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Advisory

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HEALTH LAW

OIG Issues New Guidance on Pharmacy Issues and Joint Ventures

In the past month, the Department of Health and Human Services' Office of Inspector General (OIG), which enforces the federal laws targeted at preventing fraud and abuse in the Medicare and Medicaid Programs, has issued two important guidance documents that should be of interest to participants in the health care industry. The first document is the final guidance to pharmaceutical manufacturers concerning fraud and abuse issues that may arise in the provision of pharmaceutical products. The second is a special advisory bulletin that focuses on the growing number of joint ventures that are created through contract, rather than shared ownership arrangements. Both documents highlight particular practices that are of concern to the OIG.

Final Compliance Program Guidance for Pharmaceutical Manufacturers

On April 28, 2003, the OIG issued its final voluntary guidance for pharmaceutical manufacturers (the "Guidance"). This Guidance is one of a series of such guidances that the OIG has issued periodically, highlighting fraud and abuse concerns in particular industries. While this Guidance is specific only to pharmaceutical manufacturers, and is intended to assist them with their compliance activities, the OIG stated that the Guidance should also be useful to hospitals, physicians and other health care providers. In addition, the Guidance addresses manufacturer arrangements with pharmacy benefit managers (PBMs), and notes that the safe harbor for group purchasing organizations—which, if applicable, would immunize entities from liability under the anti-kickback law—may be available to protect PBMs in certain circumstances.

Like the draft version issued in October 2002, the Guidance identifies three major potential fraud and abuse risk areas to which pharmaceutical manufacturers should be sensitive. These are: 1) the integrity of data used to establish or determine government reimbursement, such as Average Manufacturer Price and Medicaid rebate provisions; 2) kickbacks and other illegal remuneration; and 3) compliance with laws regulating drug samples. The Guidance includes several significant changes from the draft version, which may indicate a refinement in the OIG's position on these issues.

These changes include the following:

- The Guidance identifies two categories of purchasers of pharmaceuticals: direct purchasers (such as hospitals, nursing homes, pharmacies and some physicians); and indirect purchasers (such as health plans), whereas the draft version made no such distinction. Although the federal kickback provisions do not distinguish purchasers in this manner, such an expansive interpretation of the term “purchaser” by the OIG may suggest that there will be an increased focus on entities that have not previously been the subject of such scrutiny.
- The Guidance has an expanded discussion of educational grants and research funding, and notes that such activities could raise issues under the anti-kickback law if the grants or funding are conditioned in whole or in part on the purchase of pharmaceuticals. The Guidance advises that “grant making functions” should be separated from “sales and marketing functions” and that payments for research should be at fair market value for legitimate, reasonable, and necessary services.
- The Guidance adds a detailed discussion of “drug formularies,” and notes that formularies are a well-established tool for managing drug benefits. It states that the determination of clinical efficacy and appropriateness of formulary drugs by the formulary committee should precede consideration of the drugs’ costs

so as to avoid issues under the anti-kickback provisions. The OIG further highlights several risk areas that have the potential for abuse, including: 1) relationships between manufacturers and formulary committee members; 2) payments to PBMs; and 3) formulary placement payments.

- The Guidance cites extensively from the “Code on Interactions with Healthcare Professionals,” adopted on April 18, 2002, by the Pharmaceutical Research and Manufacturers of America (PhRMA), which represents the pharmaceutical industry. According to the Guidance, compliance with this Code will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements.
- Finally, the Guidance eliminates the cautionary language contained in the draft version that discounts or rebates based on “movement of market share” could implicate the anti-kickback provisions, a revision that may suggest a change in the OIG’s views on such discounts.

Although adherence to the Guidance is voluntary, the issuance of the Guidance indicates the OIG’s interest in increased enforcement, both within the pharmaceutical industry and within those industries that have close ties to the pharmaceutical industry. The areas addressed could be likely targets of future OIG enforcement activity.

Special Advisory Bulletin on Contractual Joint Ventures

In April the OIG also issued a Special Advisory directed at “contractual joint venture” arrangements that raise questions under the federal fraud and abuse laws. The OIG has always had concerns about joint ventures between those who are in a position to make referrals and those who provide the requested items or services. In 1989, the OIG issued a special fraud alert directed at precisely such arrangements.

The new joint venture advisory builds on the previous fraud alert, noting that now many joint ventures involve contractual arrangements, rather than shared ownership arrangements. In these new ventures, a health care provider in one line of business (“the Owner”) attempts to expand into a related line of business that would be useful for its existing patient population. Often, according to the OIG, this expansion is effected by the Owner contracting with an entity (“the Manager/Supplier”) that is already in this new line of business, which then oversees the operations and supplies equipment and personnel to the venture. The Manager/Supplier takes care of the inventory, hires the employees, leases the space, and handles billing and other services. In other words, the Owner is contracting out substantially the entire operation of this line of business to the Manager/Supplier, a company that would otherwise be a competitor of the new entity.

