House
Legislative
Analysis
Section

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# EXPAND PHYSICIAN SELF-REFERRAL OPTIONS

**Senate Bill 517 (Substitute H-1)**
**First Analysis (2-20-01)**

**Sponsor: Sen. Bev Hammerstrom**
**House Committee: Health Policy**
**Senate Committee: Health Policy**

## *THE APPARENT PROBLEM:*

Both state and federal law restrict a physician's ability to "self-refer," i.e., to refer a patient (or patient's specimen) to a facility in which the physician holds a financial interest. The state's Public Health Code prohibits a licensed health professional from engaging in various forms of unprofessional business conduct, including "[*d]irecting* or *requiring* individuals to purchase or secure a drug, device, treatment, procedure, or service from another person, place, facility, or business in which the licensee has a financial interest." (emphasis added) The scope and effect of this prohibition was controversial when it was first enacted, and if anything, the controversy has heightened since 1995, when the Michigan Court of Appeals upheld a 1988 Board of Medicine ruling concerning physician self-referrals. The case, known as "Indenbaum" (for Dr. Samuel Indenbaum, who was one of the appellants), examined the following question: May licensed physicians, each of whom holds partial interest in a free-standing health care facility while also maintaining a separate private practice, *refer* patients from their private practices to the free-standing facility for health services, if they give their patients the option to choose another facility? In the Indenbaum case, the physicians informed patients of their choice of facilities by means of a written notice posted in their offices stating that, unless a patient explicitly requested otherwise, each physician would refer the patient to the free-standing facility in which the physician held financial interest, "where appropriate." The court's decision hinged on whether "referring" patients, under these circumstances, counted as "directing" or "requiring" patients to use the free-standing facility that the referring physicians partially owned. The court deemed that "referring" and "directing" have "analogous meanings," and ultimately upheld the board's judgment that the physicians had violated the state's health code.

Throughout the late 1980s and 1990s, while Michigan debated interpretations, and considered revisions of, this controversial provision of the health code, the federal government enacted laws and promulgated regulations on the issue of physician self-referrals. The Omnibus Budget Reconciliation Act (OBRA) of 1989 added Section 1877 to the Social Security Act to prohibit, with some exceptions, a physician from referring Medicare patients to an entity for clinical laboratory services, if the physician or immediate family member has a financial relationship with that entity. The relevant section of the 1989 OBRA, originally sponsored by U.S. Rep. Pete Stark, came to be known as "Stark I." "Stark II," part of the 1993 OBRA, amended Section 1877 by expanding the self-referral prohibition to include a number of categories of "designated health services" (in addition to clinical laboratory services), qualifying some of the exceptions made by Stark I, adding several new exceptions, and extending aspects of the prohibition to include Medicaid patients. The Health Care Financing Administration (HCFA) issued Phase I of the final regulations for Stark II in January 2001, but the HCFA has not yet issued Phase II of the final regulations.

Many physicians in the state believe that the Indenbaum ruling unduly restricts physicians' ability to self-refer, and they think that Section 1877 and the Stark II "final rule" create a more appropriate framework for today's health care industry.

## *THE CONTENT OF THE BILL:*

Under the Public Health Code, the Department of Consumer and Industry Services may investigate activities related to the practice of a licensed health professional and must report its findings to the appropriate disciplinary subcommittee. A disciplinary subcommittee may take various actions against a licensee if it finds certain grounds for action, such as unprofessional conduct. Unprofessional conduct includes "directing or requiring an individual to purchase or secure a drug, device, treatment,

procedure, or service from another person, place, facility, or business in which the licensee has a financial interest."

Senate Bill 517 would amend this provision of the Public Health Code (MCL 333.16221) to specify instead that a licensed health professional *other than a physician* could not *require* an individual to purchase or secure a drug, device, treatment, procedure, or service from another person, place, facility or business in which the licensee had a financial interest. The bill would also include as unprofessional conduct a referral *by a physician* for a "designated health service" that violated either Section 1877 of Part D of Title 18 of the Social Security Act (42 USC 1395 nn) or a regulation promulgated under that section. The bill states that Section 1877 and the regulations promulgated under it, as they exist on the bill's effective date, would be incorporated by reference for purposes of the unprofessional conduct provisions. A disciplinary subcommittee would have to apply Section 1877 and the regulations promulgated under it, regardless of the source of payment for the designated health service referred and rendered.

