

CHALLENGES OF COMPLYING WITH THE ADVAMED CODE:

**ANALYSIS OF THE *2007 MEDICAL TECHNOLOGY*
*INDUSTRY BENCHMARKING SURVEY***

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2007 MEDICAL TECHNOLOGY INDUSTRY BENCHMARKING SURVEY

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EXECUTIVE SUMMARY

In January 2006, PricewaterhouseCoopers, King & Spalding and Compliance-Alliance surveyed medical device company compliance with the AdvaMed Code of Ethics on Interactions with Health Care Professionals (“AdvaMed Code” or “Code”). The results indicated that medical technology firms overwhelmingly accepted the Code and were taking steps to implement its requirements. However, the extent of the compliance practices varied with the company size, market presence and geography.

In January 2007, the three organizations conducted a follow-up survey to determine the Code’s effect on firms’ internal operations and the challenges that companies experience in administering their compliance programs. The *2007 Medical Technology Industry Benchmarking Survey* (“*Survey*”) was sent to several hundred lawyers, compliance professionals, regulatory affairs personnel and others who are employed by small, medium and large device companies in various sectors of the industry. Seventy-two medical device officials returned completed surveys.

The results of the *Survey* indicate that the Code continues to play an important role in driving sales and marketing compliance efforts within the medical device and diagnostics sectors.¹ Specifically:

- As of February 2007, more than 500 medical device companies and/or subsidiaries have designated a compliance officer to oversee their company’s compliance with fraud and abuse laws and implementation of AdvaMed Code; and
- Several dozen companies have signed onto the AdvaMed Logo program, which requires companies to self-certify that they have taken specific steps to implement the AdvaMed Code.

The results confirm that companies are continuing to implement the AdvaMed Code and enhance their sales and marketing compliance functions through activities such as training, monitoring and auditing. Specifically:

- 72% of respondents said their companies audit for compliance with the AdvaMed Code. Most often (more than 75%), these audits are handled by internal personnel; and
- 47% of respondents said their companies had added headcount to implement the AdvaMed Code, with 25% reporting that their company added two or more FTEs to support the Code’s implementation.

One of the most interesting findings in the *Survey* is that 92% of respondents reported that implementing the AdvaMed Code had no negative impact on (82%) or actually improved (10%) their companies’ financial results.

¹ For brevity, we refer to both device and diagnostics companies as “device companies” throughout this report.

Despite this progress, the *Survey* found that companies face significant challenges in implementing the Code. For example:

- Lack of clarity from regulatory and enforcement agencies as to the legality of sales and marketing practices and other customer relationships that are specific to the medical device industry;
- Continued resistance from certain physicians and institutional customers to compliance with legal requirements and industry codes of conduct;
- Lingering management questions about how tightening sales and marketing policies may impact their business, particularly when the “rules” are unclear and competition is intense; and
- A belief that government agencies do not give proper credit to companies that adopt strong compliance programs, particularly pro-active monitoring and auditing activities.

The authors believe there are many opportunities to bolster compliance efforts within the medical device industry and a strong commitment among the companies surveyed to do so. However, increasing adoption of the Code and increasing compliance with the Code’s suggested sales and marketing practices will require efforts by three important stakeholders:

- 1) Medical technology manufacturers,
- 2) Regulatory and enforcement agencies, and
- 3) Physician professional societies.

The authors suggest specific steps that each group of stakeholders could take to improve compliance with and beyond the AdvaMed Code. We believe that modest investments of time and resources by each group would go a long way toward improving sales and marketing compliance efforts within the device industry.

More guidance from regulatory agencies, while welcome, is unlikely to be quickly forthcoming or sufficiently detailed to establish a perfect roadmap to fraud and abuse compliance by industry. In the interim, medical device companies, individually and through AdvaMed, can take steps now in the following areas to strengthen their compliance efforts:

- Expand sales and marketing compliance policies beyond activities specifically set out in the AdvaMed Code;
- Enhance controls around highest-risk activities, including consultants, speaker programs and educational and research funding;
- Take steps to ensure sales compensation, performance evaluations and accountability mechanisms strike the proper balance between sales performance and compliance requirements;
- Increase the level and intensity of sophisticated training for personnel in key activities (e.g., sales and marketing, pricing/contracting);

- Implement or expand compliance monitoring and auditing as a standard part of overall compliance programs;
- Develop accepted methodologies for the determination of “fair market value,” possibly in consultation with the Department of Health and Human Services’ Office of Inspector General; and
- Work with leading medical centers to develop guidelines and enhance education on proper interactions between industry, physicians and other customers.

