

## MEMORANDUM

TO: HEALTH CARE CLIENTS

DATE: May 15, 2003

RE: Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers

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### I. INTRODUCTION

On April 29, 2003, the Office of Inspector General (“OIG”) of the Department of Health and Human Services (“HHS”) released its final “Compliance Program Guidance for Pharmaceutical Manufacturers” (“Final Guidance”), which outlines voluntary actions manufacturers should consider to promote compliance with Medicare, Medicaid, and other federal health care program rules and guidelines.<sup>1</sup> This Final Guidance finalizes the draft Compliance Program Guidance (“Draft Guidance”) issued by the OIG on October 3, 2002, and described in detail in our memorandum to clients on that date. The Final Guidance retains many of the policies and principles set forth in the Draft Guidance. At the same time, the OIG has added clarifications and additional discussion in a number of areas, including the relationship between pharmaceutical manufacturers and pharmacy benefits managers (“PBMs”), the practice of “preceptorship” or shadowing and other consulting arrangements, manufacturer influence on formulary decisions, and more. Also, unlike in the Draft Guidance, the OIG notes that the compliance program elements and potential risk areas identified in the Final Guidance “may have application to manufacturers of other products that may be reimbursed by federal health care programs, such as medical devices and infant nutritional products.”

In developing the Final Guidance, the OIG considered comments and recommendations it received in response to its initial solicitation of comments, published

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<sup>1</sup> The OIG has posted the final Compliance Program Guidance for Pharmaceutical Manufacturers on the internet at <http://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf>; see also 68 Fed. Reg. 23,731 (May 5, 2003).

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in the Federal Register on June 11, 2001,<sup>2</sup> and to its Draft Guidance.<sup>3</sup> The OIG also met with four groups of industry stakeholders – representatives of the Pharmaceutical Research and Manufacturers of America (“PhRMA”) and other pharmaceutical manufacturer representatives; representatives of health plan and health plan associations; representatives of PBMs; and representatives of the American Medical Association (“AMA”) and its member organizations.

This memorandum focuses on selected features of the Final Guidance that we believe will be of greatest interest to our clients. Please feel free to contact us if you would like additional information about any aspect of the document.

## **II. DESCRIPTION OF COMPLIANCE PROGRAM ELEMENTS**

As in the Draft Guidance and other guidance documents,<sup>4</sup> the OIG identifies seven compliance program elements: (1) distribution of written standards of conduct addressing areas of compliance risk; (2) designation of a compliance officer; (3) implementation of regular training programs; (4) creation of hotline or other reporting system; (5) use of audits or risk evaluation techniques; (6) policies and procedures addressing the non-employment or retention of excluded individuals or entities; and (7) investigation procedures for identified instances of non-compliance.

The Final Guidance makes no significant changes to the discussion of how manufacturers should develop and implement these program elements, which are described in greater detail in our October 2002 memorandum.<sup>5</sup> These elements are also discussed at length in other OIG Guidances. The most significant changes in the Final Guidance occur in its discussion of specific pharmaceutical risk areas, and the OIG’s view of how existing law applies.

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2 66 Fed. Reg. 31,246.

3 67 Fed. Reg. 62,057.

4 The OIG has issued compliance program guidance for a number of segments of the health care industry. These documents are available on the OIG website at <http://oig.hhs.gov/fraud/complianceguidance.html>.

5 October 3, 2002, Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers Memorandum, (“Draft Guidance Memo”) at page 4, available at [www.reedsmith.com](http://www.reedsmith.com).

### **III. THE OIG'S DISCUSSION OF SPECIFIC PHARMACEUTICAL RISK AREAS CONTAINS ADDITIONAL PROVISIONS, CLARIFICATIONS**

As in the Draft Guidance, the OIG identifies the following three risk areas to be of significant concern for pharmaceutical manufacturers:

- ? The integrity of data used by state and federal governments to establish payments under federal health care programs;
- ? Kickbacks and other illegal remuneration; and
- ? Compliance with laws regulating drug samples.

The OIG cautions that the Final Guidance does not create any new law or legal obligations. Rather, according to the OIG, manufacturers should use the guidance as a starting point to review their own practices, and for development of policies and procedures to reduce or eliminate potential risk. Nevertheless, the Final Guidance, in certain areas, advances positions taken in litigation by various private and governmental parties that have been challenged by many segments of the industry.

