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In This Issue:

FRAUD AND ABUSE

Charitable Organizations May Subsidize Medicare and Medicaid Patients' Premium Obligations . . . 1

OIG Advises ASC Against Selling Ownership Interests to Local Hospital

MEDICAL STAFF PRIVILEGES

TAX EXEMPT STATUS



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FRAUD AND ABUSE

Charitable Organizations May Subsidize Medicare and Medicaid Patients' Premium Obligations

In Advisory Opinion No. 07-07, the Office of Inspector General of the Department of Health and Human Services ("OIG") found that an arrangement for a charitable organization to subsidize the financial obligations of indigent Medicare and Medicaid patients presents minimal risk of violating the Anti-Kickback Statute.

One party to the arrangement is a non-profit foundation ("Foundation") that provides charitable funds to indigent patients who have insurance coverage, but cannot afford the costs associated with coverage. The Foundation offers financial assistance for out-of-pocket premiums and cost sharing amounts associated with outpatient drug treatment to patients with certain diseases, including Medicare and Medicaid beneficiaries. The second party is a health care consulting company ("Administrator") with clients whose products might be used by patients participating in the arrangement. The Administrator's employees created the Foundation, and they provide services that include administering the funds, processing applications for assistance, and providing the financial assistance for documented cost-sharing needs.

The Foundation processes and awards grant applications using established, objective eligibility criteria which are based on medical condition and financial need. Grant determinations are made without regard to the interests of any donor or affiliate, the applicant's choice of product, provider, supplier, or insurance company, or the identity of the referring person or organization. In addition, grant recipients have complete freedom regarding the aforementioned services and providers.

Neither the Foundation's Board Members, nor any of its officers, has a financial or employment relationship with the Administrator or its affiliates. Compensation paid to Foundation employees, officers, and Board Members is consistent with fair market value in an arm's length transaction and does not reflect the volume or value of business generated for donors. Both parties certified that the Administrator's role in furthering the arrangement is to remain entirely separate from the Administrator's commercial operations.

The OIG found that the arrangement does not constitute grounds for the imposition of civil monetary penalties and stated that even though the arrangement could potentially generate prohibited remuneration under the Anti-Kickback Statute, it would not impose administrative sanctions against the parties. The OIG found a number of convincing factors, including that: (1) the donors do not control the Foundation or its programs; (2) the Foundation awards assistance irrespective of any link between donors and beneficiaries; and (3) the Foundation does not provide donors with any data that would indicate a correlation between the amount or frequency of a donation with the amount or frequency of the use of its products or services.

OIG Advises ASC Against Selling Ownership Interests to Local Hospital

In Advisory Opinion No. 07-05, the OIG opined that a proposal in which physician investors in an established ambulatory surgery center ("ASC") would sell a portion of their ownership interests to a local hospital would potentially violate the Anti-Kickback Statute and subject the investors to administrative sanctions under sections 1128(b)(7) or 1128A(a)(7) of the Social Security Act.

Fraud and Abuse continued from page 1

The ASC, a freestanding and multi-specialty facility, is owned and operated by a six member limited liability company ("LLC"). These six individuals exclusively provide professional services to patients of the ASC, and most routinely bill third party payers, including Federal Health care programs, for the services they provide. Three of the members, each orthopedic surgeons, founded the ASC and together own shares representing approximately 94 percent of the equity in the LLC.

The three orthopedic surgeons proposed to sell a portion of their shares, equivalent to a 40 percent ownership interest in the LLC, to a general acute care hospital positioned to make direct or indirect referrals. Because the current value of the interests is greater than the amount originally invested by the orthopedic surgeons, the result of the transaction would be that each investor would receive a return in proportion to the investor's ownership share, while the distributions of profits and losses would not be in direct proportion to capital invested. Accordingly, the surgeons would realize a gain on their original investment.

Although the hospital agreed to take measures to limit and/or discourage its ability to make referrals to the ASC, the OIG determined that the proposal would potentially violate the Anti-Kickback Statute. The statute makes it a crime to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. Furthermore, the statute is violated where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program. The proposal also failed to meet the strictures of the safe harbor provision promulgated by the Department of Health and Human Services to protect returns on investments in hospital/physician-owned ASCs that are unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952(r)(4).

According to the OIG, the proposal "failed to fall under the safe harbor" because: (1) the arrangement would permit the orthopedic surgeons to realize a gain on their original investment in the LLC; (2) the arrangement raises the possibility that one purpose of the hospital's investment is to reward or influence a subset of the physician-investors whose referrals of patients to the hospital or to the ASC may be particularly valuable; and (3) the return on the investment would not be directly proportional to the amount of the capital invested by each investors. For these reasons, the OIG concluded that the proposal would potentially generate prohibited remuneration under the Anti-Kickback Statute and that the OIG could potentially impose administrative sanctions.

Providing Patients With Free CHF Assessment Could Warrant Sanctions

In Advisory Opinion No. 07-08, the OIG advised that an proposed arrangement to provide congestive heart failure ("CHF") patients with free in-home services may constitute the imposition of civil monetary penalties under section 1128A(A)(5) of the Social Security Act. The program also potentially generates prohibited remuneration under the Anti-Kickback Statute.

