Legal Issues Affecting Medical Device Manufacturer and Provider Relationships

Increased federal investigation into alleged lavish arrangements between the pharmaceutical industry and providers has led to scrutiny of other industry arrangements with providers, including those of medical device manufacturers.

In 1999, the Office of Inspector General (OIG) published the final compliance guidance for the durable medical equipment, prosthetics, orthotics and supply industry. The guidance contained compliance program elements common to other programs developed by OIG. Special areas of concern include delivering or billing items or supplies before receiving certificates of medical necessity (CMN), falsifying CMNs, providing incentives to referral sources, billing for services under a prohibited referral arrangement, improper telemarketing activities and improper patient solicitation practices. In addition to these concerns, a myriad of laws, regulations and industry guidance govern arrangements between medical device manufacturers and providers, which could present significant traps to organizations and individuals that conduct business in this industry.

Anti-Kickback Statute

The federal Anti-Kickback Statute proscribes the offering, payment, solicitation or receipt of any remuneration in exchange for a patient referral or referral of other business for which payment may be made by a federal health care program, including Medicare and Medicaid. Violations of the Anti-Kickback Statute can result in significant criminal penalties, including prison, and civil penalties of up to $50,000 for each violation.

OIG has historically taken the position that under certain circumstances, gifts, free items and fees for sham consulting arrangements could violate the Anti-Kickback Statute. The argument is that the transfer of anything of more than nominal value to a provider may induce the provider to recommend to his patients the purchasing or ordering of items or services that could be reimbursed by a federal health care program.

Since providers often recommend medical devices to their patients, any value transferred by a manufacturer of such devices to providers with the expectation of a recommendation from the provider could present significant risk to the parties. Given the severity of the criminal and civil sanctions under the Anti-Kickback Statute, medical device manufacturers need to be very careful when providing any gifts or free items to providers, and ensure that any consulting services arrangement is consistent with the personal services safe harbor of the Anti-Kickback Statute.

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What to Expect in Health Care in 2005

Health care providers can anticipate a number of new challenges and initiatives in 2005. Two major forces at work are the potential impact of federal and state proposed budgets and the technology initiatives being promoted by the Bush Administration throughout the industry. Let’s take a brief look at some of the areas that you may have to deal with in the coming year:

Federal and State Budget Cuts — The Bush Administration’s budget for the Medicare and Medicaid programs demonstrates that it desires to promote more Medicare patients into the new Medicare Advantage program, the rejuvenation of Medicare’s idea of managed care. Many managed care plans left the old program, when it became clear that CMS was not providing adequate funding for patient care. This time, Medicare Advantage programs have many attractions, including numerous demonstration projects and new concepts such as e-prescribing and chronic care management. The federal government is clearly looking for a way to cut its subsidies to Medicaid, and is investigating “improper” payments by state regulators in the past. Most state budgets will see either eligibility restricted to Medicaid, reduced benefits, or other restrictions on care such as co-pays.

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Stark

Generally, the Stark law prohibits a physician (or immediate family member) who has a financial relationship with an entity from making referrals to that entity for the furnishing of designated health services for which payment may be made under the federal health care programs, unless an exception or safe harbor is satisfied.

Stark is often implicated in the medical device context because providers (who have a financial relationship with the medical device manufacturer) are in a position to influence their patients’ purchasing of federally reimbursed health services. For example, suppliers may engage providers as consultants or to provide educational or training services to patients, which could implicate Stark.

Although suppliers have a responsibility to make product training and education available, and the U.S. Food and Drug Administration mandates such training and education to facilitate the safe and effective use of certain medical technology, any services agreement with providers for providing such services would have to satisfy the requirements of the personal services safe harbor under Stark to avoid any risk to the parties.

Violations of Stark could result in denial of payment, civil penalties, disgorgement of reimbursements received and exclusion from federal health care program participation.