(Section 1877 essentially prohibits a physician who has a financial relationship with an entity specified in the act, or whose immediate family member has such a relationship, from making a referral to the entity for designated health services for which payment otherwise may be made. Section 1877 also prohibits an entity from presenting a claim or bill to an individual, third party payor, or other entity for designated health services furnished pursuant to a prohibited referral. The act and regulations specify numerous exceptions and exemptions to these basic prohibitions. See "Background Information" below for more details on Section 1877 and its regulations.)

Whenever section 1877 or a regulation promulgated under it was revised (after the bill's effective date), the Department of Consumer and Industry Services (CIS) would have to officially take notice of the revision. Within 30 days of taking notice, CIS would be required to decide whether the revision pertained to referrals by physicians for designated health services (DHS) and whether it continued to protect the public from inappropriate physician referrals. If CIS decided that the revision both pertained to physician referrals for DHS and that it continued to protect the public from inappropriate physician referrals, CIS could promulgate rules to incorporate the revision by reference. If CIS did incorporate the revision, however, it could not make any changes to the revision.

## *HOUSE COMMITTEE ACTION:*

The substitute reported by the House Health Policy Committee reflects two amendments to Senate Bill 517 as passed by the Senate. First, the House version would prohibit all licensed health professionals other than physicians from requiring that an individual purchase or secure a drug, device, treatment, procedure, or service from another person, place, facility, or business in which the licensee had a financial interest. The Senate version did not include this prohibition. Second, the House version would require CIS to review future revisions of the federal law and regulations and would authorize CIS to incorporate such revisions. The Senate version stated only that the federal law and regulations would be incorporated as they existed on the bill's effective date.

## *BACKGROUND INFORMATION:*

Senate Bill 517 would incorporate Section 1877 of the Social Security Act and its regulations, i.e., the Stark II "final rule," as of the bill's effective date. Since Phase II of the final rule has not been promulgated yet, the "final" rule is not quite final. Although they are not lengthy, Section 1877 and the final rule are complex and allow for many exceptions and exemptions. The following summary is based on the Health Care Financing Administration's January 4, 2001 "Federal Register" entry concerning the final rule's implementation of the statutory prohibition of physician self-referrals and its "Physician Referral Frequently Asked Questions" list. (The HCFA is now the Center for Medicare and Medicaid Services, but most of the information on Section 1877 and Stark II still refers to the HCFA.) For more complete information, the Federal Registry and FAQ list can be found on the HCFA web site (www .hcfa. gov/regs/ physicianreferral/default.htm and www. hcfa. gov/ medlearn/ faqphys. htm).

Section 1877 of the Social Security Act generally prohibits a physician from *referring* a patient to an entity for the furnishing of a *designated health service* (DHS) if there is a (direct or indirect) *financial relationship* between the referring physician (or an immediate family member of the physician) and the entity, unless the financial relationship meets one of the *exceptions* specified in the act or its regulations. (Section 1877 also prohibits entities that provide services from billing for those services if they are furnished pursuant to a prohibited referral. This discussion, however, focuses on the self-referral prohibition rather than the compensation/

reimbursement prohibition.) The Federal Register entry focuses on the four italicized concepts in its description of the history of and changes to this prohibition and its implementation. In general, however, the HCFA offers the following test as a "sensible approach" for determining whether a referral constitutes a violation: "(1) Is there a direct or indirect financial relationship between the referring physician and the entity furnishing DHS? (2) Is there a referral for DHS from the physician to the entity? If the answer to both questions is affirmative, section 1877 of the Act is violated, unless an exception applies."

The HCFA offers several general guidelines for approaching Section 1877 and the regulations. First, the HCFA states that it tried "to interpret the prohibition narrowly and the exceptions broadly," believing that Congress' intent was not to prohibit beneficial financial arrangements but rather to reduce the overutilization of services and increase in costs that result when physicians financial relationships are left completely unregulated. Second, the HCFA states that Section 1877 establishes a "minimum threshold for acceptable financial relationships," warning that some acts that may be permissible under section 1877 may nonetheless "merit prosecution" under other statutes that address health care fraud and abuse. In particular, the HCFA refers to the anti-kickback statute (i.e., Section 1128B(b) of the Social Security Act). Likewise, actions that do not violate the anti-kickback statute may violate Section 1877. Third, the HCFA states that it has attempted to ensure that the final rule will not negatively impact people's ability to obtain access to quality medical care, while recognizing that it might require a provider with a financial interest to refer a patient to an alternative provider in certain cases.

