The Stark Referrals Bill— Wanted Oversight or Wasteful Overkill?

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While most physicians agree that there exists a potential for abuse in self referrals, they are divided over how to tackle that abuse. Several medical specialty societies support a recent congressional proposal that clearly delineates what's allowed and what's not, while other groups say that approach would stifle legitimate operations and would put such operations under the aegis of business and jeopardize quality control.

The House Ways and Means Committee included a modified version of Representative Fortney H. (Pete) Stark's (D-CA) anti-kickback bill in its Medicare Reconciliation Bill on June 27, and, according to a Senate staffer, the Finance Committee was to consider developing "a less onerous version" of the legislation when Congress returned from its summer recess after Labor Day. Reportedly, the Bush Administration favors the Stark bill.

Rep. Stark, chairman of the Ways and Means Subcommittee on Health, was joined by other members of the Subcommittee — Representatives Brian Donnelly (D-MA), William J. Coyne (D-PA), Sander M. Levin (D-MI), and Jim Moody (D-WI) — in reintroducing the legislation, The Ethics in Patient Referrals Act of 1989 (HR 939), on February 9, 1989. (Rep. Stark had introduced a similar bill in August, 1988 that was unsuccessful.) The Health Subcommittee, along with the House Energy and Commerce Subcommittee on Health and Environment, oversees the Medicare Part B.

The latest House version of the physician self-referrals bill would prohibit a physician from referring a Medicare patient to a provider in which he (or a family member) has an ownership or investment interest or compensation arrangements. The Ways and Means Committee version allows more exemptions than Stark had originally included. It would exempt services provided directly by a physician or his employees; services in a group practice; services of radiologists, radiation therapy specialists, and pathologists; services in pre-paid plans; ownership of investment securities in large, publicly held corporations; certain non-public pharmacies providing cancer treatment; services of any rural provider; services by free-standing and hospital-based renal dialysis centers; and services by hospitals if a physician has admitting privileges and the ownership interest is in the hospital as a whole. Services provided by entities substantially in operation before March 1, 1989 also would be exempt but subject to new reporting and registration requirements. Penalties include denial of Medicare payment, exclusion from the Medicare program, and fines of $15,000 plus an amount equal to twice the amount billed for the services in question.

An Attempt to Eliminate Conflicts

In a prepared statement issued the day the bill was introduced, Rep. Stark indicated the bill would attempt to eliminate conflicts of interest "inherent" in physician referrals of patients to certain medical facilities, most often involving radiology, physical therapy, clinical laboratory, durable medical equipment, and home health care services. According to Rep. Stark, "Physician referral deals have the potential of being the medical version of the Pentagon procurement scandal. There is the real danger of excessive costs and excessive utilization of procedures being permanently embedded in health care costs."

In re-introducing the legislation, Rep. Stark told members of the House, "Self-referrals raise three major policy concerns. First, there is a risk that physician-partners may not refer patients to the facility that provides the best care.... Second, patients may be referred for costly services which are unnecessary.... Finally, honest competition is undercut. These problems stem from the fact that a physician's objectivity in making referrals is threatened by these financial tie-ins. The point is not intended as a criticism of physicians. Few physicians will consciously refer a patient to a poor quality pro-

vider simply due to ownership. But, anyone's judgment can be subtly influenced by financial interests."

Regulations Already in Place

Critics of the Stark bill acknowledge that conflicts of interest can lead to abuses in referrals, but they maintain that a conflict of interest is not inherently unethical and that Stark's approach is uncalled for because controls already exist.

In a commentary in the July 21, 1989 issue of *The Journal of the American Medical Association* (JAMA), James S. Todd, MD, AMA's senior deputy executive vice president, and Janet K. Horan, JD, legislature attorney in the AMA's department of Federal legislation, gave the AMA's view on self-referrals (*1*). "Physician ownership interest in a commercial venture with the potential for abuse is not in itself unethical," they wrote.

Robert L. Meckelnburg, MD, director of the department of nuclear medicine, Medical Center of Delaware, told *Newsline*, "There are mechanisms already in place for taking care of unethical behaviors of physicians. . .through the state boards of medical practice. . . .What Stark is proposing would be a duplication of effort. You don't need to reinvent the wheel. . . .It is overkill to invoke his legislation."

Sweeping Prohibitions Are Undesirable

E. Haavi Morreim, PhD, from the department of human values and ethics, College of Medicine, University of Tennessee, Memphis, wrote an article on physician referrals that also appeared in the July 21 issue of JAMA (*2*). Dr. Morreim wrote, "Although investment conflicts pose profound ethical challenges, I believe that sweeping legislative prohibitions are undesirable. Patients are better protected by existing common-law principles that honor patients' rights to self-determination, full information, and a high standard of medical care and that are less intrusive on the fragile physician-patient relationship. Payers, in turn, are better protected by careful utilization review and quality assurance than by broad prohibitions that could restrain trade and perhaps even deter the development of better and more cost-effective ways of providing care."