#### **A. Integrity of Data Used to Establish Government Reimbursement**

The Final Guidance focuses on federal and state health care programs that “establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using pricing and sales data directly or indirectly furnished by pharmaceutical manufacturers.”

As noted in our earlier client memorandum on the Draft Guidance, the government has for the last several years investigated manufacturer practices relating to the average wholesale prices (“AWPs”).<sup>6</sup> As in the draft, the OIG notes in the Final Guidance that a pharmaceutical manufacturer may be liable under the federal False Claims Act (“FCA”) if government reimbursement for the manufacturer’s product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly failed to generate or report such information completely and accurately. Such manufacturers also may be liable for civil money penalties under various authorities. The OIG adds that in some circumstances, inaccurate or incomplete reporting also may be probative of liability under the anti-kickback statute. Notwithstanding numerous public comments criticizing these AWP liability theories, the OIG provides no guidance concerning the

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<sup>6</sup> The Medicare program, and many state Medicaid programs, currently base reimbursement to providers on a percentage of a product’s AWP.

definition of an “accurate” AWP, which has long been generally recognized within the industry as a non-binding “sticker price” that is not intended to reflect actual sales prices by manufacturers.

The Final Guidance states that manufacturers’ reported prices should, as appropriate, accurately account for price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments (referred to elsewhere in the Guidance as “prebates”), coupons, goods in kind, free or reduced price services, grants, or other price concessions or similar benefits offered to some or all purchasers. If a discount, price concession, or similar benefit is offered on purchases of multiple products, that benefit should be apportioned fairly among the products. Moreover, underlying assumptions for reported prices should be reasoned, consistent, and appropriately documented. Pharmaceutical manufacturers are urged to retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements.

Finally, the OIG highlights the importance of Medicaid rebate program price reporting requirements. The Guidance encourages manufacturers to pay particular attention to ensuring that they accurately calculate Average Manufacturer Price (“AMP”) and Best Price (as defined in the Medicaid statute) and that they pay appropriate rebate amounts for their drugs.

B. Kickbacks and Other Illegal Remuneration

The anti-kickback statute prohibits anyone from knowingly or willfully offering, paying, soliciting, or receiving remuneration in order to induce or reward business reimbursable under federal or state health care programs. The OIG also emphasizes that the anti-kickback statute extends equally to the solicitation or acceptance of remuneration for referrals, and it notes that the statute prohibits some practices in the health care industry that are common in other business sectors. The OIG Final Guidance recommends that pharmaceutical manufacturers structure arrangements whenever possible within the terms of a safe harbor, and it reminds manufacturers and their agents that safe harbor protection under the statute requires “strict compliance with all applicable conditions” of the safe harbor in question. Interested parties also can seek an OIG opinion for guidance on the potential applicability of the anti-kickback statute to a particular business arrangement.

The Final Guidance recommends that manufacturers identify any remunerative relationship between themselves (or their representatives) and persons or entities positioned to generate directly or indirectly federal health care business for the manufacturer. According to the OIG, these types of persons or entities include purchasers, benefits managers, formulary committee members, group purchasing organizations (“GPOs”), physicians and certain allied health care professionals, and pharmacists.

The OIG reiterates the “one purpose test” in determining whether remuneration is intended to induce or reward a referral or recommendation of business payable by a federal health care program, noting that “a lawful purpose will not legitimize a payment that also has an unlawful purpose.” The Final Guidance goes on to list “aggravating considerations” identified by courts, which can be used to judge problematic arrangements or practices, and which, according to the OIG, present the “greatest risk of prosecution.” These include:

- ? Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making? Does it have a potential to undermine the clinical integrity of a formulary process? If the arrangement or practice involves providing information to decision-makers, prescribers, or patients, is the information complete, accurate, and not misleading?
- ? Does the arrangement or practice have the potential to increase costs to the federal health care programs, beneficiaries, or enrollees? Does the arrangement or practice have the potential to be a disguised discount to circumvent the Medicaid Rebate Program Best Price calculation?
- ? Does the arrangement or practice have the potential to increase the risk of overutilization or inappropriate utilization?
- ? Does the arrangement or practice raise patient safety or quality of care concerns?