The proposal, brought forth by a durable medical supplier that furnishes home oxygen products and services, sought to provide CHF patients with free in-home assessments with oximetry testing, in addition to education regarding their condition and tips to self-manage symptoms. The supplier provides durable medical equipment to a national patient population that includes Medicare and Medicaid beneficiaries; however, the proposal indicated that it would not seek federal reimbursement for the oximetery tests, nor any other evaluative or educational services performed in connection with the agreement.

The OIG evaluated the proposal under the Social Security Act, which imposes civil penalties against any person who gives something of value to a beneficiary of Medicare or Medicaid that the benefactor knows or should know is likely to influence the beneficiary's selection of a provider or supplier. The proposal was also measured against the Anti-Kickback Statute, which makes it a crime to knowingly or willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. For the purposes of the statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The threshold issue facing the OIG was whether the free CHF assessment with oximetery testing would constitute remuneration paid to the beneficiaries who receive them. The OIG focused on the value of the gift, noting that "incentives that are only nominal in value are not prohibited by the statute" and interpreted nominal value "to be no more than \$10.00 per item of \$50.00 in the aggregate on an annual basis." Because the supplier estimated the economic value of just one component of the assessment to be \$22.00, the OIG found the assessment and testing to be more than nominal, constituting prohibited remuneration.

The OIG determined that the value of the testing could lead a reasonable beneficiary to believe that he or she is receiving a valuable service that may expedite access to covered oxygen supplies and contribute to a successful clinical outcome. The OIG also found that, because the beneficiary's own physician would be responsible for recommending the supplier and the proposal did not indicate whether the beneficiaries would be obligated to make future purchases of oxygen and other supplies, the potential remuneration provided under the proposal would be likely to influence beneficiaries to select requestors as their supplier of oxygen or other Medicare-payable goods and services.

No Sanctions On Charitable Donation To Senior Residence Program

In Advisory Opinion No. 07-08, the OIG found that although a proposed donation would potentially generate prohibited remuneration under the Anti-Kickback Statute, it would not impose administrative sanctions on either the donor or donee.

The proposal involved a cash donation from a local health system's charitable foundation ("Foundation") to a senior residence program ("SRP"). The health system formed the

Fraud and Abuse Continued from page 2

Foundation in order to assist hospitals and other non-profit providers of health service within the region and to provide grants and scholarships to ensure the continuation and improvement of quality health care offered to the residents of the region and surrounding areas. Both the Foundation and the SRP operate in medically underserved areas and are themselves non-profit corporations exempt from Federal taxation. The entities share several of the same officers and directors.

The SRP developed an innovative \$3.9 million residential project to serve residents insured by Medicare, Medicaid, and private companies and sought financial backing from various sources. The SRP asked the Foundation to provide a single, unrestricted contribution of \$100,000. This sum was proportionate to the contributions made by other businesses of comparable size to the Foundation.

According to the proposal, the SRP is not required to purchase items and services from the health system, nor is the donation based on any linkage to potential referrals. Additionally, the Foundation made the donation contingent on several safeguards: (1) the donation will be in the form of a written grant specifying its terms and conditions; (2) the SRP will not require or encourage its physicians to refer residents to the health system; (3) the SRP will not track patient referrals to or other business generated for the health system; (4) any payment to the health system will be consistent with fair market value in arm's length dealing; and (5) the SRP will advise residents in writing of their freedom to choose health care providers.

The OIG found that because neither the health system nor the Foundation influenced the use of funds, the donation represented a one-time only, fixed advance payment. Additionally, the Foundation safeguarded against any improper influence so the donation was unlikely to result in fraud or abuse under the Anti-Kickback Statute. The OIG also recognized that charitable donations play an essential role in sustaining and strengthening the health care system, and that the majority of donors and donees who solicit or accept these donations are motivated by bona fide charitable purposes. As such, the OIG concluded that the proposal presented nothing more than a legitimate charity arrangement.

MEDICAL STAFF PRIVILEGES

Federal District Court Rules Physicians May Sue Under ADA Title VII for Denial of Staff Privileges

A physician with a disability claiming a Wisconsin hospital improperly denied him staff privileges may bring suit under Title III of the Americans with Disabilities Act ("ADA"), a federal court recently ruled. *Hetz v. Aurora Medical Center of Manitowoc County*, Case No. 1:06-C-636 (E.D. Wis. June 18, 2007).

Nolan Hetz brought suit against August Medical Center of Manitowoc County ("Hospital"), under Title III of the ADA, claiming the Hospital denied him staff privileges because of a disability, bipolar disorder and sleep apnea. Title III of the ADA prohibits places of public accommodation such as hospitals from discriminating against individuals on the basis of a disability. Because physicians at the Hospital are independent contractors not employees, Hetz could not sue under Title I of the ADA, which prohibits discrimination against employees only.

The Hospital brought a motion to dismiss Hetz's complaint, arguing that ADA Title III applies only to the clients or customers of a public accommodation, not to its independent contractors. Finding that the plain language and intent of ADA Title III does not support such an interpretation, the Court held that a physician acting as an independent contractor may sue a hospital under ADA Title III for the denial of staff privileges.

