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- *AudioConference on HHS OIG Guidance for*
- *Pharmaceutical Manufacturers*
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In-Depth Analysis: Key Risk Areas



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Summary of Presentation

- Initial Thoughts
- Scope of the Guidance
- Risk Areas: Centerpiece of a Compliance Program
- Areas in the Pharmaceutical Guidance
 - Data Integrity
 - Kickbacks and Other Inducements
 - Drug Samples
- Thoughts and Implications

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Initial Thoughts on Risk Areas

- More detailed discussion of risk areas, concise summary of factors to be considered in analyzing sales/marketing practices
- Retains focus on sales/marketing practices -- doesn't stray into FDA-regulated issues
- Final guidance is more favorable to industry in a number of important respects
- Discussion of PhRMA Code drops “minimum” language, focused on benefits of compliance
- Dropped language on “indirect” switching

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Initial Thoughts (cont'd)

- Reasonable language on PBM relationships, including GPO safe harbor
- Virtually no change in discussion of integrity of reported data
- Recommendation to divorce education and research funding activities from sales and marketing operation
- Heavy emphasis on Best Price concerns, but little additional guidance on how to comply

Scope

- While primary focus is on pharmaceutical manufacturers, other sectors are implicated (since liability attaches to both parties to an illegal kickback):
 - Pharmacy benefit managers
 - Physicians
 - Hospitals and other “customers” of pharma manufacturers
- While focused primarily on sales and marketing, the HHS OIG does outline concerns regarding educational (e.g., CME) and research funding
- Medical devices -- Footnote 5 is clear signal that OIG views “risk area” discussion as largely applicable to medical device, infant formula product companies

Risk Areas: Centerpiece of a Compliance Program

- Under the HHS OIG guidances, the identification of risk areas is a critical component of a compliance program.
- The HHS OIG recommend that companies should develop specific policies, procedures, and internal controls to ensure compliance in identified risk areas.
- Much of the compliance program should flow from such policies:
 - Training on policies/procedures, with advanced training for personnel in specialized fields
 - Internal process for employees to ask questions on, and report potential violations of, policies
 - Monitoring and auditing of compliance with policies
 - Consistent enforcement of sanctions for violations
 - Procedures for responding to detected violations

Risk Areas

- **Integrity of data used for gov't reimbursement**
 - The guidance asserts that a manufacturer may be liable under the False Claims Act if: (1) government reimbursement (including Medicare or Medicaid reimbursement) for a product depends partly on pricing information it reported “directly or indirectly”; and (2) the manufacturer knowingly (including recklessly) failed to report such information “completely and accurately.”
 - “Where appropriate,” manufacturers’ reported prices should take into account discounts, rebates, “free goods contingent on a purchase agreement . . . up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits” offered to purchasers.

Risk Areas (cont'd)

- **Integrity of data (cont'd)**
 - The guidance makes clear that accurate net prices must be calculated in bundled sales, stating that “any discount...offered on purchases of multiple products should be fairly apportioned among the products.”
 - The guidance urges manufacturers to “pay particular attention to . . . calculating Average Manufacturer Price and Best Price accurately,” but does not provide instructions on Medicaid rebate calculations specifically.

Risk Areas (cont'd)

- Kickbacks, Other Illegal Remuneration (partial list)
 - Discounts
 - Educational and research activities
 - PBM arrangements
 - AWP
 - Consulting and other fee-for-service arrangements
 - Sales Agents
 - Miscellaneous
- Offers guidance on activities “at greatest risk of prosecution”
 - Does arrangement skew clinical decision-making?
 - If info is provided, is it complete, accurate, non-misleading?
 - Have potential to increase costs to Fed HCPs?
 - Have potential to be “disguised discount” -- circumventing BP?
 - Result in inappropriate over- or under-utilization?
 - Raise patient safety, quality of care concerns?

Risk Areas (cont'd)

- Kickbacks -- Discounts
 - In pharma context, discounts “deserve careful scrutiny” because of potential to implicate Best Price requirements
 - Discounts should be structure to fit within discount safe harbor when possible. Generally only protects discounts at time of sale or fixed at time of sale (rebates). Does not protect “prebates” or other forms of “upfront” payments.
 - Final guidance drops language suggesting bundled discounts never qualify for safe harbor protection, but doesn’t explain how
 - Any remuneration to a purchaser that is “expressly or impliedly related to a sale” should be carefully reviewed. Examples: prebates, upfront payments, free or reduced-price services, payments to cover purchaser’s cost of converting from competitor’s product.
 - Remuneration offered only to selected set of purchasers increases risk if selection relate directly/indirectly to volume of business

Risk Areas (cont'd)

- Kickbacks -- Educational and Research Funding
 - To reduce their risks, manufacturers should divorce educational and research grants and contracts from their sales and marketing functions.
 - Educational and research funding should not be linked in any way to the funding recipient's purchases or capacity to generate business for the manufacturer.
 - Manufacturers should have no control over the content of funded educational activities.
 - It is not altogether clear why this is an anti-kickback issue, but in any event the OIG has embraced FDA's CME guidance and "codes of conduct promulgated by the CME industry."
 - Makes the proposed changes to the ACCME standards more critical, since the ACCME standards are apparently viewed by the OIG as pertinent to anti-kickback compliance.
 - Post-marketing research and research not reviewed by a manufacturer's science component deserve heightened scrutiny. 11

Risk Areas (cont'd)

- Kickbacks -- Relationships with PBMs
 - In several cases, the OIG's pronouncements on formularies and PBM payment arrangements involve practices under the control of the PBM - - not the manufacturer.
 - Formularies are unlikely to raise significant anti-kickback issues as long as “the determination of clinical efficacy and appropriateness of formulary drugs by the formulary committee precedes, and is paramount to, the consideration of costs.”
 - Manufacturers should “review their contacts with sponsors of formularies to ensure that price negotiations do not influence decisions on clinical safety and efficacy.” Any remuneration from a manufacturer to a person capable of influencing formulary decisions is “suspect” and warrants careful scrutiny.