ANALYSIS OF BENCHMARKING SURVEY RESULTS

The 2007 Medical Technology Industry Benchmarking Survey ("Survey") sought to:

- 1) Examine how the AdvaMed Code of Ethics on Interactions with Health Care Professionals ("AdvaMed Code" or "Code") is being implemented by device manufacturers;
- 2) Identify the major challenges to further adoption of the Code and/or other sales and marketing compliance activities; and
- 3) Determine what various stakeholders -- industry, government agencies, physicians and professional societies -- can do to encourage more robust and effective compliance measures in the medical device industry.

I. PROGRESS ON IMPLEMENTATION OF THE ADVAMED CODE

The AdvaMed Code continues to play an important role in bolstering and enhancing sales and marketing compliance efforts within the medical device and diagnostics sectors. The following evidence supports this premise:

- As of February 2007, more than 500 medical device companies and/or subsidiaries have designated compliance officers who to oversee their company's compliance with fraud and abuse laws and implementation of AdvaMed Code.
- In 2006, AdvaMed rolled out a Code of Ethics Logo program to both promote awareness among the industry, health care providers and the general public of the AdvaMed Code and to provide a means of demonstrating a company's commitment to the ethical standards embodied by the Code. To display the Logo, a company must self-certify that it has at least eight elements in their compliance program for implementing the AdvaMed Code. To date, several dozen companies have signed onto the Logo program, and many more are considering doing so.

These findings confirm the 2006 survey results and attest to the widespread adoption of the Code in the device industry. Specifically the 2006 survey found that:

- Nearly 100% of the companies surveyed had adopted the Code in its entirety;
- Nine out of 10 companies applied the AdvaMed Code to all company professionals, regardless of title or seniority; and
- Approximately 2/3 of company presidents or CEOs have personally endorsed the AdvaMed Code in a written statement addressed to company employees and/or customers.

The 2007 Survey found that 83% of respondents said the AdvaMed Code was of high or medium relevance in shaping their company's compliance policies. Companies are continuing to implement the AdvaMed Code and enhance their sales and marketing compliance functions through such activities as training, monitoring and auditing. Specifically:

- 72% of respondents said their companies audit for compliance with the AdvaMed Code. Most often, internal personnel handle these audits (more than 75%).
- 47% of respondents said their companies had added personnel to implement the AdvaMed Code, with 25% reporting that their company added two or more FTEs specifically to aid in Code implementation.

The authors believe this reflects a strong commitment by many companies to move beyond mere adoption of the Code on paper and toward functional implementation through changes in policies, education and monitoring/auditing.

One of the most interesting findings in the Survey is that 92% of respondents said implementing the AdvaMed had no negative impact on (82%) or actually improved (10%) their companies' financial results. The authors believe this provides powerful evidence that robust compliance programs do not hinder financial success. Indeed, while not addressed comprehensively in the Survey, the authors have spoken with industry personnel who report that tightened sales and marketing practices have reduced wasteful and inefficient spending on meals, entertainment and some forms of educational and charitable giving. This has made resources available for other more effective (and more compliant) sales and marketing programs.

II. BARRIERS TO ADOPTION OF THE CODE AND OTHER COMPLIANCE SAFEGUARDS

One of the primary goals of the Survey was to gain a better understanding of the barriers that hinder more widespread adoption of the Code and other sales and marketing compliance safeguards. The Survey found that the three most significant barriers are:

- 1) A lack of clear regulatory guidance on what sales and marketing practices are and are not unlawful;
- 2) A lack of awareness or acceptance by certain physicians and other customers that old business practices are no longer acceptable; and
- 3) Insufficient recognition by top management at medical device companies of the resources (time, technology and personnel) required at the company level to fully implement the Code.

Lack of Regulatory Guidance

- 66% of respondents rated lack of governmental guidance as among the top three challenges to implementing a comprehensive commercial compliance program;
- 56% of respondents said lack of regulatory guidance was a barrier to implementing the AdvaMed Code; and
- Almost 60% of respondents agreed that government enforcement agencies have not made public clear guidance as to what types of sales/marketing activities are and are not unlawful.

