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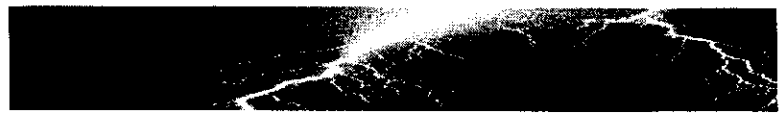

OIG Rejects Gainsharing Arrangements Between Hospitals and Physicians

On July 8, 1999, the DHHS, Office of Inspector General ("OIG") released a Special Advisory Bulletin on "Gainsharing Arrangements and Civil Monetary Penalties for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries." According to the OIG, most gainsharing arrangements are prohibited by federal law and are subject to civil monetary penalties ("CMPs") established at sections 1128A(b)(1) and (2) of the Social Security Act ("SSA).

Gainsharing Arrangements

"Gainsharing" broadly refers to a common practice whereby hospitals share a portion of cost-savings achieved by the institution with its physician staff in return for efforts by the physicians to reduce hospital clinical costs. A typical gainsharing arrangement is structured such that hospital physician staff receive a predetermined percentage of some identified balance of money.

For example, a hospital may agree to pay its medical staff a percentage of any surplus capitation payments received by the institution from managed care plans to provide hospital services to plan enrollees. Under such health plan contracts, the hospital carries the financial risk to provide plan enrollees with all medically necessary covered benefits within the confines of the capitated payments received. If the hospital's costs are greater than the total capitated payments, the institution suffers a loss, and, if costs are less, a profit. To encourage physicians to reduce medically unnecessary care or avoidable use of institutional services, the hospital agrees to share its profit and losses with its medical staff.

II. Federal Law Prohibition

Although the OIG recognized that hospitals have "legitimate interest in enlisting physicians in their efforts to eliminate unnecessary costs," it concluded that section 1128A(b)(1) and (2) of the SSA prohibit gainsharing arrangements. Under this provision a hospital may not knowingly make a payment, directly or indirectly, to a physician as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make, or physicians that receive such payments may be found liable for CMPs of up to $2,000 per patient covered by the payments where, in the OIG's view, the hospital knows that payment may influence the physician to reduce or limit services to a patient. According to the OIG, there is no requirement that the payments actually lead to a reduction in medically necessary care. Neither is it relevant, under the OIG's interpretation of the statute, whether the payments might restrict or limit medically necessary or medically unnecessary services.

The OIG concluded that the CMP prohibition is broad and without statutory or regulatory exception. Significantly, OIG states that Congress did not grant the Secretary of the Department of Health and Human Services authority to approve some hospital-physician incentive plans as it did in relation to risk-based Medicare managed care plans. As a result, a statutory amendment would be required before gainsharing arrangements violative of sections 1128A(b)(1) and (2) could be condoned.

Possibly even more crucial to the viability of gainsharing arrangements in the future than the statutory prohibition was OIG's assertion that, even if it had regulatory authority to protect an individual gainsharing arrangement through a favorable advisory opinion, it would be precluded from doing so due to the high risk of abuse it believes gainsharing poses. Under the OIG Advisory Opinion Process, the Department only will protect those arrangements that "pose little or no risk of fraud or abuse to the Federal health care programs."[1] Gainsharing raises significant risk of abuse, according to the OIG, because hospitals could be pressured by competitors and physicians to "game" the arrangement to create phantom savings or income to increase payments to referring physicians.

Based on the broad scope of the Advisory Bulletin, it appears that hospitals should reconsider gainsharing arrangements as soon as possible The OIG has taken the position that in deciding to take enforcement action against the parties to a gainsharing arrangement, it will consider, in the absence of any evidence that the arrangement vio-

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lated any other statutes or adversely affected patient care, whether a gainsharing arrangement at issue was terminated expeditiously following release of its guidance.

III. Alternatives to Gainsharing

Hospitals do have other options to consider in attempting to increase the cost-efficiency awareness of its medical staff. First, it is important to note that the CMP provision only applies to Medicare and Medicaid services, although there can be Stark Law implications even in non-Medicare and Medicaid gainsharing situations. Second, the OIG stated that hospitals may encourage physicians to achieve cost savings through personal services contracts where hospitals pay physicians based on a fixed fee that is fair-market value for services rendered rather than a share of cost savings. Although it is difficult to make the OIG's support of personal services agreements consistent with its broad reading of section 1128A(b)(1), the OIG did not qualify this statement in the Advisory Bulletin.

Another alternative is to explore the option of having gainsharing programs through managed care plans or Medicare risk programs that meet the requirements of section 1876 of the SSA. Hospitals should be cautious however, in attempting to follow this course. The statutory prohibition applies to "direct[ ] or indirect[ ]" payments by a hospital. The government could take the position that any agreement to have the plan, rather than the hospital, pay the medical staff on the same basis as the gainsharing arrangement, constitutes an "indirect" payment by the hospital.

