

Health Law ADVISORY

Current legal insights for health care executives

November 29, 2006
Julie A. Knutson, Editor

How Far Can You Go With Outreach Services?

This topic was scheduled to be presented at the Health Law Forum in October 2006. In order to provide timely information from Randy J. Stevenson on the Roseland (Nebraska Supreme Court) case, the session was pre-empted with the promise that an article would follow. This was fortuitous, as the OIG issued a pertinent Advisory Opinion in the interim which is discussed in the following article. Ed.

Providing outreach services to potential referral sources implicates the Medicare Anti-kickback statute. Such services will also require Stark analysis if provided for or involving physicians. If the facility extending outreach services is tax-exempt, the rules governing tax exempt organizations must also be considered.

Outreach services take many forms: telemedicine, physician travel, laboratory services, services related to ambulances (restocking, sleeping quarters for crew, helipad, equipment and linen exchanges) and loans of equipment. Each situation requires fact-specific analysis under the relevant statutes and regulations.

The Anti-kickback Statute is a criminal statute that prohibits payments to induce the referral of Medicare or Medicaid beneficiaries or the beneficiaries of other federal health care programs. It targets any person or entity that knowingly and willfully solicits or receives any

remuneration or offers or pays any remuneration directly or indirectly, overtly or covertly, in cash or in kind, related to furnishing, arranging for or otherwise obtaining items or services paid by a federal health care program. The range of activity covered is very broad and encompasses outreach services extended to potential referral sources—physicians, hospitals, clinics, health care agencies.

Criminal penalties for violation include fines, imprisonment up to five years, exclusion from the Medicare and Medicaid programs and civil monetary penalties of \$50,000 per violation.

Safe harbors are available for some activities and protect against prosecution when all requirements are met.¹ Outside a safe harbor, there is no *per se* violation. However, the arrangement will be subject to factual review including analysis of whether even one purpose of the arrangement was to induce referrals.

When **Stark Law** is implicated because physicians are involved, the provision of goods or services creates a financial relationship which must fit within an exception or the statute will be violated regardless of the parties' intent. Stark prohibits the entity from billing federal health care programs for any designated health services referred by the physician

ALSO IN THIS ISSUE

Federal Attention to Medicaid Integrity Intensifies	4
Our Readers Write	4

¹Following numerous Advisory Opinions approving various restocking arrangements and other assistance to ambulance services, safe harbor protection has been made available for general ambulance restocking, fair market value restocking and government mandated restocking. (See 42 CFR 1001.952(v).)

with whom the entity has a financial relationship unless the financial relationship fully conforms to an exception. Sanctions include refund of payment for improper claims, civil monetary penalties (\$15,000 per claim, \$10,000 per day for failing to report information, and \$100,000 for any circumvention scheme), exclusion from the Medicare and Medicaid programs and possible violation of the False Claims Act.

Analysis under Stark Law will turn on the whether there is a financial relationship and referrals of designated health services and upon the availability of an appropriate exception. The Anti-kickback analysis is less straightforward, although there is extensive guidance available. If a pertinent safe harbor exists, the arrangement should be conformed to meet as many of the requirements as possible, even if all requirements cannot be met. Outside of a safe harbor, guidance from Inspector General (IG) advisory opinions should be considered. Safeguards against program abuse that are noted favorably in the opinions should be incorporated into the proposed arrangement to the extent possible and disfavored facts avoided. Some arrangements may continue to carry an unacceptable degree of risk and should be abandoned if they cannot be modified to conform more closely to a safe harbor or IG guidance.

The IG has issued a number of advisory opinions that address outreach services. While advisory opinions may only be relied upon by the parties requesting the opinion, they are published on the IG's Web site www.oig.hhs.gov for their instructive value in understanding the IG's approach to various circumstances. The advisory opinions distinguish "technical violations" of the statute which would not result in the imposition of penalties due to low risk of program abuse and/or satisfactory safeguards in view of the potential for benefit from arrangements that could result in sanctions. The following Advisory Opinions (AO) are particularly relevant to outreach services:

AO 99-14 January 6, 2000: This opinion analyzed a rural telemedicine program subsidizing transmission line charges and equipment maintenance for 10 health care facilities. The conclusion was that the activity involved a technical violation, but

no penalties would be imposed. The IG found that the risks of program abuse were minimal in view of the considerable benefits to rural providers and patients, plus there was a clear Congressional policy in the form of telemedicine oversight by the Office of Rural Health Policy and the Office for Advancement of Telehealth.

