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In This Issue:

FRAUD AND ABUSE

OIG Approves Hospital-Physician Group Gainsharing Arrangement....Page 1

Medigap Insurer May Contract with MCO for Hospital Discounts....Page 2

OIG Approves Motivational Incentives Offered in Substance Abuse Treatment Program....Page 2

OIG Refuses to Rule Out Sanctions on Physician Group's Lease Proposal....Page 3

LABOR AND EMPLOYMENT

Federal Court Rejects Claim of Nurse Fired for Refusing to take Drug Test....Page 3

TAXATION

Medical Residents May be Eligible for IRC Student Exemption....Page 4

FRAUD AND ABUSE

OIG Approves Hospital-Physician Group Gainsharing Arrangement

In Adv. Op. 08-15, issued October 14, 2008, the U.S. Department of Health and Human Services Office of Inspector General (the "OIG") approved an existing gainsharing arrangement between an acute care hospital and two cardiology groups under which the hospital would share a percentage of its cost savings generated by the groups' implementation of cost-reduction measures recommended by the Program Administrator overseeing the arrangement. The cost-reduction measures fell into three general categories: product standardization, use-as-needed cardiac medical devices, and product substitution. The hospital agreed to pay each group 50% of the yearly cost savings directly attributable to each group's implementation of 30 cost-reduction measures in their cardiac catheterization laboratories over a three-year period, with payments to be made to each group at the end of each of the three years.

The OIG recognized that the arrangement implicates both the Civil Monetary Penalties Law and the Anti-Kickback Statute (as well as Stark and the IRS' regulations governing the conduct of tax-exempt health care entities, both of which are outside of the OIG's opinion authority). The OIG declined to impose sanctions based on the factual circumstances and safeguards at issue, which were viewed as reducing the risk of fraud and abuse under the arrangement. As is customary, the OIG declined to provide any opinion as to whether amounts to be paid under the arrangement are consistent with fair market value.

The OIG placed significant importance on the existence of the following safeguards:

- specific cost-reduction actions and resulting savings were clearly and separately identified, creating sufficient transparency to allow for public scrutiny and individual physician accountability for patient care;

- credible medical support indicated that implementation of the cost-reduction measures had not adversely affected patient care, as confirmed by periodic reviews of the arrangement;
- amounts to be paid to the groups were based on all procedures, regardless of the patients' insurance coverage, subject to the cap on payment for federal healthcare program procedures;
- the procedures at issue were not disproportionately performed on federal healthcare program beneficiaries;
- the arrangement protected against inappropriate reductions in services by ensuring that individual physicians have available the same selection of devices and supplies as before the arrangement;
- the hospital and groups disclosed their participation in the arrangement in writing to patients;
- financial incentives under the arrangement were reasonably limited in duration and amount;
- participation in the arrangement was limited to cardiologists already on the hospital's medical staff;
- potential savings derived from procedures for federal healthcare program beneficiaries were capped based on the physicians' prior year's admissions of these beneficiaries, which were monitored for changes; and
- the structure of the arrangement (e.g., the groups' physician members are the sole participants in the arrangement) eliminated the risk that it would be used to reward other cardiologists or physicians referring patients to the groups or their cardiologists.

The above safeguards will undoubtedly be of interest to others contemplating a similar arrangement and are informative as to the OIG's current thought process on gainsharing arrangements.

Providers seeking more information about this OIG Advisory Opinion or other compliance issues should contact their Vorys health care attorney.

Medigap Insurer May Contract with MCO for Hospital Discounts

On October 2, 2008, the OIG issued an advisory opinion responding to a request by a Medigap insurer to determine whether an arrangement between a managed care network and its network hospitals that would provide discounts for plan beneficiaries who used in-network hospitals for inpatient stays would violate the Anti-kickback statute.

Under the proposed arrangement, a hospital network would enter into contracts with a MCO as a part of the preferred network. Pursuant to these contracts, Medigap policyholders would be given discounts of up to 100% off of Medicare inpatient deductibles (which would be the responsibility of the Medigap plan under normal circumstances). The Medigap insurer would pay the MCO an administrative fee each time a policyholder receives a discount. In return for choosing a network hospital, the policyholders would share in the savings by receiving a $100 credit toward their next renewal premium.