The lack of regulatory clarity was cited more often than any other factor as an obstacle to compliance, including lack of internal resources and inadequate support from senior management.

A major problem for medical device firms is that they are forced to rely on one-time enforcement actions -- and not clear-cut regulatory guidance -- in shaping their compliance policies. Respondents said FDA warning letters, FDA untitled letters, DOJ settlements and Corporate Integrity Agreements were more relevant than HHS OIG guidance or advisory opinions in crafting such policies. The fact that few of these documents address the myriad sales and marketing activities and other manufacturer-customer relationships that are specific to the medical device industry also hinders their usefulness.

One-time enforcement actions are often so fact-specific that they offer only limited guidance for companies in establishing general rules of conduct for sales and marketing activities. Moreover, enforcement actions (particularly DOJ settlements and CIAs) often are based on conduct that is several years old, limiting their relevance in shaping current compliance policies and practices in the dynamic medical device industry.

Respondents offered concrete examples of where additional regulatory guidance would be particularly useful. These include:

- The appropriate circumstances for bundling of goods and/or services;
- When free goods may/may not be provided;
- The appropriate use of data from post-market studies without violating off-label promotion rules;
- Guidance on the payment of royalties to physicians or others who often are the inventors of medical devices;
- Guidance on the difference between formal claims/indications and clinical applications;
- A better definition of what constitutes unlawful marketing activities for in-vitro diagnostic devices ("IVDDs"); and
- A method for determining how to establish whether a gift or payment is "reasonable."

The authors believe that it should not be difficult for government agencies to offer guidance in at least some of these areas. For example, guidance could be issued that would describe the methodologies a manufacturer could use in determining reasonable compensation for services provided by physicians where the service rendered results in the creation or improvement of a device. Manufacturers that rely on such methodologies would be presumed to have acted in good faith.

There also is a clear need for further guidance in specific industry sectors. For example, the sales, marketing and reimbursement of IVDDs differs from that of other types of medical devices, and the discussion of risk factors in the *HHS OIG Compliance Program Guidance for Pharmaceutical Manufacturers* ("*OIG Pharma Guidance*"), which is relevant to medical device manufacturers generally, has less relevance to manufacturers of IVDDs.

Finally, the *HHS OIG's Special Fraud Alert on Prescription Drug Marketing Practices* (December 19, 1994) provided helpful guidance to manufacturers and physicians alike. It would be very helpful were OIG to issue a new round of alerts that describe current issues of concern in the medical device industry.

Physician/Customer Attitudes

The *Survey* found troubling evidence that some physicians and customers continue to expect and sometimes press for financial and other forms of support that are unethical or illegal. The “demand” side of the equation is a major challenge for companies in the implementation of effective compliance programs. Specifically:

- 44% of respondents said the need to meet customer expectations (i.e., the expectations of physicians) was the first or second biggest challenge to implementing a comprehensive sales and marketing compliance program;
- 76% of respondents rated customer expectations as among the top three challenges to implementing a comprehensive commercial compliance program;
- 75% of respondents said their companies had received resistance from customers in striving to comply with the AdvaMed Code; and
- 64% of respondents said that to improve compliance within the industry, prosecutors should pursue healthcare entities that receive inappropriate payments from medical device firms.

Respondents offered a number of interesting suggestions on how to further educate physicians and customers about sales and marketing compliance issues. These include:

- 1) Teaching compliance issues in medical school;
- 2) Working with physician professional societies to increase awareness (a step AdvaMed has taken and could possibly expand); and
- 3) Sponsoring compliance seminars at scientific conferences.

Management Support

At the company level, the *sine qua non* of an effective compliance program is strong and consistent support from senior management. Many respondents indicated that CEO involvement was the catalyst for developing compliance committees, implementing sales and marketing policies and other compliance measures. This year’s *Survey* found that compliance issues are receiving attention at the highest levels of management within device companies. Specifically:

- 64% of respondents said compliance personnel periodically provide reports to the CEO and Board of Directors and 82% said they provide such reports to the CEO.