Risk Areas (cont'd)

- Kickbacks -- Relationships with PBMs (cont'd)
 - Manufacturer rebates to PBMs (and other payments to PBMs based on sales to the PBM's clients) can be protected under the GPO safe harbor, essentially by requiring the PBM to make the same disclosures about vendor payments to its clients that a GPO makes to its members. This is likely to fuel the growing trend toward transparency in the PBM industry.
 - Manufacturers should still avoid (“carefully scrutinize”) “lump sum” payments to PBMs for formulary inclusion or placement. Payments to fund PBM formulary support activities - - “especially communications with physicians and patients” - - also have a semi-suspect status.

Risk Areas (cont'd)

- Kickbacks -- Average Wholesales Price (AWP)
 - AWP discussed in context of kickback statute -- not integrity of data -- but seems an implicit focus of the integrity of data section.
 - The guidance states that “it is illegal for a manufacturer knowingly to establish or maintain a particular AWP if one purpose is to manipulate the ‘spread’ to induce customers to purchase its product,” and manufacturers should thus “review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process.”
 - The guidance states that pharmaceutical manufacturers generally report either AWP “or pricing information used by commercial price reporting services to determine AWP,” but does not specifically mention WAC or specify whether its recommendation regarding AWP reporting applies to WAC.

Risk Areas (cont'd)

- Kickbacks -- Consulting Arrangements
 - At least generally, fair market value payments to “small numbers” of physicians for bona fide consulting and advisory services are unlikely to raise significant concerns.
 - Manufacturers should structure these arrangements to fit within the personal services safe harbor whenever possible
 - Certain types of service arrangements with physicians create heightened concerns, i.e.:
 - Services connected to a manufacturer’s marketing activities, “such as speaking, certain research, or preceptor or ‘shadowing’ services” and “ghost-written articles”; and
 - “Consulting” arrangements where the physician attends meetings or conferences “primarily in a passive capacity.”

Risk Areas (cont'd)

- Kickbacks -- Sales Agents
 - Payments to sales agents should be “carefully reviewed” if they do not fit within a safe harbor (i.e., the employee safe harbor or, for contracted sales agents, the personal services safe harbor).
 - Even if compensation payments to sales agents do fit within a safe harbor, they “can still be evidence of a manufacturer’s improper intent when evaluating the manufacturer’s relationships with [potential referral sources]” - - for example, providing sales agents with “extraordinary incentive bonuses and expense accounts” might support an inference that the manufacturer “intentionally motivated the sales force to induce sales through lavish entertainment or other remuneration.”

Risk Areas (cont'd)

- Kickbacks -- Miscellaneous
 - Paying physicians for their time spent listening to marketing presentations is “highly susceptible to fraud and abuse, and should be discouraged.”
 - The same is true for variations on pay-for-detail arrangements (paying “consulting” fees for a physician to complete “minimal paperwork,” or paying physicians for the time spent “accessing websites to view or listen to marketing information or perform ‘research’”).

Risk Areas (cont'd)

- Drug Samples
 - Basic message in the OIG's discussion of drug samples is that manufacturers should adhere strictly to the Prescription Drug Marketing Act (PDMA), which forbids the sale of samples.
 - The guidance does not address “sample” programs not covered by the PDMA, such as “virtual” sample programs or sample programs involving products other than drugs. However, the guidance recognizes that when physicians cannot sell or bill for samples this “vitiat[es] any monetary value of the sample,” thus suggesting that measures to prevent the sale or billing of samples should reduce the anti-kickback risks associated with any type of sample program.

PhRMA Code

- Drops language regarding “minimum” for compliance (which implied PhRMA Code was a floor)
- Describes the PhRMA Code as “useful and practical advice for reviewing and structuring relationships” with physicians and others in a position to prescribe or influence the purchase of a company’s products.
- While not a legal safe harbor, Guidance states that compliance “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.”
- This is a strong endorsement of the PhRMA Code in OIG speak

Miscellaneous

- **Vendors and other agents:**
 - CO should “ensur[e] that independent contractors and agents ... are aware of company’s compliance program ...”
 - CO should “ensure that the List of Excluded Individuals/Entities has been checked” with respect to all independent contractors, and the company should “carefully consider” whether to do business with excluded individuals/entities.

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Thoughts and Future Implications

- Guidance is an important milestone in evolution of compliance activities for pharmaceutical industry
- With respect to compliance program structural issues, the final guidance closely resembles the draft -- thus, companies already have had months to assess their compliance programs
- In many areas -- including gifts and business courtesies -- the impact will be minimal in light of the more detailed guidance in the PhRMA Code (which most manufacturers have endorsed)

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Thoughts and Future Implications (cont'd)

- In other areas, the guidance makes recommendations that could require changes in industry practice (depending on the company)
 - Separation of educational and research funding decisions from sales/marketing functions
 - Discussion of CME activities and, implicitly, ACCME guidelines
- Discussion of PBM relationships is more nuanced than prior OIG statements -- possibly reflecting Administration's embrace of PBM model for Medicare Rx proposal
- PBMs likely to respond to the OIG's invitation to use the GPO safe harbor, take further steps down the transparency road

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Questions?

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