False Claims Act

The False Claims Act prohibits suppliers and providers from submitting or causing to submit a false or fraudulent claim for payment to the government. The False Claims Act could be implicated when, among other things, claims for durable medical equipment (DME) payment are submitted based on false certifications.

In January 1999, OIG issued a special fraud alert concerning provider liability for certifications in the provision of medical equipment and supplies and home health services. OIG was concerned with the providers’ laxity in reviewing and completing certifications of medical necessity for DME in home health care and reminded them of the substantial criminal, civil and administrative penalties for knowingly signing a false certification or acting with reckless disregard as to the truth of the information being submitted.

Violations may occur when providers sign a certification as a courtesy to a DME supplier, causing a false claim to be submitted or when receiving any financial benefit in return for signing the certification. Sanctions for violating the False Claims Act include treble damages, fines and administrative penalties.

Civil Money Penalties Law

Generally, the Civil Money Penalties Law (CMP) prohibits a supplier from offering or transferring remuneration to any individual eligible for Medicare or Medicaid that such supplier knows or should know is likely to influence the individual to order or receive from the supplier any item or service for which payment may be made under Medicare or Medicaid. Violation of the CMP can result in fines of up to $10,000 for each wrongful act.

By now, most suppliers know that giving anything of more than nominal value to a patient or prospective patient with the intent of influencing the individual’s selection of a supplier is improper. In a Special Advisory Bulletin, OIG indicated that inexpensive gifts or services (with a retail value of no more than $10 individually, and no more than $50 in the aggregate annually per patient and excluding cash or cash equivalents) may be provided to beneficiaries.

Suppliers may offer beneficiaries more expensive items and services that fit within an enumerated CMP exception, including waivers of cost-sharing amounts that are based on financial need, practices permitted under the federal Anti-Kickback Statute (such as permissible discount arrangements), and incentives to promote the delivery of certain preventive care services. Suppliers need to understand these restrictions when marketing and advertising their products and services, and structure their marketing and advertising programs in compliance with these guidelines.

Medical device manufacturers also need to be mindful of the prohibitions concerning telemarketing of medical equipment and supplies. In March 2003, OIG issued a special fraud alert regarding telemarketing by DME suppliers, reminding suppliers of the general prohibition concerning unsolicited telephone calls to Medicare beneficiaries.

Federal law generally prohibits suppliers of DME from making unsolicited calls to Medicare beneficiaries regarding the furnishing of a covered item unless:

- the beneficiary has given written permission to the supplier to make contact
- the supplier is contacting the individual regarding a previously furnished item, or if the call is about furnishing of a covered item (other than a covered item already furnished to the individual)
- the supplier has furnished at least one covered item to the individual during
the 15-month period preceding the date on which the supplier makes contact.

OIG also noted that suppliers could not do indirectly what they could not do directly – so they could not use independent marketing firms or other third parties, including providers, to make such solicitations. Accordingly, medical device manufacturers should review their marketing arrangements to ensure compliance with these restrictions. Violation of the federal anti-solicitation provisions could result in denial of payment for any item furnished pursuant to an improper solicitation.

**AdvaMed Code**

With increased scrutiny over relationships between providers and pharmaceutical manufacturers, the Advanced Medical Technology Association (AdvaMed), the largest medical technology trade association, has updated its ethical code for medical device companies in identifying appropriate gifts, charitable contributions, hospitality and reimbursement practices.

Key guidance provided by the code includes the following:

- **Consultants may receive reasonable compensation for bona-fide consulting services** such as research, advisory board participation and presentations at supplier-sponsored training and product collaboration.
- **Suppliers may meet with providers to discuss products, sales terms and contract negotiations.** Occasional hospitality in the form of modest meals and receptions that are conducive to the exchange of information may be permissible.
- **Modest gifts to providers having a fair market value of less than $100 are permissible provided the gifts benefit patients or serve a genuine educational function.**
- **Suppliers may make donations to charitable organizations for charitable purposes such as medical research, indigent care or public education.**

**Medical device manufacturers also need to be mindful of the prohibitions concerning telemarketing of medical equipment and supplies.**

Additionally, the code provides that any arrangement should encourage ethical business practices and socially responsible industry conduct. Importantly, an arrangement’s compliance with the code does not necessarily equate to compliance with applicable laws and regulations, which may impose stricter requirements.