Other courts addressing the same issue have reached varying results. Nonetheless, it is prudent for hospitals whose physicians are independent contractors rather than employees to consider whether the denial of a physician's staff privileges could implicate Title III of the ADA.

TAX EXEMPT STATUS

IRS Official's Remarks Limit Recent PLR on Unrelated Business Taxable Income from Professional Corporations

During a recent speech to health care attorneys, an IRS official limited the application of Private Letter Ruling 200716034 (the "PLR"), which concluded that income from professional medical corporations affiliated with a hospital and its parent was taxable to the hospital as unrelated business income. At a June 26, 2007 luncheon hosted by the American Health Lawyers Association, Marvin R. Friedlander, chief of the IRS's Exempt Organizations Technical Branch, Office of Rulings and Agreements, commented that the PLR involved an "atypical" situation, is limited to the facts described therein, and does not reflect the IRS's view of affiliations between hospitals and professional corporations under different factual circumstances.

The PLR, dated January 26, 2007 and released April 20, 2007, involved six professional corporations, each of which had a hospital employee-physician as its sole shareholder. No patients of the professional corporations were patients of the hospital. The PLR ruled: (1) the hospital controlled the professional corporations within the meaning of Section 512(b)(13)(A) of the Internal Revenue Code (the "Code"); (2) the income from the professional corporations from providing medical services to their patients was unrelated to the performance of the hospital's exempt functions under Section 512(b)(13)(B) of the Code; and (3) interest received or accrued by the hospital and parent on loans made to the professional corporations was derived from an unrelated trade or business and therefore taxable.

The PLR concluded that the hospital controlled the professional corporations, even though physicians were the legal shareholders, and state law mandated that only physicians could hold such stock. The PLR also determined that the professional corporations' provision of medical services to their own patients did not have a substantial causal relationship to the achievement of the hospital's

Tax Exempt Status Continued from page 3

exempt purposes, and the professional corporations therefore were conducting activities on a larger scale than reasonably necessary for the performance of the hospital's exempt functions. As a result, the professional corporations were engaged in an unrelated trade or business with respect to the hospital, and the professional corporations' income was taxable.

The IRS official's remarks limiting the application of the PLR are consistent with commentary which questioned how the professional corporations could be controlled by the hospital and composed of hospital employees, while their activities were not related to the performance of the hospital's exempt functions.

Grassley Issues Minority Staff Proposal Challenging Community Benefit Standard

On July 18, 2007, U.S. Senator Charles Grassley (R-IA), ranking Minority Member of the Senate Finance Committee, released a "staff discussion draft" recommending dramatic revisions to the community benefit standard for hospitals to obtain and maintain tax-exempt status under IRC $\S 501(c)(3)$. The discussion draft proposes to significantly revise the existing community benefit standard by setting forth specific standards that hospitals must meet in order to qualify for exemption under IRC § 501(c)(3). Chief among these standards is a proposal that hospitals must attain a 5 percent minimum charity care benchmark in order to qualify for exemption under IRC § 501(c)(3). The discussion draft states that the staff is concerned that many nonprofit hospitals receive substantial federal income tax benefits and subsidies without providing commensurate benefits to society.

The discussion draft recommends implementation of a taxexempt hospital structure where some hospitals are exempt under IRC $\S 501(c)(3)$ and other hospitals are exempt under IRC $\S 501(c)(4)$. While both IRC $\S 501(c)(3)$ and 501(c)(4) organizations are exempt from federal income tax, IRC $\S 501(c)(3)$ organizations receive additional benefits of being able to issue tax-exempt bonds and receive tax deductible contributions.

The staff recommends setting specific standards for hospitals that seek exemption under IRC § 501(c)(3), including: (i) establishing a charity care policy and wide publication of that policy; (ii) quantitative standards for charity care (a "5 percent test," based on annual patient operating expenses or revenues, whichever is greater); (iii) requirements for joint ventures between nonprofit hospitals and for-profit entities; (iv) board composition and other governance requirements and executive compensation; (v) limiting charges billed to the uninsured; (vi) placing restrictions on conversions; (vii) curtailing unfair billing and collection practices; (viii) transparency and accountability requirements; and, (ix) sanctions for failure to comply with applicable requirements for an IRC § 501(c)(3) or § 501(c)(4) hospital.

The staff recommends setting standards for hospitals that seek exemption under IRC $\S 501(c)(4)$ including: (i) a quantitative amount of community benefits annually; (ii) limiting charges billed to the uninsured; (iii) governance reforms; (iv) restrictions on conversions; (v) curtailing unfair billing and collection practices; (vi) heightened transparency; and (vii) sanctions for failure to comply with applicable requirements.

The discussion states at length that it is not intended to constitute a legislative proposal. However, the theme of the draft is a dramatic revision of the community benefit standard of tax-exempt status for hospitals, and thus should be closely considered by hospital leadership and its counsel. A public comment period on the concepts presented in the discussion draft closed August 24, 2007.

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 VSSP Health Care Group.

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