The OIG identifies potential risks arising from pharmaceutical manufacturers’ relationships with three groups: purchasers; physicians and other health care professionals; and sales agents. The OIG notes that this discussion is not exhaustive of potential risk areas.

1. Relationships with Purchasers

a. Discounts and Remuneration to Purchasers

Generally, pharmaceutical manufacturers offer purchasers price concessions and similar benefits to induce the purchase of their products. Purchasers include direct purchasers (e.g., hospitals, nursing homes, pharmacies, and some physicians), as well as indirect purchasers (e.g., health plans). Inducements offered to purchasers potentially implicate the anti-kickback statute if the products are reimbursable to the customers, in whole or in part, directly or indirectly, by a federal health care program. The OIG recommends review of any remuneration (including grants) from a manufacturer provided to a purchaser that is related to a sale that may implicate the anti-kickback statute.

According to the OIG, discounting arrangements in the pharmaceutical industry require “special scrutiny” because of their potential to implicate the Best Price requirements of the Medicaid Rebate Program. The Medicaid Rebate Program requires that states receive rebates based on the Best Price offered by a pharmaceutical manufacturer to other purchasers. The OIG believes that manufacturers

have strong financial incentives to conceal *de facto* pricing concessions to other purchasers to avoid passing on the same discount to states. Recently, the government entered into a \$49 million settlement with a manufacturer based on allegations that the manufacturer offered educational grants in lieu of traditional price concessions to an HMO in order to avoid establishing a new Best Price. Although we do not believe that all non-price relationships or terms of sale need to be viewed as discounts, this settlement highlights the increased focus on these issues.

*Discounts.* The anti-kickback statute contains an exception for discounts offered to customers that submit claims to federal health care programs if the discounts are properly disclosed to the customer and appropriately reported to the government where required. Under this exception, the discount must be in the form of a reduction in the *price* of the good or service based on an arms-length transaction. Moreover, the discount must be given at the time of sale or, in certain cases, set at the time of sale, even if finally determined subsequent to the time of sale (*i.e.*, a rebate).

The Final Guidance asserts that manufacturers offering discounts should thoroughly familiarize themselves with the discount safe harbor provisions.<sup>7</sup> Additionally, the Final Guidance emphasizes that manufacturers should pay attention to safe harbor requirements applicable to “sellers” and “offerors” of discounts, particularly those requiring sellers/offers to (i) inform customers of any discount and of the customer’s reporting obligations with respect to that discount, and (ii) refrain from any action that would impede a customer’s ability to comply with the safe harbor. To fulfill the safe harbor requirements, the Final Guidance points out that manufacturers need to know how their customers submit claims to federal health care programs (*i.e.*, whether the customer is a managed care, cost-based, or charge-based biller), because the applicable standards vary based on the type of customer.

*Product Support Services.* The Final Guidance also raises the issue of product support services in connection with the sale of a manufacturer’s products.<sup>8</sup> If a manufacturer provides a service with no independent value (such as limited reimbursement support services in connection with its own products) together with another service providing a benefit to a referring provider (such as a reimbursement guarantee that eliminates normal financial risks), the arrangement could raise kickback concerns.

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<sup>7</sup> 42 C.F.R. § 1001.952(h). The safe harbors for price reductions in the managed care context, 42 C.F.R. §§ 1001.952(m), (t), and (u) also may offer protection for some arrangements.

<sup>8</sup> Examples given by the OIG include “billing assistance tailored to the purchased products, reimbursement consultation, and other programs specifically tied to support of the purchased product.” We note that these types of services are referenced as appropriate in the Code of Ethics on Interactions with Health Care Professionals, recently adopted by the Advanced Medical Technology Association (“AdvaMed”) for its device company members.

Educational Grants. The Final Guidance addresses grant funding for a wide range of educational activities. The OIG states that, while providing an educational benefit to the entire industry, manufacturers' grants to purchasers, GPOs, PBMs, and similar entities raise concerns under the anti-kickback statute. Even if the educational or research purpose is legitimate, funding that is conditioned, in whole or in part, on the purchase of product implicates the statute. Furthermore, there is a risk that the educational program may be used for inappropriate marketing purposes to the extent the manufacturer has any influence over the substance of an educational program or the presenter.