The OIG determined that although waivers of Medicare cost-sharing amounts and relief of a financial obligation would normally constitute prohibited remuneration under the Anti-kickback statute and the civil monetary penalties statute, the arrangement presented a very low risk of fraud and abuse.

The OIG found that the discount would not increase or affect per service Medicare payments, utilization would not be increased because patients already had purchased the supplemental insurance, and competition among hospitals would not be unfairly affected since the program would be open to any accredited, Medicare-certified hospital. Additionally, because physicians would not receive any remuneration and the patient could go to any hospital without incurring out of pocket charges, professional judgment would not be affected.

Further, the OIG found that the premium credit would essentially fall within the statutory exception for differentials in coinsurance and deductibles as part of a benefit plan design (as found in Section 1128A(a)(6)(C) of the Social Security Act). Even though the premium credit was not technically a "differential," it would have the same purpose and effect.

OIG Approves Motivational Incentives Offered In Substance Abuse Treatment Program

On September 24, 2008, the OIG issued an Advisory Opinion concluding that a "motivational incentive" program rewarding a patient's achievement of certain substance abuse treatment goals would not violate the Anti-kickback statute or result in the imposition of civil monetary penalties.

In Advisory Opinion 08-14, the OIG considered an arrangement in which a substance abuse treatment center would provide motivational incentives ($5 - $10 gift certificates redeemable at certain grocery stores, food outlets and gas stations) in order to help a patient overcome difficulty with achieving abstinence, or maintaining attendance and participation in a treatment plan. While noting that motivational incentive programs could, as a general rule, be considered an inducement which would violate both the anti-kickback statute and the civil monetary penalty provisions, however, the OIG concluded that the program at issue in the Advisory Opinion would not violate these statutes because the following safeguards are in place:

1. The program follows the therapeutic guidelines of the National Institute on Drug Abuse and the Substance Abuse and Mental Health Services Administration's

Centers for Substance Abuse Treatment.

2. The incentives never take the form of cash, and are of low monetary value ($5 - $10, not to exceed $200/month or last for longer than three months).
3. The incentives are only introduced are only introduced into a patient's treatment on the basis of a clinical determination that such incentives are clinically indicated for the particular patient's treatment under an established treatment plan.
4. A patient must "earn" the motivational incentives through active, verifiable participation in core elements of his or her treatment plan, such as providing drug-free urine samples and attending sessions.
5. The treatment plans are certified to be medically necessary and appropriate;
6. The incentives are not advertised and are not offered to all participants (the incentives will be clinically indicated for only 25% of the participants).

Based on these safeguards, the OIG determined it would not impose civil monetary penalties or administrative sanctions in connection with the Anti-kickback statute, but further noted that the same analysis would not apply to a motivational incentive program in which incentives routinely exceed $200 or are offered for longer than three months.

OIG Refuses to Rule Out Sanctions on Physician Group's Lease Proposal

In Advisory Opinion 08-10, the OIG concluded that a proposed "block lease" arrangement between an oncology physician practice and a group of urologist referral sources would potentially violate the Anti-kickback statute.

The oncology group in question provides various cancer treatments in a facility setting, including a procedure called Intensity-Modulated Radiation Therapy ("IMRT") which is used to treat prostate cancer. Patients who receive IMRT are typically referred by urologists.

The proposed arrangement involved the leasing of space, equipment and personnel to the urologists so that the urologists could see patients at the facility at least eight hours per week and could also perform the IMRT procedures (through the lease arrangements) instead of referring the services to the oncology physician group.

The OIG noted its longstanding concern about certain joint venture arrangements between those in a position to refer business and those who furnish items or services for which Medicare and Medicaid pay, especially when all or most of the business of the joint venture is derived from one of the joint venturers. The following points were found to be problematic:

1. The urologist group would be expanding into a related line of business which is dependent on referrals from urologists.
2. The urologists would not actually participate in the performance of IMRT, but rather would contract out substantially all IMRT operations (including the professional services).
3. The urologist group would commit little in the way of financial, capital or human resources and would assume very little real business risk.
4. The urologist group would be in a position to ensure the success of the business by referring to the facility's IMRT operations and also choosing IMRT over other forms of treatment.
5. The oncology physician group is a provider of IMRT services and could provide the services in its own right.
6. The urologist group would use the leased facilities, equipment and personnel to serve the very same patient base that used to be referred to the oncology group.
7. The aggregate income to the urology group would be based on volume/value of referrals because historical data could be used to fit the historical value of referrals.
8. Both groups would share in the economic benefit of the IMRT.