IV. Specialty Hospitals and Clinical Joint Ventures

Within the same Advisory Bulletin the OIG also raised, in a somewhat cursory but sufficiently concerning manner, that it believes some clinical joint ventures between hospitals and physicians, including freestanding specialty hospitals and arrangements where high revenue-generating services are reorganized into a legally separate hospital, also may violate sections 1128A(b)(1). In addition, the OIG opined that these entities may violate the federal anti-kickback statute. In light of the OIG's comments, institutions of this type are recommended to seek legal analysis on this issue.

1. Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG, 63 Fed. Reg. 38311, 38312 (July 16, 1998).

Recent Decisions Clarify Legality of Percentage-based Physician Management Contracts

On June 25, 1999, in PhyMatrix Management Co., Inc. v. Bakarania, Fla. Dist. Ct. App., No. 97-4534, 6/25/99, the Florida First District Court of Appeal, in a per curium decision, affirmed a 1997 Board of Medicine ruling that a physician practice paying a percentage of net income to a physician practice management company ("PPMC") in return for "practice-expansion activities" is engaging in illegal fee-splitting in Florida. The PPMC's "practice-expansion activities" involved developing contracts with insurers, hospitals, and other medical providers designed to generate patient referrals to the practice. The court's decision cannot be appealed.

The Bakarania case came before the Board of Medicine in 1997 when Dr. Bakarania asked the Board for advice about the legality of a contract between PhyMatrix Management Co. and Access Medical Care, Inc., a group medical practice which he was considering joining. Noting that the management company received 30 percent of the physicians' net income in return for services which included practice enhancement activities, attorneys for Dr. Bakarania argued that the payment methodology violated the prohibition against fee splitting in the Florida Medical Practice Act. The Board of Medicine agreed. As written, the ruling could be interpreted to bar all percentage-fee contracts. While not binding outside of Florida, because the Florida statutory provision is similar to those in other states, the decision had a chilling effect upon the growth of PPMCs across the country.

Another recent decision from Florida, however, is not so restrictive. Two weeks before the Florida appellate court's affirmance of the Bakarania decision, the Florida Board of Medicine issued a declaratory statement, ruling that percentage fees paid to a management firm are permissible under the fee-split bar if the percentage fees are not tied to activities that are designed to bring more patients into the practice. The case involved a proposed contract between an anesthesiology practice and a management company, where the management company would be paid 50 percent of net collections up to $10,000 a month to be responsible for office space, staff, equipment, personnel, and billing and collection services but not for the types of "practice enhancement" activities with which the Board took issue in the Bakarania case. Although the specific rationale underlying the Board's decision will not be known

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until its final order is published sometime next month, the decision is significant for the PPMC industry since it appears to confirm that percentage-based arrangements involving only basic management services will not run afoul of the Florida fee-splitting law.

Reading the two decisions together, it appears the legality of percentage-based contracts between PPMCs and Florida physicians depends upon the types of services the PPMC is contractually required to provide. To the extent the management company provides traditional administrative services, such as billing and collections, the fee-split law should not be implicated. However, PPMCs wishing to furnish marketing services designed to generate referrals appear to be restricted to contracts which provide a flat fee for practice expansion activities.

It is ironic that these developments arise from Florida, one of a handful of states which does not prohibit the corporate practice of medicine. Thus, PPMCs operating in Florida can achieve the financial results they seek by restructuring their relationships with physicians from independent contractors to employees. Should other states follow the lead of the Florida Board of Medicine, that option may not be available and PPMCs will be forced to consider alternative financial arrangements with its physicians.

Online Prescriptions by Physicians Undergoing Increased Scrutiny

The growing number of Web sites that offer consumers the opportunity to obtain prescription medications pursuant to an online medical consultation have been attracting considerable regulatory scrutiny from state and federal health officials.

For example, in Illinois, the Department of Professional Regulation suspended the license of Dr. Robert Filice for prescribing Viagra via an Internet pharmacy for patients he had never seen. Dr. Filice was working as a consultant for The Pill Box, a San Antonio, Texas-based pharmacy chain that sells online. The state suspended Dr. Filice's license immediately because it determined his actions put people in danger. The agency later reinstated his license when he admitted that his conduct was "unprofessional." The physician was fined $1,000, put on a two-year probation, and ordered to not prescribe medication to patients without personally interviewing and examining them.

Patients who wanted a prescription drug like Viagra logged onto The Pill Box's site and filled out a health questionnaire. The completed form went to the company's medical consultants, including Dr. Filice, who would reviewed the forms, and, if he found no health conditions that would preclude him from prescribing the drug, he would write a prescription for the drug, which the Pill Box would fill. In the meantime, Illinois legislators are considering a bill to regulate online and mail-order pharmacies that sell products in the state. The bill would require Internet pharmacies to register with the state annually.