**Conclusion**

Supplier arrangements with providers and patients should, at a minimum, comport with the following guidelines:

- **Any services arrangement between a supplier and provider should be for legitimate and justifiable services such as the provision of training and education required of patients, provide for reasonable compensation which is set at fair market value and satisfies the requirements of the personal services safe harbor under Stark and the federal Anti-Kickback Statute.**
- **Suppliers should not, directly or indirectly, make unsolicited calls to Federal health care program beneficiaries to market its products and services unless a permitted exception applies.**
- **Nominal gifts to providers may be permissible provided that any such gifts benefit patients and serve a genuine educational function and, provided that there is no quid pro quo arrangement between the parties.**
- **Supplier sales representatives should not provide gifts or other remuneration to providers to induce the providers to meet with them regarding a supplier’s products and services.**
- **Suppliers may sponsor conferences provided that the conferences are primarily dedicated to promoting scientific and educational activities and, provided further, that any subsidy is directed to the conference’s sponsor and not to providers as payment.**
- **Suppliers may provide reasonable honorarium to faculty members of conferences and reimbursement of reasonable expenses (subsidies to attendees of conferences for cost of travel, lodging and personal expenses, however, would not be permissible).**
- **Any discount arrangement offered by a supplier to patients should fall within the discounts safe harbor of the Anti-Kickback Statute.**
- **Incentive to promote the delivery of preventive care services may be permissible provided that, among other things, the delivery of such preventive services is not tied to the provision of other services and provided further, that the value of the incentive is not disproportionately large in relationship to the value of the preventive care services.**
- **Inexpensive gifts or services (other than cash or cash equivalents) may be provided to an individual, provided that the gifts or services have a retail value of no more than $10 individually and no more than $50 in the aggregate annually per patient (e.g., exercise videos, pens and t-shirts would be permissible, but not club memberships) and provided further, that the provision of the gifts does not have the purpose of securing the physician’s services to the patient.**

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and annual limits on care, which will result in additional charity care costs shifted to providers.

Charity Care — Lawsuits over the provision of charity care by hospitals will continue in 2005, with more finding their way to state courts and perhaps a warmer reception than the federal courts have provided. In states with elected judges, and where the rules for tax exemption are more attuned to an accounting for charity care, the plaintiffs could see some success. Hospitals, other health care organizations and physicians should review their charity care policies and distinguish those patients who are unwilling to pay from those who are unable to pay at the time of registration. It is most important to look at collection policies and collection vendor agreements to review the imposition of penalties on individuals who simply will never be able to pay the bills. The recent imposition of taxes on ambulatory surgery centers that are not hospital-owned in New Jersey is something to watch carefully, as those funds are earmarked for charity care in acute care hospitals in that state. Since CMS issued its statement in January 2005 that the discounting of charges to charities will not affect outlier payment calculations, providers should approach this issue aggressively.

Infection Reporting — The public and consumer watchdog groups are promoting the reporting of medical errors, physician malpractice and hospital-acquired infections. Maryland legislators are planning legislation to require the reporting of infection data—one of 25 states considering such reporting requirements. Of course, Pennsylvania’s Health Care Cost Containment Council started collecting such data last year with mixed compliance to date. Infectious disease officials in hospitals and other settings will be forced to take steps to reduce the incidence of infections from the 2 million that the CDC reports are sickened annually. While the reporting carries a burden, infectious disease specialists at some institutions are able to use the data to reduce the incidence of infection and the cost of care to those individuals, with material amounts saved.