The OIG gives several examples of such suspect contractual arrangements, including the following:

- A hospital establishes a subsidiary to provide Durable Medical Equipment (DME) and enters into a contract with an existing DME company to operate the new subsidiary. The existing DME company already provides these services and bills insurers and patients for them.
- A DME company sells nebulizers to health care beneficiaries. Then a mail-order pharmacy suggests the company form its own mail-order pharmacy to provide nebulizer drugs. However, through a management agreement, the existing mail-order pharmacy runs the DME company's pharmacy, providing personnel, equipment and space.
- A group of nephrologists establishes a company to provide home dialysis supplies to their dialysis patients. The new company contracts with an existing supplier of home dialysis supplies to operate the new company and to provide all goods and services to the new company.

The OIG notes that all of these arrangements share certain common elements. First, they involve an entity expanding from one line of business into a related line of business, which is dependent on referrals from the Owner's existing business. Second, the Owner does not operate the new entity, nor commit substantial financial, capital, or human resources to it; rather, it contracts

out all of the operations of the new business. In some cases, the contractual arrangements may result in the Manager/Supplier receiving exclusive access to the patients of the Owner, through non-competition provisions or restrictions on access. Third, the Manager/Supplier would be a competitor to the new business entity were it not for the contractual arrangements. Fourth, the Owner and the Manager/Supplier share an economic benefit from the new business. The Manager/Supplier takes its payment from its contracts with the Owner, while the Owner receives a share of profits from the billings of the new business. Finally, payments to the Manager/Supplier typically vary, either directly or indirectly, with the value or the volume of business generated for the new business by the Owner.

The OIG finds that these types of arrangements are not eligible for safe harbor treatment, which would immunize them from prosecution under the anti-kickback law, because they are not part of an arm's-length transaction and often do not involve payment for actual services rendered. The OIG provides a list of the indicia of suspect contractual joint ventures, including the following:

- The Owner expands into a health care line of business that can be provided to its existing patients.
- The new business serves a captive referral base that the Owner serves through its existing business.
- The Owner is undertaking little or no *bona fide* business risk because of the captive referral base.

- The Manager/Supplier of the new enterprise would be a competitor to the new line of business but for the contractual arrangements.
- The Manager/Supplier, not the Owner, provides all or most of the day-to-day services needed by the enterprise.
- Usually, the Owner is profiting from the business otherwise provided by the Manager/Supplier.
- The parties agree through a non-competition clause that the Manager/Supplier is prohibited from supplying services, on its own, to the Owner's patients.

The full scope of the OIG Advisory is still somewhat unclear because, taken literally, it could reach a broad range of conduct. In some ways, the Advisory reads more like an antitrust opinion than a fraud and abuse one. The OIG seems especially concerned about the ability of the new enterprise to tie up a stream of referrals, and the elimination of potential competitors in the market. Nonetheless, it is the existence of this captive referral base that also raises the possible kickback issue: the Owner is able to profit from its ability to refer patients to this new entity, with little risk or investment of capital.

In the past, when the OIG issues a special Advisory Bulletin such as this, it is because the OIG has learned of the conduct through some other investigation or inquiry. Thus, it is likely that the special bulletin is a precursor to other OIG activities in this area.

CMS Issues New Rules on Provider Enrollment

Recently, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule that could change the process by which health care providers obtain Medicare billing privileges. This rule, which was published in the *Federal Register* on April 25, 2003, sets out the requirements for provider enrollment, certification, revalidation and timely reporting of updates. This rule will, if enacted, apply to all providers and suppliers except those who have specifically "opted out" of the Medicare program. Comments on the proposal must be submitted to CMS by June 24, 2003.

Although Medicare providers have always had to enroll in the Medicare program, this proposed regulation sets out the most specific set of requirements detailing how a provider obtains the necessary Medicare billing number. Also accompanying the rule are four separate versions of the enrollment form (CMS Form 855) to be used by hospitals; suppliers and practitioners; DME compa-

nies; and those practitioners who are assigning their rights to bill to another entity.

The new rule would require that all providers have enrolled with Medicare in order to bill for Medicare services furnished. In addition, providers will be required to update their information within 90 days of a change or within 30 days of a change in ownership. CMS will also periodically request that providers revalidate the information that they have submitted to CMS. In addition, the rule establishes a new procedure by which billing privileges can be revoked, separate and apart from the Medicare exclusion process. Billing privileges also can be deactivated if a particular number is not used to submit claims for a significant period of time.

The new rules are quite specific concerning who has the authority to sign and make changes to the new 855 form. Entities must specifically designate an "authorized official" who is the individual within the company with author-

ity to enroll it in the Medicare program, report changes, and update the enrollment record. In signing the form, providers must certify that they are in compliance with all Medicare statutory provisions and applicable regulations, as well as other licensure and regulatory requirements.

Finally, the rule specifically states that providers are prohibited from selling their billing numbers to any individual entity and from allowing another individual or entity to use their billing numbers. The only time it is permissible to transfer a billing number is as part of a larger change in ownership. In that case, both the current and the new owner would be required to complete and submit a new Form 855.

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Please contact us if you have additional questions about the matters discussed in this Advisory or if we can be of any assistance to your organization.

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