



The Seventh Annual _____
Pharmaceutical Regulatory and Compliance Congress
_____ *and Best Practices Forum*

Pharmaceutical Compliance Current Trends:

Hot Button Issues to Look at this Year in
Sales, Marketing, Clinical, Medical Affairs and
Government Pricing

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CONSULTING GROUP

Sales & Marketing: Are We Okay?

Paul J. Silver
Managing Director
Huron Consulting Group

John Alivernini
Vice President & Chief
Compliance Officer
Wyeth Pharmaceuticals

“Hot Button” Issues in Sales & Marketing

- I. Are we paying too much to physicians for fee-for-service agreements?
- II. Do we have the proper controls to monitor off-label promotions?
- III. Are we tracking the proper payments for State Law Reporting?
- IV. Perspectives from the field

I. Payments to Physicians

- ◆ Regulators are increasingly concerned that any type of payment to a healthcare professional (HCP) could influence their judgment.
- ◆ Payments to physicians should be made for “bona fide” services at “fair market value”.
- ◆ FMV means the compensation that would be included in a service agreement as a result of “bona fide” bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party. (42 CFR §411.351)

I. Payments to Physicians

Manufacturers should assess their overall approach to HCP compensation arrangements and ensure consistency across brands, divisions, and functional areas:

- ◆ Generalist vs. specialist
- ◆ KOL vs. Non-KOL
- ◆ Commercial vs. clinical
- ◆ By activity type (speaker programs, advisory boards, consultant meetings, etc.)

I. Payments to Physicians

Developing Monitoring Controls:

- ◆ Maintaining up-to-date speaker databases
- ◆ Developing “totality of spend” reports
- ◆ Performing field audits to ensure compliance with SOPs

II. Off-Label Promotions

Assessing risk in the sales and marketing process:

- ◆ Physician targeting and call plan development
- ◆ KOL thought leadership activities
- ◆ Advisory boards
- ◆ Peer to Peer discussions

II. Off-Label Promotions

Developing Monitoring Controls:

- ◆ Ensuring speakers use only approved materials
- ◆ Establishing clear and concise SOPs for handling unsolicited requests for “off-label” information
- ◆ Performing field audits of promotional activities to ensure compliance

III. State Law Reporting

- ◆ Several states have passed laws regarding pharmaceutical sales and marketing (CA, VT, MN, ME, etc.)
- ◆ Several others have legislation pending in various forms
- ◆ Each state has a unique set of requirements for the type of payments that need to be tracked
- ◆ Variations also exist with regard to the definition of healthcare professional

III. State Law Reporting

- ◆ In general, payments made for “bona fide” services at “fair market value” are exempt from most tracking limits.
- ◆ Some states require reporting of “totality of spend”.

III. State Law Reporting

Challenges to consider:

- ◆ Developing a customer master file to effectively track unique prescribers
- ◆ Developing reporting standards to capture third-party payment data
- ◆ Developing an appropriate set of business rules to determine what is vs. what is not a “trackable” event

III. State Law Reporting

Monitoring Controls--Develop a robust auditing program to test the following areas:

- ◆ Accuracy of customer master file
- ◆ Data capture at all relevant direct and indirect customer “touch points”

IV. Perspectives from the Field

- ◆ Why can't we use grants to build relationships with KOLs?
- ◆ Have we gotten to the point where we can't give money to the people who like and support our product, i.e. our friends?
- ◆ Doctors prefer to hear from speakers with product experience. Can we exclude non-users from our speakers bureau?
- ◆ How can we incentivize reps who sell a product with substantial off-label use?

IV. Perspectives from the Field

- ◆ Why can't sales and marketing people participate in grant decisions? Some of them know more about this product and how it is used by our customers than the people in Medical.
- ◆ CME is the best way to get our message to doctors because it is not limited by the PI.
- ◆ MSAs should be part of the sales team because they can cover off-label topics with customers.

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Questions?