Designated health service. A designated health service is a service (or item) for which a physician with a financial interest *may not* refer. In general, the HCFA focuses in the final rule on services and items, including both professional and technical components, that are or could be subject to overutilization. The basic categories of services include: clinical laboratory services; physical therapy services; occupational therapy services; radiology and certain other imaging services; radiation therapy; durable medical equipment; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. The HCFA plans to designate specific DHS by using both Medicare definitions and codes that are familiar to those in the health care industry (i.e., Current Procedural Terminology codes, or CPT, and HCFA Common Procedure Coding System codes, or HCPCS).

Referral. In its responses to Frequently Asked Questions, the HCFA states: "In general, a referral means a *request* for, or the ordering of, a DHS by a physician. Also, a referral includes the establishment of a plan of care and certification or recertification of patients needs for any DHS for which payment may be made under Medicare. A referral also includes a request for a consultation with another physician and any test or procedure ordered by the physician-consultant, except for certain services performed or supervised by a pathologist, radiologist, or radiation oncologist." Defining "referral" as a "physician's request" has two important consequences. First, noting that a person "cannot make a 'request' of him or herself for services he or she *personally* performs," the HCFA has ruled that a request for DHS is not a referral if the physician personally performs the service himself or herself. Second, since a referral is a *physician's* request, Section 1877 does not directly affect non-physician practitioners, such as physician assistants or nurse practitioners. If a physician directs or controls a referral made by a non-physician practitioner, however, the referral is treated as an "indirect" referral of the physician.

Financial relationship. As the HCFA explains in the Federal Register, "The existence of a financial relationship between the referring physician (or an immediate family member) and the entity furnishing DHS is the factual predicate for triggering the application of section 1877 of the Act." A financial relationship includes both ownership or investment interests and compensation arrangements, and whether the financial relationship is related to the specific DHS is immaterial. Moreover, a financial relationship may be direct or indirect. In the case of an indirect financial relationship, a DHS entity that does not know or have any reason to suspect (and is not acting in reckless disregard of the fact) that a referring physician has a financial interest in the entity may still submit a claim for reimbursement.

Exceptions. The statute and regulations allow for many exceptions. As mentioned above, a physician who performs services him- or herself and a provider of DHS that does not know about an indirect financial relationship are exempt from the act. A statutory exception applying to services furnished to enrollees of Medicare prepaid health plans covers some Medicare coordinated care plans, some prepaid Medicare managed care demonstration projects, and

some health maintenance organization plans, among others. The final rule also allows for certain exceptions for items and services that are provided at "fair market value," DHS that are furnished under the personal supervision of another physician in the same group practice as the referring physician, in-office ancillary services, bona fide risk-sharing arrangements between a managed care organization and a physician for services provided to enrollees of a health plan, and many others.

## *FISCAL IMPLICATIONS:*

With regard to the bill as it passed the Senate, the House Fiscal Agency has reported that the bill would have no fiscal impact on the state or local governments. (12-4-01)

## *ARGUMENTS:*

### *For:*

The state Public Health Code prohibits a licensed health professional from "directing or requiring" a patient to purchase or secure medicine, equipment, or medical services from an entity in which the licensee has a financial interest. Since the 1995 Indenbaum ruling, physicians and other health professionals who refer their patients to such entities have faced the threat of prosecution and a range of sanctions including not only reprimands and fines but also the revocation of the professional's license. Although the Department of Consumer and Industry Services (CIS) has not taken disciplinary action against any professionals for such referrals because it has not received any complaints, the department reports that it would have to enforce the relevant section of the health code if a complaint was submitted.

Advocates of restrictions on health care providers' ability to "self-refer" point to studies that suggest that in the absence of such restrictions, providers tend to make more unnecessary referrals leading to an overall increase in health care costs. Although many people agree that unscrupulous providers would likely take advantage of a framework that gave them an unlimited ability to refer patients, many physicians in the state believe that the state's restrictions are unduly harsh. The state's prohibition on self-referrals is a blanket, catch-all prohibition, which has no clear justification and which may, in the end, owe more to the court's strong interpretation than it does to the legislature's original intention. The federal law and regulations on physician self-referrals reflect a more nuanced approach to physician self-referrals by designating certain categories of medical items and services as health services for which a financially interested physician may not self-refer. Early last year, the Health Care Financing Administration (now the Center for Medicare and Medicaid Services), which administers and promulgates rules for Section 1877 of the Social Security Act, adjusted the act's list of "designated health services" (DHS). In doing so, the HCFA emphasized that it was following Congress' lead in focusing on those items and services that are especially prone to overutilization. According to the HCFA, the federal law was not enacted to prevent health care providers from establishing potentially beneficial financial relationships. Instead, the law was intended to ensure that physicians' financial relationships do not provide physicians with an incentive to make more referrals than they would otherwise make.