Rep. Stark expressed skepticism with Dr. Morreim's support of reliance on common law to keep abuses in check in an accompanying editorial in JAMA (*3*). "It seems clear that if the common law were capable of doing such a good job, we would not now be debating "the best way" to put a stop to these abuses. . . .the amount of litigation in every jurisdiction that would be needed to achieve Dr. Morreim's desired results is absolutely mind-boggling. 'Common law' took a thousand torturous years to develop; 'common law' is the law of malpractice suits."

The Department of Health and Human Services proposed rules for Medicare and Medicaid Fraud and Abuse — the so-called safe harbor rules — in the January 23, 1989 *Federal Register* (*4*). The safe harbor regulations specify payment practices that will not be subject to criminal prosecution or a civil penalty of exclusion from the Medicare and Medicaid programs, whereas the Stark bill delineates those practices that are subject to civil or criminal penalties.

Rep. Stark and his supporters claim that the current regulations — the state board regulations, the safe harbor regulations, and common law — are not enough. "One of the most serious shortcomings of the current law is the enormous difficulty involved in proving to the satisfaction of a judge that a particular arrangement is deliberately structured to induce referrals. . . .The enforcement resources simply aren't there. . . . What is needed is what lawyers call a 'bright line' rule to give providers and physicians unequivocal guidance as to the type of arrangements that are prohibited," Rep. Stark told the House.

In response, the AMA wrote, "We propose to develop those 'bright lines' — not ban legitimate investments. From its founding, the AMA has recognized the need for physicians to operate in accordance with ethical guidelines. Obviously, individual physicians can avoid potential conflicts altogether by avoiding financial interests in health care facilities or products or devices. However, an outright prohibition on physicians having a financial interest in an outside entity, aside from being anticompetitive, overlooks the benefits of physician investments being used to broaden access to care, introduce new technology to a community, improve quality, and reduce costs. Furthermore, an outright ban on physician ownership could create serious access problems for patients in nonrural and even large urban areas."

Rep. Stark claims that his critic's contentions "that capital from referring physicians is needed to finance health care facilities. . . [are] a smokescreen. If there is a need for the service in the community," he told the House, "traditional lenders will make the funds available."

What Is the Extent of the Problem?

How widespread are these abuses? Rep. Stark maintains that the abuses are rampant and that the profession cannot adequately police itself, while others consider the situation less dire. Rep. Stark told the members of the House, "The integrity of our Nation's physicians is being threatened by seductive deals promoted by fast buck artists. Further proliferation of these ventures is bound to undercut public confidence in the medical profession."

"There are some abuses out there . . . it's sporadic," Raymond Marty, MD, director of nuclear medicine/ultrasound, The Swedish Hospital

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Medical Center, chairman of The Society of Nuclear Medicine's Socio-economic Affairs Committee, told *Newsline.* "Anytime you have physician investors involved in a free-standing clinic and part of the return is predicated on the volume of referrals — that is an abuse. If that's what they're aiming at, that's legitimate." Dr. Marty added, however, that he did not consider the abuses to be as widespread as Rep. Stark suggests.

Hirsch Handmaker, MD, director of nuclear medicine, Children's Hospital of San Francisco, told *Newsline,* "There's no question that there are abuses, but I'd bet that it is a very small group that could be easily identified through practice patterns."

The AMA contends that it is not clear that the abuses are prevalent. ". . .While some abuses have been identified, and others suspected, specific data on the nature and extent of these are lacking," wrote Dr. Todd and Ms. Horan.

A report from the Office of the Inspector General (OIG) on physician ownership and compensation from health care entities issued in June indicated that 12% of physicians billing Medicare own or have an interest in a facility to which they refer patients. Dr. Todd and Ms. Horan point out that a similar survey conducted by the AMA in 1988 found that "7% of all physicians had an ownership interest in a facility and referred patients to that facility." They added, "It remains to be proved that referral to a facility in which the physician has a personal financial interest is a major problem. Eighty-eight percent to 93% of physicians do not have any ownership interest in a facility to which they refer patients."

In addition, they noted that although patients of referring physicians who own facilities to which they refer tended to receive more services, "the OIG admits that there is no evidence to indicate that these services were 'unnecessary'. . .'additional' services may be a consequence of the increased availability. . .and may represent a higher standard of care for these Medicare patients."

> ". . .'Common law' took a thousand torturous years to develop; 'common law' is the law of malpractice suits."

Dr. Handmaker agreed. "It's a fallacy that because of the site and nature of ownership, there's over-utilization. It might be that their diagnostic modalities are more available." He further suggested that "under-utilization could be economically more ruinous than over-utilization."