**Until high jury verdict awards are resolved somehow, it appears that insurance underwriters will continue to have the upper hand in a seller’s market with no controls on potential losses.**

Physician/Hospital Relations — The number of new facilities owned by physicians opened in the past few years in non-CON states shows that hospitals and physicians are on a collision course regarding winning the hearts and minds of the insured patient. The current moratorium from the Stark law exception on specialty hospitals is due to expire in June. Each side in the debate is attempting to assure victory. Perhaps a closer look at joint ventures or gainsharing (recently permitted by the OIG in certain limited cases) holds the answer to resolving physician demands to be involved in how care is provided in an ambulatory setting. In the meantime, if more constructive arrangements are not found between physicians and hospitals, we will continue to see more litigation arising out of medical staff relations and economic credentialing. In addition, payers and employers are examining the proliferation of physician-owned facilities from a cost perspective.

Medical Malpractice Insurance — Not much progress has been made to date on reforming the tort system in most states, including Pennsylvania. In fact, the most dramatic changes in Pennsylvania appear to be as a result of new and aggressive court rules on venue, remitter and certification. Until high jury verdict awards are resolved somehow, it appears that insurance underwriters will continue to have the upper hand in a seller’s market with no controls on potential losses. Even with insurance premiums supported by the taxpayers, the crisis is far from over. Tort reform continues to be on the agenda, but without much political will to get it passed. Others are busy promoting alternatives to court cases, the most recent being JACHO, which published a report calling for a change in the culture of patient safety and professional responsiveness to problems. In light of certain payers indicating that they will not pay for procedures involving a major error, financial and professional liability concerns appear to have a nexus in the coming year.

Health Care Technology — The introduction of interoperable health information technologies has recently received attention from President Bush and Congress. David J. Brailer was appointed as so-called IT czar over the development and implementation of such a system (Dr. Brailer’s official title is national coordinator for health information technology). In addition, the Bush Administration has reportedly told its various health care regulatory agencies to find a way to make such a system happen. This has become apparent from discussions with federal regulatory officials and their acknowledgment that approaches need to be found within the regulatory framework around issues involving the anti-kickback law; Stark; private inurement and antitrust policies. Vendors are aggressively looking at their options, and the recent announcement by the largest IT vendors that they would work towards open-architecture in designing software systems was certainly helpful to permit the technologies to flourish. Look for more demonstration projects and funding grants for hospitals and physicians in the future.

This year brings with it multiple challenges for health care providers. Our Health Care Practice Group intends to stay abreast of all these areas and new ones as they emerge. Let’s keep in touch!

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Four Pepper lawyers are on the faculty of the Pennsylvania Bar Institute’s 11th Annual Health Law Institute, scheduled for March 15-16, 2005, at the Pennsylvania Convention Center in Philadelphia.

All Pepper lawyers will be speaking on March 16. Gregory J. Nowak will speak on “Rethinking Investment Strategies,” Henry C. Fader will speak on “Advising the Hospital Audit Committee,” John W. Jones, Jr. will speak on “Group Purchasing Arrangements Coming Under Government Scrutiny,” and Rebekah A.Z. Monson will speak on “Records Reproduction Costs — HIPAA v. State Law.”

Like no other event, the Health Law Institute zeros in on the practice of health law in Pennsylvania. Each year hundreds of health law professionals, in both the public and private sectors, gather together to meet, learn and have fun. Whether you represent health care providers, physicians, individuals, group plans, or any other health care client, this is the event to attend to make sure there’s nothing you’ve been missing about the ever changing field of health law.

Each day of this program has been approved by the Pennsylvania Continuing Legal Education Board for 6 hours of CLE credit. Workshop choices will determine whether credits are in substantive law, practice & procedure or ethics, professionalism or substance abuse.

For more information or to register, visit www.pbi.org.
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Feedback Wanted

What health care issues keep you up at night? Drop us a line and let us know, and we’ll write about it in an upcoming issue of Health Care Law Alert. Contact Henry C. Fader at 215.981.4640 or faderh@pepperlaw.com.