The OIG did not comment on whether any of the individual contracts might meet the Anti-Kickback safe harbors for personal services or equipment and space leases, but indicated that if the intent of the relationship was to pay remuneration through the IMRT services for referrals to the cancer treatment facility, then the Anti-Kickback Statute would be violated.

Providers and their counsel should be very aware of arrangements such as this, that might technically meet various safe harbors, but still contain an overriding prohibited intent to induce referrals.

LABOR AND EMPLOYMENT

Federal Court Rejects Claim of Nurse Fired for Refusing to Take Drug Test

The U.S. District Court for the Western District of Arkansas ruled on September 12, 2008 that a nurse who was fired for failing to submit to drug testing is not able to pursue a wrongful termination claim against her employer. *Hamilton v. Tenet Corp.*, W.D. Ark., No. 08-6057 (9/12/08).

Hamilton, a registered nurse, was accused by a patient of being under the influence of drugs while working. As a result of the patient's claim, Hamilton's direct supervisor requested that she submit to a drug test; Hamilton refused. She was terminated within days of her refusal.

The hospital employee handbook stated all employees were at-will and could be terminated by either party at any time. However, the handbook also contained a section specifically devoted to mandatory drug-testing and listed three grounds under which an employee could be drug tested: post-accident, for reasonable suspicion, or random testing for employees previously testing positive. If the employee refused drug testing in any of these three circumstances, the handbook stated the action would be considered insubordination and the employee could be terminated.

Hamilton argued the provision of the employee handbook dealing with drug testing converted the at-will relationship to non-at-will and the hospital required just cause to terminate her employment.

The court found the handbook provisions did not convert the employment relationship from at-will to non-at-will. The Eighth Circuit had previously held that when supervisors make uncontested statements that employees will not be fired unless they refuse to take a drug test, a genuine issue of material fact exists as to whether the employment is at-will. However, the court also explained the provisions that convert employment from at-will to non-at-will, "share the commonality of expressly concerning termination and limiting the discretion of the employer to terminate employees." Hamilton's situation did not fall under this exception because the handbook provisions Hamilton referenced did not limit the discretion of her employer to terminate her employment. Further, Hamilton did not allege an express promise by a supervisor not to terminate her unless certain conditions were met.

TAXATION

Medical Residents May be Eligible for IRC Student Exemption

The U.S. Court of Appeals for the Seventh Circuit decided September 23, 2008 that medical residents are not categorically excluded from claiming the student exception under the Federal Insurance Contributions Act ("FICA").

The decision came after of the University of Chicago Hospitals ("UCH") filed a refund action for FICA contributions it had paid for its medical residents during 1995 and 1996. UCH claimed that its medical residents qualified for the student exception from the FICA tax. The government argued that medical residents were per se ineligible for the student exception.

The student exception exempts from FICA tax liability employment which meets the description of a service performed in the employ of:

(A) a school, college, or university, or

(B) an organization described in section 509 (a)(3) if the organization is organized, and at all times thereafter is operated, exclusively for the benefit of, to perform the functions of, or to carry out the purposes of a school, college, or university and is operated, supervised, or controlled by or in connection with such school, college, or university.

The government argued that medical residents could not be considered students within the meaning of the exception because residency programs were commenced post medical school, after the residents had already obtained their medical degrees. The government added that a hospital did not fall within the common meaning of a "school, college, or university."

Learn More!

To contact a member of the Vorys, Sater, Seymour and Pease LLP Health Care Group, please contact any of our offices and simply ask to speak to an attorney member of the Vorys Health Care Group.

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The court looked to the applicable Treasury Regulation for guidance in interpreting the student exception. The statutory requirement for determining eligibility for the student exception include investigation of:

(1) the character of the organization in the employ of which the services are performed as a school, college, or university; and

(2) the status of the employee as a student enrolled and regularly attending classes at the school, college, or university.

The status of the employee as a student performing the services is determined on the basis of the relationship of such employee with the organization. An employee who performs services in the employ of a school, college, or university, as an incident to and for the purpose of pursuing a course of study at such school, college, or university has the status of a student in the performance of such services.

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