OPERATIONALIZING THE GUIDANCE

A. **Implementation where resources or culture may present resistance**

B. **Some structural issues**

C. **Specific marketing practices**
   - Consultants
   - Preceptorships
   - Grants
   - PBMs

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IMPLEMENTATION OF CPG

Previous motivators for compliance programs:

- Reports from Jim Sheehan's nationwide appearances
- Dissemination of news articles and copies of U.S.S.G. sentencing grids
- Favorable influence on prosecutorial charging / OIG exclusion decisions
- Reduction of sentence under U.S.S.G. § 8C2.5(f) by 3 levels and § 8C2.5(g) by 5 levels (for self-reporting)
- Hallmark of good corporate citizenship

IMPLEMENTATION OF CPG

CPG provides, in one document:

- Systems and controls designed to "promote adherence to applicable statutes, regulations, and requirements of the federal healthcare programs."
- Description of conduct that is "currently of concern to the enforcement community."
- An alternative to "chicken little" approach

CPG Structural Points - Company Status Assessment

If subpoenaed, could company employee:

1. ID formal compliance program?
2. ID compliance officer / committee?
3. Describe training received (systematic, diversified)?
4. Speak about OIG's risk areas?
5. Access readable written policies manual?
6. Access corporate hotline?
7. Cite endorsement of compliance by senior mgt?
8. Show compliance training as comp evaluation item?

CPG Marketing Practice Risk Area - Consultants

- **Per CPG (p.32)**
  - Arrangement set out in writing
  - Legitimate need for services
  - Services are provided
  - Compensation at FMV
  - All documentation prior to payment
- **Need to fit within personal services safe harbor (42 CFR 1001.952(d))**

CPG Marketing Practice Risk Area - Consultants

"[F]air market value payments to small numbers of physicians for *bona fide* consulting or advisory services are unlikely to raise any significant concern. Compensating physicians as 'consultants' when they are expected to attend meetings or conferences primarily in a *passive capacity* is suspect. Also of concern are . . . speaking, certain research . . . or 'shadowing' services." (CPG, p.32)

CPG Marketing Practice Risk Area - Consultants

Proposed Actions - General:

- No field access to templates
- Request form requires specific, relevant info from field:
  - Can consultant prescribe or influence prescriptions?
  - Why this consultant was selected
  - Specific nature of services (when, where, what) to be provided
  - Why services are needed / how services will be used

CPG Marketing Practice Risk Area - Consultants

Proposed Actions - Advisory Boards:

- Accurate minutes recorded and submitted as part of contract file
- If 3rd party vendor arranged ad board and entered into contracts with physicians, provide suggested template contract as exhibit to contract with vendor

CPG Marketing Practice Risk Area - Consultants

Proposed Actions - Preceptorships:

- Need legitimate educational purpose (new product, indication, administration mode, or rep)
- Preliminary letter to physician describing specific educational objective
- Consultation agreement with physician
  - Sales rep, purpose of preceptorship disclosed to patient in advance
  - Preceptorship disclosed in Notice of Privacy Practices (re. HIPAA Privacy Rule)
- Follow-up memo from rep

CPG Marketing Practice Risk Area - Grants

"While educational funding can provide valuable information to the medical and health care industry, . . . manufacturer grants raise concerns under the anti-kickback statute. . . To reduce the risks that a grant program is used improperly to induce or reward product purchases or to market product inappropriately, *manufacturers should separate their grant making functions from their sales and marketing functions*." **(CPG, p. 20)**

CPG Marketing Practice Risk Area - Grants

"Manufacturers should 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* . . . Compliance with such procedures should be documented and regularly monitored."

(CPG, p. 21)

CPG Marketing Practice Risk Area - Grants

Examples:

- So-called “unrestricted” grants by sales reps
- Grants for specific purpose (e.g., sponsorship of website or construction of new facility)
- Educational / research funding
- Charitable contributions (e.g., to hospital foundation, 501(c)(3) entities)
- Post-marketing investigator-sponsored clinical studies

CPG Marketing Practice Risk Area - Grants

Proposed Actions - General:

- Elimination of sales rep / sales unit discretion over grants
- Corporate structure - grants centrally budgeted and approved by separate unit (independent of sales / mkting)
  - No linkage to grantee's capacity to generate business
  - Database with aggregate funding information (e.g., consultation compensation, grants, etc.) to ensure informed decisions

CPG Marketing Practice Risk Area - Grants

Proposed Actions - Specific Purpose Grants:

- Letter from grantee stating need
- Contract between grantor and grantee specifying
  - Purpose of grant
  - Amount
  - Grantor's right to inspect and audit
  - Repayment by grantee to grantor of any excess of grant over cost of project

CPG Marketing Practice Risk Area - ISS Grants

CPG (p.21) on investigator-sponsored clinical studies:

"Post-marketing research activities should be especially scrutinized to ensure that they are legitimate and not simply a pretext to generate prescriptions of a drug. *Prudent manufacturers will develop contracting procedures that clearly separate the awarding of research contracts from marketing.*"

CPG Marketing Practice Risk Area - ISS Grants

Proposed Actions -
Investigator-sponsored clinical studies:

- ISS Committee assesses scientific merit of research and propriety of funding level
  - Consists of scientists / researchers (no marketing/ sales)
  - Reviews protocol / concepts, how funding to be used
  - Selects investigators based on expertise
  - Maintains minutes of meetings
- Written contract
- Follow-up reports from investigator

Specific CPG Risk Area - PBMs

CPG (p. 25) on PBMs:

"Any rebates by drug manufacturers to PBMs that are based on . . . the PBM's customers' purchases potentially implicate the A-K statute. Protection is available by structuring such arrangements to fit in the GPO safe harbor at 42 CFR 1001.952(j). . . requir[ing] . . . that the *payments be authorized in advance by the PMB's customer* and 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."

Specific CPG Risk Area - PBMs

CPG's additional PBM focus areas:

- Relationships of manufacturers with PBM formulary committee members
- Support activities (e.g., mfgr. funding communications between PBMs and patients)
  - Is such funding tied to specific drugs or categories?
  - Are categories especially competitive?
  - Does mfgr. fund similar activities for other drug categories?
  - Has such funding increased as rebates passed back to PBM customers?

Specific CPG Risk Area - PBMs

Proposed Actions: Inclusion of exemplar language in rebate-driven market share Manufacturer/PBM contracts:

"[E]ach party represents to the other that it is in compliance, and shall continue to comply, with the provisions of 42 U.S.C. 1320a-7(b) which, among other things, prohibit illegal remuneration, and remuneration disclosure provisions of 42 C.F.R. 1001.952(j), the "GPO safe harbor," as such may apply to this Agreement. In furtherance thereof, at least annually, Manufacturer shall provide notification to Customer of the value of any rebates paid hereunder."