The OIG urges in the Final Guidance that manufacturers separate their grant making functions from their sales and marketing functions, in order to reduce the risks that a grant program would be used improperly to induce or reward product purchases. According to the OIG, effective separation of these functions will help insure that grant funding is not inappropriately influenced by sales or marketing motivations and that the educational purposes of the grant are legitimate.<sup>9</sup> The OIG also encourages manufacturers to establish objective criteria for making grants that do not take into account the volume or value of purchases made by, or anticipated from, the grant recipient and that serve to ensure that the funded activities are *bona fide*. Additionally, the manufacturer should have no control over the speaker or content of the educational presentation. Compliance with such procedures should be documented and regularly monitored.

Research Funding. The Final Guidance also is far more specific than the Draft Guidance in discussing manufacturer payments to purchasers of their products to conduct research activities on a fee-for-service basis. The OIG recommends that such contracts be structured "whenever possible" to fit within the personal services safe harbor, with payments for research services reflecting fair market value for legitimate, reasonable, and necessary services. The OIG cautions that post-marketing research activities should be reviewed carefully to ensure that they are legitimate and "not simply a pretext to generate prescriptions of a drug." Further, manufacturers are directed to develop contracting procedures that clearly separate the awarding of research contracts from marketing. Research contracts that originate through the sales or marketing functions – or that are offered to purchasers in connection with sales contacts – are particularly suspect, according to the OIG.<sup>10</sup>

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<sup>9</sup> As a practical matter, sales and marketing personnel are likely to have some involvement in the grant process because they are the primary points of contact between the company and third parties. Thus, while the OIG's general suggestion is appropriate, the most important aspect is that sales considerations not affect the decision process on grant applications.

<sup>10</sup> Again, while the OIG's general point that research grants should not be awarded based on sales and marketing considerations is well-taken, the suggestion of absolute exclusion of marketing and sales personnel reflects some misunderstanding of the marketing function by the OIG.

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The OIG notes that pharmaceutical manufacturers sometimes provide funding to their purchasers for use in the purchasers' own research. Although such research has a public health benefit, research grants can be misused to induce the purchase of business without triggering Medicaid Best Price obligations, if linked directly or indirectly to the purchase of product. To reduce risk, manufacturers should insulate research grant making from sales and marketing influences.

Other remuneration to purchasers. The Final Guidance states that any remuneration from a manufacturer provided to a purchaser that is related to a sale potentially implicates the anti-kickback statute and should be carefully reviewed. Examples of potentially problematic remuneration in connection with a sale, include, but are not limited to, "prebates" and "upfront payments," other free or reduced-price goods or services, and payments to cover the costs of "converting" from a competitor's product. According to the OIG, selective offers of remuneration (i.e., offers made to some but not all purchasers) may increase the potential risk if the selection criteria relate directly or indirectly to the volume or value of business generated. In cases where manufacturers contract with purchasers to provide services to the manufacturer, such as data collection services, these contracts should be structured to fit in the personal services safe harbor. In all cases, the remuneration should be fair market value for legitimate, reasonable, and necessary services.

b. Formularies and Formulary Support Services

The OIG has added to the Final Guidance a detailed discussion of the role of formularies in the drug delivery process. While the Guidance technically is not directed at the managed care industry and the roles played there by health plans and PBMs, the principles articulated in this section likely will have a direct impact on how these entities interact with pharmaceutical manufacturers.

According to the Final Guidance, formularies are a well-established tool for the effective management of drug benefits. The OIG states that, so long as the determination of clinical efficacy and appropriateness is the first and paramount consideration – over the consideration of costs – then formulary development is unlikely to raise significant issues under the anti-kickback statute. In

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Marketing departments generally are charged with developing product messages that will resonate with customers. Often, the most effective way to identify and develop those messages is through post-marketing research. Moreover, as noted above, sales personnel often have a role in providing information on new studies because they are the company's primary point of contact with clinicians.

addition, the OIG acknowledges the need for formulary support activities, including communications with patients and physicians to encourage compliance. It states that PBMs have multiple functions in this regard: purchasing agent/price negotiator, and formulary and benefit manager.

The OIG notes that, to date, Medicare and Medicaid involvement with outpatient drug formularies has been limited primarily to Medicaid and Medicare managed care plans, and they have received relatively little scrutiny under the anti-kickback statute. The OIG asserts, however, that as federal program expenditures for, and coverage of, outpatient pharmaceuticals has increased, scrutiny under the anti-kickback statute also has increased. The OIG lists several practices that it believes have “the potential for abuse.”