The AMA suggested, "All the evidence points to the fact that physicians do not abuse their patients, that physician investment has been of considerable value in providing new technologies and facilities not otherwise available, and that patients wish to be free to pursue their physician's recommendations. Any egregious activities of physicians are already against the law, the gray areas of conflicts can never be legislated, and adherence to long-standing ethical principles should continue to serve us well."

The AMA, the OIG, the Congressional Research Service, and the Government Accounting Office continue to conduct studies to determine how common abuses in referrals are.

Cure Worse Than the Disease

Some physicians forsee problems resulting from the Stark bill. "If they take physicians out of the control of laboratories, they're going to make a situation that's much worse. That vacuum will be filled by businessmen whose bottom line is money. . .you have no control over those people at all," Dr. Meckelnburg said, adding, physicians can be sanctioned through state boards, which issue "very clear laws" governing ethical conduct. "That's a very prudent control that you have over physicians that you'll never have over a businessman."

Furthermore, said Dr. Meckelnburg, "[The Stark bill] doesn't adequately address the problem. The government should "beef up the investigative capabilities of the state boards so they can go after the bad apples and get rid of them."

"Shouldn't utilization be controlled by screening the indications for the exams and by other quality assurance steps. . .routinely use[d] to assure the efficacy of procedures? Do we need this cynical law motivated by an avowed adversary of physicians to prevent over-utilization or unnecessary exams?" asked Dr. Handmaker in an editorial in the May issue of *Diagnostic Imaging* (*5*). "It would seem more logical to examine the standards of medical practice and to control the abusers than to indict financial arrangements used to acquire expensive medical equipment," he wrote.

Dr. Handmaker told *Newsline* that while he is "not in support of the bill" he does think it is "justified to look at patterns of referral and the motivations of individuals ordering these tests through more peer review and quality assurance." But, he added, "Control of efficacy and the responsi-

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on Alzheimer's research to $300 million. This increase from the current $123 million budget would increase Alzheimer's research centers from 12 to 15, and fund half of NIH research applications in this area. (Currently only 20% are funded.) Senator Howard Metzenbaum (D-OH) recently introduced S. 1255, which calls for $179 million for Alzheimer's research and training. If these increases are enacted, there will be more funding available for nuclear medicine diagnostic research applications.

Veterans Care Congress has enacted and President Bush has signed into law a provision for $340 million in emergency funds for veterans health. The emergency funds, which had been held up due to political infighting, will allow Veterans Administration (VA) hospitals to rebuild their staffs and physical plants. The VA indicates that its top priority will be to rejuvenate its alcohol and drug abuse programs.

New SNM/ACNP Assistant Director Valerie A. Fedio joins the SNM/ACNP Joint Washington Office as assistant director of Government Relations. With a nursing degree from Georgetown University and a Masters degree in Health Services Administration from the Sloan Program at Cornell, Ms. Fedio brings with her a knowledge of the health care field. While in past positions as a health care consultant, including a stint at the American Hospital Association, she gained valuable experience in health policy analysis. Ms. Fedio will manage the new SNM/ACNP Key Contact program and will assist in the various issues SNM/ACNP faces before Congress and the regulatory agencies.

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bility to monitor appropriateness should be in the hands of the physicians most capable of making those decisions."

Organizational Support and Opposition

In addition to the AMA, the American Society of Internal Medicine, the Americal Hospital Association, the American College of Cardiology, and the American College of Physicians are on record as opposed to the Stark bill, though some would support less rigorous Federal intervention. The American Society of Clinical Pathologists, the American Clinical Laboratory Association, and the American College of Radiology (ACR) are among those who have supported the measure. ACR adopted a resolution in September, 1988 that "Referring physicians should not have direct or indirect financial interest in diagnostic or therapeutic facilities to which they refer patients."

Dr. Handmaker expressed concern about the implications of ACR's endorsement of the Stark bill. Acknowledging the potential for abuse, he wrote, "...the appropriate use of diagnostic imaging procedures has been and should always be the responsibility of practicing radiologists, not the Federal government. Nor should the use of these procedures be reduced to a purely economic equation....The ACR resolution endorses the position that physicians who invest in imaging centers are accepting bribes, while radiologists and hospitals who own equipment never influence referrals or perform unnecessary exams."

Rep. Stark's critics are not against eliminating abuses in referrals, but they consider his bill an inappropriate and ineffective way to achieve that. Dr. Handmaker suggested that the various professional medical organizations should establish programs to ensure quality outpatient services before the government attempts to. "Gross misuse of labs is easily discernable by everyone. State boards can obviously see where there is this misuse. If this is what [Stark's] talking about, this is stuff that should be gotten rid of," said Dr. Meckelnburg. "But some of the gray areas are never going to be gotten rid of because the science is not absolute."

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