AO 03-14 June 26, 2003: The arrangement involved a cooperative effort between a hospital serving a 17 county rural region and an ambulance company to provide 24/7 emergency transport. The ambulance company provided the staff and helicopter equipped with a mobile ICU and the hospital provided the landing pad, modest crew quarters and related utility and security services. The IG concluded that the arrangement could generate prohibited remuneration if the requisite intent to induce referrals was present, but sanctions would not be imposed because there was little risk of over-utilization or increased cost to federal health care programs. The IG also found it favorable that the referral/transport pattern was governed by State and local trauma protocols pursuant to a State-mandated plan. It was also of importance that the arrangement was likely to have a very beneficial impact on the quality of trauma care in the region.

AO 05-08 June 6, 2005: This opinion concerned a laboratory proposal to provide free blood sample collection supplies to physicians and pay physicians to collect samples. The IG response was that there was potential to generate prohibited remuneration and possible administrative sanctions. The benefits to the physicians were clear with few, if any, offsetting safeguards or benefits.

AO 06-18 November 2, 2006: In this most recent opinion, the IG addressed whether the Requestor could pay travel costs for volunteer practitioners to travel to rural areas. The Requestor is a limited liability company owned by a nonprofit corporation which is the largest health care provider in the area. The proposed program involves a network of volunteer physicians and other health care professionals who regularly travel to rural communities to provide specialty medical care and consultation services as well as health screening and educational activities. The Requestor administers the program-

Some arrangements may continue to carry an unacceptable degree of risk and should be abandoned if they cannot be modified to conform more closely to a safe harbor or IG guidance.

-selecting the outreach sites from a pool of requests submitted by local communities according to a needs criteria and matching the sites to practitioners. The criteria pertain health care practitioner shortage and unmet health care needs.

The Requestor pays the travel costs for the volunteers who are required to spend at least 20% of their time onsite performing educational or consulting services that are not billable (the 20% requirement). Volunteers are not paid for making the trip, but they may bill third party payors for their professional services. To be eligible for free travel, volunteers must sign a written agreement, document all activities, comply with program policies and document travel expenses. Failure to meet the 20% requirement or comply with the agreement results in recoupment of the travel costs from the volunteer. To prevent inappropriate benefit to providers, the volunteers may not have an office or practice site in the community to which they will travel under the program. To assure quality, the volunteers must be credentialed at a facility operated by the Requestor. Volunteers are not encouraged to refer to Requestor's facilities and referrals or admissions are not tracked in any way.

The IG concluded that, although paying the travel costs confers a benefit on the volunteers and the education and consultation confers a benefit on the local facilities, there was low risk of program abuse or improper payment for referrals. The IG found that the requirements placed on volunteers assured that they would not profit unduly from the trip. The Requestor was not found to benefit inappropriately because the rural communities requested the services and the sites were selected based on the need for services and not on any basis related to referrals. In fact, improved specialty care in the local communities might reduce referrals to the Requestor. Local facilities did not unduly benefit because the education and consultation was not a type that would ordinarily be purchased, such as CME; it is more on a par with mentoring. Finally, no beneficiaries benefit improperly because the services are not free or discounted. In summary, the IG found significant community benefits coupled with sufficient safeguards and thus declined to invoke sanctions.

Tax-exempt organizations must analyze arrangements to provide goods or services to

private, for-profit entities including privately practicing physicians and for-profit, non-governmental businesses, e.g., pharmacies and DME suppliers. Arrangements must involve a fair market value exchange. Failure to meet the fair market value test could result in imposition of fines in the form of excise taxes under the intermediate sanctions rules or possible loss of tax-exemption for the organization. In addition, fees charged for services to private individuals and entities would likely be considered unrelated business income (UBI). If the good or service is not provided to a patient of the hospital, the income is UBI. UBI exceeding 20-30% of the hospital's total income may jeopardize the hospital's tax-exempt status. Further, UBI must be properly reported to the IRS and is subject to income tax.

An exception to the patient relationship rule is providing lab and radiology services in an isolated area. There is at least one private letter ruling stating that income from lab and radiology services performed by a hospital in an isolated area are related (and thus not UBI) even though there is no strong evidence of a hospital-patient relationship between the hospital performing the test and the patient. Revenue Ruling 85-110 states that lab patients are unrelated (causing the income to be considered UBI) if the services are otherwise available in the community.

In addition, Section 513(e) of the Internal Revenue Code states that UBI does not include the furnishing of certain services to one or more hospitals if furnished solely to hospitals with less than 100 beds, at a fee which does not exceed the actual cost of providing the services and if such services would be exempt functions of the recipient hospital if performed directly by such hospital.

Many outreach activities are permissible, or require minimal restructuring to be permissible, particularly when offered to non-profit organizations or facilities in the presence of safeguards to address possible Anti-kickback concerns. Services to private individuals or entities require additional analysis under rules governing tax-exempt organizations as well as Stark Law, if physicians are involved in the arrangement.