- ? *Relationships with formulary committee members.* The OIG stresses the need for independence in formulary committee decision-making. Any remuneration from a manufacturer or its agents directly or indirectly to person in a position to influence formulary decisions related to the manufacturer’s products will be “suspect.”<sup>11</sup>
- ? *Payments to PBMs.* The OIG states that rebate or other payments by drug manufacturers directly to PBMs that are based on, or otherwise related to, the PBM’s customers’ purchases potentially implicate the anti-kickback statute.<sup>12</sup> The OIG for the first time suggests that such payments may be protected if structured to fit the GPO safe harbor,<sup>13</sup> which requires that the payments be authorized in advance by the PBM’s customer and, according to the Guidance, that all amounts actually paid to the PBM on account of the customer’s purchases be disclosed in writing at least annually to the customer.<sup>14</sup>
- ? *Formulary placement and support payments.* The OIG specifically states that lump sum payments for inclusion in a formulary or for exclusive or restricted formulary status are problematic. It further questions manufacturer payments to PBMs for formulary support activities that are linked directly or indirectly to drug purchases. The OIG recommends that manufacturers, in assessing the appropriateness of payments for formulary support activities, determine whether they receive a benefit from the payments, or whether the formulary sponsor is benefiting. In this regard, the OIG recommends that manufacturers consider a series of questions in evaluating payments to PBMs: Is the funding tied to specific drugs or categories? If so, are the categories especially competitive? Is the

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11 Such arrangements also might implicate state commercial bribery laws.

12 While the Draft Guidance specifically listed “market share rebates” as a potentially suspect practice, the Final Guidance appears to have backed off that comment.

13 42 C.F.R. § 1001.952(j).

14 With respect to rebates, however, this approach may fundamentally differ from manufacturers’ traditional view of rebates as pricing concessions for the benefit of plans. Rebates passed through by a PBM to a health plan might be viewed as discounts to the health plan, and therefore potentially protected under either the discount safe harbors or the managed care safe harbors.

formulary sponsor funding similar activities for other drug categories? Has funding of PBM activities increased as rebates are increasingly passed back to PBM customers?”<sup>15</sup>

c. Average Wholesale Price

The Final Guidance retains the Draft Guidance recommendations concerning manufacturers’ AWP reporting practices and methodology, including their marketing practices regarding the promotion of customer spreads. As in the previous Draft Guidance, the OIG offers no standards to guide manufacturers with respect to the “accuracy” of AWP. The OIG asserts (with somewhat more emphasis than in the draft), that “the conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute.” Such active marketing of the spread would include, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product.<sup>16</sup>

2. Relationships with Physicians and Other Persons and Entities in a Position to Make or Influence Referrals

The Final Guidance notes that pharmaceutical manufacturers have a variety of remunerative relationships with persons or entities in a position to refer, order, or prescribe – or influence the referral, ordering, or prescribing of – the manufacturers’ products, even though the persons or entities may not themselves purchase (or in the case of GPOs or PBMs, arrange for the purchase of) those products. These remunerative relationships potentially implicate the anti-kickback statute. The OIG maintains that these relationships include not only physicians, but also as other parties in a position to influence referrals, such as pharmacists and other health care professionals; while its ensuing discussion references physicians, it asserts that the same principles apply to other health care professionals.

Any time a manufacturer provides something of value to a physician (or other health care professional), it should, according to the OIG, consider whether it is providing a valuable tangible benefit with the intent to induce or reward referrals. The OIG questions a manufacturer’s providing

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<sup>15</sup> The Final Guidance does not, however, appear to preclude arrangements between PBMs and other formulary sponsors to provide services to the manufacturer, and the GPO disclosure model suggested by the OIG may offer some protection in this regard.

<sup>16</sup> On May 13, 2003, the United States District Court for the District of Massachusetts dismissed private RICO claims challenging AWP practices and allowed claims based on certain state consumer protection laws to proceed. See *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, (May 13, 2003).

goods or services that eliminate an expense the physician would have otherwise incurred (i.e., that have independent value to the physician), or providing items or services at less than their fair market value. Moreover, the OIG makes the broad assertion that a legitimate purpose for an arrangement (e.g., physician education), or a fair market value payment, will not necessarily protect remuneration under the anti-kickback statute if there is also an illegal purpose (i.e., the purposeful inducement of business).