As long as there is a mechanism in place to guard against the overutilization of health services and the increased costs associated with such overutilization, there is no reason why physicians should not be able to refer patients to entities that they have a financial interest in. In fact, a physician who has a financial interest in a medical facility may well take more interest in ensuring that the facility offers high quality care than the average investor would, and this would be good for patients. By adopting the federal law and regulations on physician self-referrals and authorizing the Department of Consumer and Industry Services to incorporate future revisions, the bill would continue to protect the public from unnecessary referrals and would recognize physicians' rights to make potentially beneficial financial arrangements. The bill would also provide a clearer regulatory framework for physicians who report having trouble reconciling the state's extremely restrictive approach with the federal government's more focused approach.

### *Response:*

It is unclear how severely "Indenbaum" affects health care providers' ability to self-refer. In "Indenbaum," the physicians posted a written notice that stated that the physicians standardly referred patients and their specimens to a facility that they partially owned, but that they would honor the request of a patient who asked to be referred to another facility. The Board of Medicine observed that its ruling was "based solely upon the factual circumstances" stipulated in the case, and it is this ruling that the court of appeals upheld. If the circumstances had been different—for example, if the physicians had orally let each patient know of his or her option—it is *possible* that the board would have ruled differently and that the case never would have gone to court. Moreover, it is still possible that the board could consider a different case

and issue a ruling that clarifies exactly at what point a referral becomes a prohibited directive or requirement.

At any rate, the issue of whether the current law is too restrictive should be kept separate from the issue of whether or not the bill proposes a sound alternative. Even if all parties agree that "Indenbaum" restricts providers' ability to self-refer too severely and that the state needs to provide some "safe harbors" for physicians, there is a large gap between the state's present law and the proposed bill. Although some physicians have reported confusion over differences between the federal and state law, there is no reason, in principle, why the state could not impose more restrictive guidelines for self-referrals than the federal government does.

### *Against:*

The bill would significantly alter the parity in scope of practice between physicians and other licensed health professionals. Under current state law, neither physicians nor non-physicians can "direct or require" a patient to obtain items or services from entities that they have a financial interest in. The bill would state that a non-physician could not *require* a patient to obtain items or services from entities that he or she has a financial interest in. This would give physician assistants, physical therapists, chiropractors, and other non-physician licensees significant latitude to *direct* patients to obtain items and services from entities, when physicians could not do so. (Such non-physician "directives" are generally permissible under Section 1877 and its regulations, unless a physician is clearly controlling the direction that a non-physician gives a patient in order to circumvent the restriction on physician self-referrals.) This does not consider the possibility that such direction by a non-physician could lead to the overutilization of certain services and the increase in health care costs that all parties wish to avoid. Moreover, the bill is silent on the issue of whether a physician could require a patient to obtain items or services that are not designated health services from entities that he or she had a financial interest in.

### *Against:*

The bill could have a devastating, if unintended, impact on the state's not-for-profit hospitals. By many accounts, the federal prohibition on physician self-referrals is fairly liberal. Section 1877 and its regulations allow for many exceptions, including, among others, exceptions for entities that provide services at "fair market value," group practices, in-office ancillary services, and services that the physician provides him or herself. Further, the federal law and regulations only apply to "designated health services." In the broad array of designated health services that a physician can provide under an exception and the services that are not DHS, some are profitable and others are not. The bill would allow physicians to "cherry pick" by referring patients for profitable services to entities in which they have a financial interest and referring patients for the unprofitable services to the hospitals. These hospitals are already burdened, treating many patients who have insurance but also treating patients who are uninsured and are unable to pay for their services. If physicians started cherry picking, hospitals might begin to see a concentration of patients who could not pay for treatment at for-profit medical facilities and might find themselves focusing on services that for-profit facilities do not provide. This could upset the balance of services that hospitals currently perform, and hospitals could be forced to eliminate certain services and/or close.

### *POSITIONS:*

The Department of Consumer and Industry Services supports the bill. (2-20-02)

The Michigan State Medical Society supports the bill. (2-19-02)

The Michigan Orthopaedic Society supports the bill. (2-20-02)

The Michigan Osteopathic Association supports the bill. (2-19-02)

The Michigan Health and Hospital Association opposes the bill. (2-19-02)

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■This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.