in the same building or complex where the laboratory is located, (b) the laboratory is not a separate corporate entity, (c) the physicians actively supervise the testing provided by the laboratory, (d) the physicians are equally responsible for the actions of the laboratory or are responsible for the services to their patients, (e) the laboratory provides services only for patients of the physicians, (f) all testing is performed on site, and (g) all services are billed by the ordering physician under

that physician's provider number. While self-referral to shared clinical laboratories is permissible, there is still an obligation to comply with the Council's guidelines in Opinion 8.032, "Conflicts of Interest: Health Facility Ownership by a Physician."

(2) May a physician refer patients to an outside pharmacy if the physician has a financial interest in the pharmacy?

A pharmacy is a health care facility for the purposes of the Council's guidelines. Hence, when a physician has a financial interest in a pharmacy, it is inappropriate to refer patients to the pharmacy unless the demonstrated need or direct provision of care requirements of the Council's guidelines are met. According to Opinion 8.06, "Prescribing and Dispensing Drugs and Devices," drugs may be dispensed within one's own office practice, provided such dispensing primarily benefits the patient.

(3) May physicians self-refer patients to outside physical therapy facilities, optical shops, or other health care facilities if they directly provide or supervise the care or services provided there?

Physicians may self-refer to an outside facility if they directly provide care at that facility. For instance, a surgeon may operate at an ambulatory surgical facility in which the surgeon has an investment interest. In general, the provision of care is "direct" only if it entails the personal, hands-on involvement of the physician on site when care is being provided to the patient.

The physician need not be present the entire time on every visit of a patient's care. However, the physician must be participating in the patient's care on site for a significant percentage of visits and a significant portion of the time during which services are rendered. The appropriate degree of physician involvement is a medical decision that will vary according to patients' needs, making it difficult to give explicit guidelines in this area. Sometimes, physician participation will be required every third episode of patient care; for other cases, every sixth visit would be adequate. However, the Council feels that physicians who directly provide care to the patient on site at least every fourth patient visit may confidently be considered to have fulfilled the direct provision of care requirement, though there will be many patients for whom more or less on-site physician care will be medically indicated.

(4) May physicians self-refer patients to an outside home infusion company or dialysis center if they continue to be responsible for the management of the patient's case?

Continuing responsibility for the patient's overall course of treatment does not necessarily mean that the physician is actively involved in the care provided to the patient by the home infusion company or dialysis center. In home infusion, for instance, the physician directly provides care only if he or she regularly travels to the patients' homes and is personally involved in the patient's care. In a dialysis center, the physician directly provides care only if he or she is personally involved in the dialysis treatment. As discussed in question 3, the physician need not be on site during the entire time that care is being delivered or during every administration of care. However, there has to be significant on-site involvement.

(5) If physicians are part owners of a hospital, may they refer patients to a physical therapy facility, laboratory, or MRI located within that hospital?

A physician may refer an inpatient to needed hospital-based facilities, as long as the physician is providing care to the patient in the hospital. However, for outpatients seen in the physician's office practice, hospital-based facilities are no different from the other outside facilities the physician may own. Thus, referral of outpatients to a hospital-based facility in which the physician has an ownership interest is inappropriate self-referral, unless it meets the demonstrated need or direct provision of care requirements.

Furthermore, physicians with an ownership interest in a hospital may admit their own patients there, but only if they continue to directly provide care to those patients while the patients are in the hospital. Physicians may not admit patients to a hospital in which they have an ownership interest if the patients' care will be turned over to other members of the hospital's staff, unless the hospital meets a demonstrated need in the community.

(6) May physicians refer patients to physical therapists or opticians they employ if they are located next door to the physicians' offices, or within the same office building?

If physicians employ therapists, opticians, or other allied professionals as part of their practice, then they can have their patients see the allied professionals, regardless of the allied professions' physical location. However, if the allied professional is employed by a physical therapy facility, optical shop, or other health care facility in which the physician has an investment interest, but which is legally separate from the physician's practice, then self-referral is generally not appropriate unless the facility meets the demonstrated need or direct provision of care requirements.

(7) If a group of physicians owns some vacant office space next door to their own group practice, may they lease that space to an independent physical therapist or optician and refer their patients there?

This would be acceptable as long as the office space is leased at its fair market value, and the amount of rent paid is not tied to the profits of the facility.

(8) If a physician serves as the medical director of his or her own outside health care facility, does this constitute the direct provision of care at that facility?

The position of "Medical Director" of a facility does not in itself necessarily mean that the physician is directly involved in the care or services there. For instance, providing only administrative duties or serving as a figurehead or spokesperson for the facility would not constitute the direct provision of care or services. The relevant factor is the physician's activity, not his or her title.

(9) If the physician-owned facility can provide higher quality services to patients at a lower price than competitors, does this indicate that the facility meets a demonstrated need in the community, thereby allowing the physician-owners to refer their own patients there?

When existing facilities do not provide medically appropriate services, this demonstrates a need for the facility in the community that is strong enough to justify self-referral. For instance, if the quality of services provided by competing facilities is so poor that they cannot be considered adequate, or competitors charge substantially higher fees than the physician-owned facility, then a demonstrated need for the physician-owned facility may exist. However, the advantages of the physician-owned facility for patients must be truly substantial; a demonstrated need would not exist if the differences in quality and price were only marginal. Moreover, the builder of the facility would still have to show that alternative financing for the facility was unavailable.

(10) If physicians start their own outside facility in response to a demonstrated need in the community, and then some years later a few competitors enter the market, are the physicians obligated to divest from their own facility?

Yes. The risks inherent in self-referral require divestment when the need for self-referral no longer exists. However, physicians who invested in facilities to meet a demonstrated need in the community should not be damaged by the requirement to later divest. If the investor were able to recover his or her original investment, plus a reasonable rate of return, there would appear to be no loss or hardship. The Council expects that, generally, physicians can fully divest within three years after the entry of competitors into the market. In the meantime, there is still an obligation to comply with the Council's guidelines in Opinion 8.032, "Conflicts of Interest: Health Facility Ownership by a Physician."

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