The Final Guidance recommends that manufacturers structure relationships with physicians to fit in an available safe harbor, such as those for employees or for personal services and management contracts.<sup>17</sup> Arrangements that do not fit squarely in a safe harbor should be reviewed in light of the totality of all facts and circumstances. According to the OIG, appropriate considerations include: the nature of the relationship between the parties; the manner in which the remuneration is determined; the value of the remuneration; the potential federal program impact of the remuneration; and potential conflicts of interest.<sup>18</sup>

Significantly, the Final Guidance again references the PhRMA Code on Interactions with Health care Professionals (“PhRMA Code”), as providing useful and practical advice for reviewing and structuring these relationships.<sup>19</sup> The OIG’s recommendations relating to the PhRMA Code are tempered somewhat from the Draft Guidance, however. In the Draft, the OIG characterized the PhRMA Code as a “good starting point” or “floor,” and asserted that arrangements not meeting the PhRMA Code “are likely to receive additional scrutiny from government authorities.” In the Final Guidance, the OIG states:

Although compliance with the PhRMA Code will not protect a manufacturer as a matter of law under the anti-kickback statute, it will substantially reduce the risk of fraud and abuse and help

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<sup>17</sup> 42 C.F.R. §§ 1001.952(d), (j).

<sup>18</sup> Within the Guidance, each of these considerations is accompanied by a series of questions to be used in reviewing arrangements between manufacturers and physicians or other health care professionals. The last of the listed considerations, involving potential conflicts of interest, did not appear in the Draft Guidance. The Final Guidance incorporates such criteria as whether a proposed business arrangement would have an impact on patient safety or quality of care, whether it would diminish the “objectivity of professional judgment,” and comparable -- and often ambiguous -- considerations.

<sup>19</sup> Adopted on April 18, 2002, the PhRMA Code had an effective date of July 1, 2002. It is available on PhRMA’s web site at <http://www.phrma.org>.

demonstrate a good faith effort to comply with the applicable federal health care program requirements.<sup>20</sup>

In other words, compliance with the PhRMA Code is viewed as a favorable evidentiary or risk management factor, as opposed to a minimum standard.

The Final Guidance lists several common or problematic relationships between manufacturers and physicians, including “switching” arrangements, consulting and advisory payments, payments for detailing, business courtesies and other gratuities, and educational and research activities. These sections contain important clarifications and additions to the Draft Guidance.

*“Switching” arrangements.* The Draft Guidance defined “switches” very broadly, to include both market share rebates and the types of switches identified in the OIG’s 1994 Special Fraud Alert on Prescription Drug Marketing Schemes.<sup>21</sup> In the Final Guidance, the OIG omits the characterization of market share rebates as improper switching arrangements, limiting its discussion to questionable switching arrangements (sometimes called “product conversion arrangements”) involving pharmaceutical manufacturers offering pharmacies, physicians, or other prescribers cash payments or other benefits *each time* a patient’s prescription is changed to the manufacturer’s product from a competing product. The OIG acknowledges that “such programs may be permissible in certain managed care arrangements,” presumably in the context of market share rebates or therapeutic intervention, but cautions that manufacturers should carefully review such arrangements.

*Consulting and advisory payments.* The OIG continues to urge caution for pharmaceutical manufacturers engaging physicians as consultants. The Final Guidance states that fair market value payments to small numbers of physicians for *bona fide* consulting or advisory services are generally unlikely to raise any significant concern. However, compensation arrangements in which the physician “consultants” are expected to attend meetings or conferences “primarily in a passive capacity” are suspect. Significantly, the Final Guidance also includes a new discussion in which the OIG questions sales and marketing “services” performed by physicians for manufacturers, including speaking, certain research (presumably, that described below under “*Payments for detailing*”), and preceptor or “shadowing agreements.” The OIG further questions the use of health care professionals for marketing,

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<sup>20</sup> This new language notwithstanding, we note that, later in the Guidance, during its discussion of sales agent relationships, the OIG urges that manufacturers familiarize their sales forces with the “minimum PhRMA Code standards and other relevant industry standards.”