Recent enforcement actions in several other states highlighted below are indicative of this increased scrutiny at the state level:

- In Washington, the Board of Health fined an orthopedic surgeon $500 for engaging in "unprofessional conduct" by writing Viagra prescriptions for patients without performing a physical examination.
- In California, state regulators recently shut down two web sites—www.drpropecia.com and www.deyarmanmedical.com.com—run by a San Diego osteopath who was using the Web to prescribe baldness treatments without performing a traditional medical examination. The state is likely to fine the doctor, who has been practicing medicine for nearly a quarter-century, and could take away his license.
- In Kansas, the Attorney General on June 9 filed civil petitions alleging violations of consumer protection laws against seven companies that were selling prescription-only medications, including Viagra and weight-loss drugs, over the Internet. The Attorney General alleged that the companies violated a variety of state laws. Primarily, the alleged misdeeds stem from the distribution of prescription drugs by a doctor or pharmacist who was not licensed in the state. The state went after not only the sites that prescribe the medications, but also three pharmacies that filled the prescriptions. One of the suits alleges that Viagra was illegally dispensed to a 16-year old boy using his mother's credit card. If found liable, the companies could face penalties of $5,000 to $10,000 per violation.
- In Missouri, the Attorney General on July 7 obtained a temporary restraining order against an

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online Texas-based pharmacy and its owner blocking the site's unlawful sale of prescription-only drugs to Missourians over the Internet. During a press conference, the Attorney General told reporters that the San Antonio pharmacy, S&H Drug Mart, and its owner, William A. Stallknecht, are violating Missouri law by providing prescription drugs to Missouri consumers without a state license and on the basis of information provided in online consultations.

- In Ohio, a family-practice doctor was recently charged with 64 offenses in connection with prescribing drugs including Viagra on the Internet. The prosecutor said this is the first Ohio doctor to be criminally charged after prescribing drugs over the Internet without seeing patients.
- In Maryland, a Baltimore doctor who gained notice by distributing diet pills over the Internet has been indicted on 34 federal charges accusing him of illegally prescribing medicine.
- In Nevada, the Board of Medical Examiners recently barred Internet sales of prescription medications unless Nevada doctors also see the patients.
- Colorado disciplined a doctor who supervises a cosmetic surgery clinic for engaging in unprofessional conduct by prescribing over the Internet.
- Wyoming recently ordered a Web site to stop selling in its state.
- Arizona has tried to stop out-of-state and overseas Internet doctors from doing business with state residents.

In addition to these recent state enforcement activities, the American Medical Association (AMA) has taken the position that online physicians who write prescriptions without patient contact are in direct violation of AMA policy. At its recent convention in Chicago on June 24, the AMA called on state medical societies, government regulators, and licensing boards to investigate doctors who dispense pills to patients without examining them. Noting that no state laws directly address the issue of online prescribing, the AMA said that it would assist the Federation of State Medical Boards (FSMB) in developing them. But in the absence of state law, the AMA says that local medical boards should take action against doctors who are prescribing drugs for patients they don't know. The AMA Board of Trustees report, which was adopted by the House of Delegates, directs the AMA to work with the FSMB, the National Association of Boards of Pharmacy, and the Food and Drug Administration to curtail inappropriate online prescribing. Recognizing the growing use of the Internet in health care, the AMA report considers online transmission of prescriptions, order refills, and electronic consults appropriate if the physician and patient have a preexisting relationship.

The National Association of Boards of Pharmacy (NABP), which represents state pharmaceutical licensing authorities, has also taken the position that any site that uses a questionnaire without a legitimate patient-physician relationship is illegal. NABP's Executive Director Carmen Caltizone explains that pharmacies can only fill valid prescriptions, and prescriptions written by cyberdoctors are not valid. Therefore, he reasons, it is illegal for druggists to fill them. The NABP also advocates licensing of online pharmacies in every state. To help guide consumers, the pharmacy association recently developed a voluntary seal program—called the NABP Verified Internet Pharmacy Practice Sites (VIPPS)—which will endorse sites that meet its criteria for dispensing drugs online. Earlier this month, the group began accepting applications from Internet drugstores that want to carry the seal. So far, about a dozen have applied. The NABP plan of voluntary seals has the endorsement and cooperation of the Drug Enforcement Agency, the Food and Drug Administration, and the AMA.

The online drug industry has also not gone unnoticed by Congress. In March, House Commerce Committee Chairman Bliley (R-VA), along with three Democratic Congressmen, asked the General Accounting Office (GAO) to address how online pharmacies prevent unqualified persons from receiving prescriptions and whether they are more susceptible to fraud or deception. The GAO has also been asked to examine the online doctor consultation which is viewed by some Congressmen as highly unethical and prone to serious problems. The House Commerce Committee's oversight subcommittee will hold a hearing on this subject on July 30th.

In summary, this increased scrutiny of the online prescription drug business seems to be *primarily* focused on those sites that sell *and prescribe* medications without requiring a physician to physically examine a patient. Although reasonable arguments can be made that a physician's face-to-face meeting with a patient may not be necessary with respect to certain drugs, the AMA, the NABP, and a number of state Attorney Generals do not agree. Accordingly, it is becoming increasingly risky to operate a site that prescribes medications without requiring a physician to conduct an in-person physical exam of a patient. With respect to those sites that *only* fill prescriptions sent to them by licensed physicians, officials appear to be focused on making certain that these sites are appropriately licensed in every state where they do business.