Many outreach activities are permissible or require minimal restructuring to be permissible...

Julie A. Knutson

Federal Attention to Medicaid Integrity Intensifies

The Deficit Reduction Act of 2005 (DRA) provided the resources to the Centers for Medicare and Medicaid (CMS) to establish the Medicaid Integrity Program (MIP). The MIP is the first national strategy to detect and prevent fraud and abuse in the 41-year history of the Medicaid program. The MIP will be lead by the Center for Medicaid & State Operations (CMSO) under the guidance of the Comprehensive Medicaid Integrity Plan. The DRA specifically requires Medicaid contractors to review the actions of Medicaid providers, conduct audits, identify overpayments and educate providers and others on payment integrity and quality of care.

Congress appropriated additional funds to CMS to employ 100 full time employees to provide support to state agencies for this initiative. Funding for this program will reach \$75 million dollars annually by FY 2009 and for each year thereafter.

The Plan states that CMSO plans to initially focus on the following areas: (a) nursing and personal care such as fraud related to long-term care facilities and home health agencies, (b) the provision of prescription drugs to beneficiaries and the underlying costs of those drugs as reported to the States, (c) durable medical equipment and other medical suppliers, and (d) improper claims for payment from hospitals and individual practitioners. A more detailed work plan will be developed and published in the coming months.

Our Readers Write

Last month, we discussed potential hospital liability in connection with patients' use or non-use of restraining devices. That article prompted comments from a hospital reader that operates a formal program to promote the proper use of child safety seats.

Sherri Blome, Special Projects Director at Western Community Health Resources, Chadron, Nebraska wrote to describe the program in Chadron. The Hospital has several staff members who are trained and certified as Child Passenger Safety Technicians. Through these trained and certified individuals, the Hospital provides services in safety seat installation and adjustment to parents of infants and children being discharged from the facility. Uncertified staff do not offer opinions or assistance in regard to safety seats.

In addition to assistance at discharge, the Hospital operates a permanent inspection station where the certified staff conduct inspections and education one day per month by appointment. Donated safety seats are collected and distributed through the program. Training is offered through pre-natal classes in order to help parents prepare for discharge.

All of the safety seat services are provided pursuant to a Hospital policy that includes a process for parents to sign a form accepting or declining the training and assistance with safety seats. Ms. Blome explained that the Hospital worked with Safe Kids Worldwide to develop the program. www.safekids.org

An organized program such as Chadron's that uses appropriately certified staff pursuant to a written policy overcomes the liability concerns expressed in our October article. Hospitals wishing to assist with safety seat instruction and installation may wish to develop a similar formal program in order to avoid the issues that could arise from providing informal assistance without specialized training.

The Medicaid Integrity Program is the first national strategy to detect and prevent fraud and abuse in the 41-year history of the Medicaid Program.

*Warm wishes for an
enjoyable holiday season
from all of your friends
at Baird Holm.*

Questions? Ideas?

We welcome your questions, ideas and suggestions.

E-mail jknutson@bairdholm.com and help make the Advisory interactive!

BAIRD HOLM^{LLP}
ATTORNEYS AT LAW

HEALTH CARE GROUP

Vickie J. Brady
402.636.8230
vbrady@bairdholm.com

Alex (Kelly) M. Clarke
402.636.8204
kclarke@bairdholm.com

John R. Holdenried
402.636.8201
jholdenried@bairdholm.com

Andrew D. Kloeckner *
40.636.8222
akloeckner@bairdholm.com

Julie A. Knutson
40.636.8327
jknutson@bairdholm.com

Barbara E. Person
402.636.8224
bperson@bairdholm.com

David W. Tomlinson **
402.636.8330
dtomlinson@bairdholm.com

*All attorneys are admitted to practice in
Nebraska and Iowa unless otherwise noted.
*Admitted to practice in Iowa. Nebraska bar
admission pending.
**Admitted to practice in Oregon and Nebraska.*

MEMBER
LEX MUNDI
THE WORLD'S LEADING ASSOCIATION OF INDEPENDENT LAW FIRMS

Health Law Advisory is published by Baird Holm LLP as a service to our clients, friends and colleagues. All comments and inquiries are welcome. Our attorneys are available for speaking engagements and written presentations at conferences, seminars and continuing education programs. Please direct your inquiries to any of the Firm's health law attorneys.

BAIRD HOLM
1500 Woodmen Tower
Omaha, NE 68102
402.344.0500
402.344.0588
www.bairdholm.com

©2006 Baird Holm LLP

*The contents of this advisory are intended for general informational purposes only and should not be construed as legal advice. Readers are urged not to act upon the information contained in this publication without first consulting an attorney.