<sup>21</sup> See 59 Fed. Reg. 65,372 (Dec. 19, 1994).

through ghost-written papers or speeches. According to the OIG, full disclosure by physicians of any potential conflicts of interest and of industry sponsorship or affiliation may reduce, but will not eliminate, the risk of fraud and abuse.

The OIG recommends that manufacturers review arrangements for physicians' services to ensure that, at a minimum: (i) the arrangement is set out in writing; (ii) there is a legitimate need for the services; (iii) the services are provided; (iv) the compensation is at fair market value; and (v) all of the preceding facts are documented *prior to* payment.<sup>22</sup>

*Payments for detailing.* The Final Guidance contains a new section addressing recent practices by some manufacturers to pay physicians for the time the physicians spend listening to sales representatives market pharmaceutical products, including both live presentations and e-detailing arrangements. The OIG identifies such practices as "highly suspect" and "highly susceptible to fraud and abuse," along with compensating physicians to complete minimal paperwork, to access web sites, to view or listen to marketing information, or to perform "research." The OIG asserts that such activities should be strongly discouraged.

*Business Courtesies and Other Gratuities.* The Final Guidance reiterates the OIG's general concerns regarding other forms of remuneration, including gifts and entertainment, which potentially implicate the anti-kickback statute if "any one purpose" of the arrangement is to generate business for the pharmaceutical company. Stating that each case will depend upon individual facts and circumstances, the OIG recommends that manufacturers comply with the PhRMA Code with respect to these arrangements to substantially reduce a manufacturer's risk of violation of the anti-kickback statute.<sup>23</sup>

*Educational and Research Funding.* In a departure from the Draft Guidance, the Final Guidance specifically discusses manufacturer contracts with physicians to provide research services on a fee-for-service basis, and urges the same type of review of such arrangements as for educational and research grants to purchasers, discussed previously. The Final Guidance lists "indicia of questionable research" that include:

- ? Research initiated or directed by marketers or sales agents;

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<sup>22</sup> These criteria generally mirror the criteria for consultants enunciated both in the PhRMA Code and the AdvaMed Code.

<sup>23</sup> The Final Guidance offers no comment on the differences between the PhRMA code and the AdvaMed code.

- ? Research that is not transmitted to, or reviewed by, a manufacturer’s science component;
- ? Research that is unnecessarily duplicative or is not needed by the manufacturer for any purpose other than the generation of business; and
- ? Post-marketing research used as a pretense to promote product.

The OIG recommends that manufacturers develop contracting procedures that clearly separate the awarding of research contracts from marketing or promotion of their products.<sup>24</sup> It acknowledges that, generally, grants or support for educational activities sponsored and organized by medical professional organizations raise little risk of fraud or abuse, provided that the grant or support is not restricted or conditioned with respect to content or faculty. The OIG recommends that the manufacturer determine whether the funding is for *bona fide* educational or research purposes.

The Final Guidance also notes that manufactures that act as sponsors of continuing medical education (“CME”) programs should take steps to ensure that neither they, nor their representatives, are using CME to generate business for the manufacturer or to influence or control the content of the program.<sup>25</sup> Unlike the Draft Guidance, the Final Guidance reminds manufacturers and sponsors of educational programs to pay attention to the relevant rules and regulations of the Food and Drug Administration. The OIG also recommends that the CME industry’s codes of conduct may provide a useful starting point for manufacturers when reviewing their CME agreements.

### 3. Relationships with Sales Agents

As in the draft, the Final Guidance notes that the OIG will measure a pharmaceutical manufacturer’s commitment to an effective fraud and abuse compliance program by its training and monitoring of its sales force. New in the Final Guidance, however, is the OIG’s somewhat attenuated characterization of sales agents’ compensation arrangements as an indication of a manufacturer’s intent. According to the OIG, a compensation arrangement with a sales agent that fits in a safe harbor can still be evidence of a manufacturer’s improper intent when evaluating the legality of the manufacturer’s relationships with persons in a position to influence business for the manufacturer. Thus, the OIG concludes, the payment of “extraordinary incentive bonuses and expense accounts” for sales agents

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<sup>24</sup> See footnote 10, *supra*.

<sup>25</sup> The Final Guidance states that CME programs with no industry sponsorship, financing, or affiliation should not raise anti-kickback concerns, although tuition payments by manufacturers (or their representatives) for persons in a position to influence referrals (e.g., physicians or medical students) may raise concerns.

could lead to an inference that the manufacturer “intentionally motivated the sales force to induce sales through lavish entertainment or other remuneration.”

The OIG states that the following should be evaluated for sales agent relationships:

- ? The amount of compensation;
- ? The identity of the sales agent engaged in the marketing or promotional activity (e.g., is the agent a “white coat” marketer or otherwise in a position of exceptional influence);
- ? The sales agent’s relationship with his or her audience;
- ? The nature of the marketing or promotional activity;
- ? The item or service being promoted or marketed; and
- ? The composition of the target audience.

#### 4. Drug Samples

The OIG’s discussion of drug samples is similar to that stated in the Draft Guidance. Generally, providing drug samples can pose a potential risk area for pharmaceutical manufacturers. Manufacturers must comply with the Prescription Drug Marketing Act of 1987 (“PDMA”), which governs the distribution of drug samples and forbids their sale.<sup>26</sup>

## IV. CONCLUSION

The Final Guidance points out that an effective compliance program is especially important for pharmaceutical manufacturers in “today’s environment of increased scrutiny of corporate conduct and increasingly large expenditures for prescription drugs.” To that end, as stated in our memorandum on the Draft Guidance, the OIG has provided a useful roadmap both for pharmaceutical manufacturers seeking to establish a compliance program and for manufacturers desiring to ensure that existing compliance programs meet OIG expectations.

At the same time, although the Final Guidance retains many of its prior recommendations, it characterizes as problematic a variety of new – and often commonplace – industry activities not addressed in the Draft and hence not addressed in public comments. For example, the OIG highlights

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<sup>26</sup> For further discussion of drug samples please refer to our Draft Guidance Memo at page 1.

preceptorship arrangements for the first time in the Final Guidance. While it states that such arrangements are “potentially beneficial,” it generally characterizes them as suspect, but provides no explanation.

As mentioned, the OIG states in an end note that the compliance program elements and risk areas identified in the Final Guidance may also apply to manufacturers of medical devices and infant nutritional products. Unquestionably, the broad precepts of the federal anti-kickback statute can be said to apply equally to all manufacturers. At the same time, there are important differences between the drug and device industries, such as the ongoing need for many device manufacturers to provide ongoing, hands-on training in device safety. Hence, manufacturers should pay attention both to the PhRMA Code and the AdvaMed Code, as appropriate. The OIG continues to stress that each compliance program must be tailored to fit the needs and resources of the particular manufacturer, depending upon its corporate structure, size, and compliance history. While certain elements of the Final Guidance may be difficult for every pharmaceutical or device manufacturer to adopt, all can benefit from the potential to reduce exposure to civil and criminal sanctions associated with kickbacks and false claims through the adoption of an effective compliance program.

As we have noted in the past, manufacturers today confront a wide variety of significant issues -- including ones with the potential for civil and criminal liability -- for which little guidance exists. For example, HHS has never issued regulations governing the Medicaid rebate statute, and while the OIG stresses in the Final Guidance the need to adhere to rebate requirements, many ambiguities in interpretation and application of the statute remain. In the face of this gap, we note with some irony that the OIG’s Fiscal Year 2003 Work Plan identifies the adequacy of drug manufacturers’ methodologies for computing AMP and best price under the Medicaid rebate program as an area for scrutiny in the coming year.<sup>27</sup> Similarly, neither the OIG nor any other governmental entity has ever suggested a precise definition for “accurate” AWP, notwithstanding that such a definition is at the heart of massive and growing litigation across the country.

On another topic, many consulting agreements into which pharmaceutical manufacturers enter do not lend themselves to the precise structure of the personal services safe harbor. Nevertheless, the Final Guidance offers few details in this regard -- while it appears to endorse the PhRMA Code for

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<sup>27</sup> The OIG Work Plan is available on the internet at: <http://oig.hhs.gov/publications/workplan.html#1>.

entertainment, gifts, gratuities, and the like, it is unclear whether that endorsement extends to consulting agreements.

In sum, through issuance of the Final Guidance, the OIG continues to demonstrate an increased understanding of many of the business and other arrangements occurring in the drug delivery system today. Many questions remain unanswered, however, and manufacturers and entities that do business with them must be vigilant in complying with standards that in many cases are unclear.

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