Unfortunately, access to senior management does not always seem to result in the necessary resources being provided for compliance activities. Some of the key resource-based challenges faced by compliance personnel in implementing the Code include:

- 35% of companies reported they did not have a cross-functional compliance committee composed of senior management personnel;
- 29% of respondents said getting management to make time was the most significant challenge in training personnel on sales and marketing compliance policies; and

- 61% of respondents said lack of management support or inadequate resources (which can be a reflection of management support) are the biggest challenges to implementing effective monitoring controls.

The *Survey* did not capture the views of senior management on compliance issues. No conclusions can therefore be drawn from these findings about their views or concerns, or about what other conflicting priorities draw these resources away. One reason for management reluctance to invest in Code compliance may be uncertainty about whether government officials recognize or credit a company's compliance efforts in the exercise of their enforcement discretion. Certainly, survey respondents are concerned about such issues. Specifically:

- 50% of respondents said they agreed or strongly agreed that companies would increase the use of internal audits if the results were kept confidential from non-governmental entities; and
- 75% of respondents said the government does not give adequate credit to companies that self-disclose potential violations of law.

The benefits and effectiveness of compliance efforts are difficult to measure, and in the face of many challenges (including long-standing industry practices, expectations or demands from customers and competitive pressures in the dynamic device industry market) senior management may be reluctant to commit substantial time or resources to efforts with limited measurable impact.

One piece of good news from the survey, however, is that 92% of respondents said implementing the AdvaMed Code had no negative impact on (82%) or actually improved (10%) their companies' financial results. This is an important finding, and one that deserves wider discussion within the device industry.

III. THE OPPORTUNITY FOR STAKEHOLDERS TO BOLSTER INDUSTRY COMPLIANCE EFFORTS

The authors believe there is an enormous opportunity to bolster compliance efforts within the medical device industry and a strong commitment to doing so within the companies surveyed. However, significant improvement in the adoption of the Code (and sales and marketing compliance practices generally) will require efforts by three important stakeholders:

- 1) Medical technology manufacturers;
- 2) Physician professional societies; and
- 3) Regulatory and enforcement agencies.

The authors offer specific steps that each group of stakeholders could take. A modest investment of time and resources by each group would go a long way toward strengthening sales and marketing compliance efforts within the device industry.

First, manufacturers need to continue implementing robust compliance programs, not only to prevent and detect potential violations of law, but also to demonstrate to regulatory agencies and the public that the industry is committed to responsible sales and marketing activities. More widespread participation in the AdvaMed Logo program, which requires companies to take concrete steps to implement compliance programs along the lines outlined

by the HHS OIG, would help improve the industry's reputation with regulatory and enforcement agencies.

Similarly, AdvaMed should consider expanding the Code to address additional topics. Such expansions could include guidelines on educational and research grant activities, fair market value compensation and other topics identified by survey respondents as in need of additional guidance. Some of this guidance could be presented through additional FAQs to the Code. This would help companies shape their internal policies in these areas.

Second, physician professional societies (with continued support from AdvaMed and other manufacturer groups) must educate their members on the benefits of complying with industry codes of conduct -- and the significant legal risks of failing to do so. The authors recognize that those physicians who pressure the medical device industry for improper benefits represent a very small minority of the universe of distinguished professionals who serve the public health. They are not representative of the profession as a whole. However, by working to reduce the demands on the industry to provide improper benefits, physician professional societies and other customer organizations can continue to promote patient health and successful outcomes as the principal therapeutic goal, and the use of medical devices based on clinical benefit and not improper considerations.

Finally, government agencies can help on two levels. First, there is clear interest in receiving greater clarity about what sales and marketing practices are and are not unlawful. When the government speaks, companies listen.

The *HHS OIG Pharma Guidance*, for example, is a powerful and positive driver of change within the pharmaceutical industry. By providing specifics on the government's expectations about the structure of compliance programs, including specific sales and marketing risk areas, the *HHS OIG Pharma Guidance* empowers management and compliance professionals to strengthen compliance programs in concrete ways. By providing detailed guidance in a number of promotional areas, it serves to level the playing field for companies that want to act ethically but face competition from those who would otherwise consider more aggressive behavior.

The *Pharma Guidance* takes much of the guesswork out of identifying what the HHS OIG considers to be important, and focuses the conversation on how to address the government's specific concerns. The *Pharma Guidance* has been somewhat helpful to device manufacturers, but it is important to emphasize that the two sectors are very different. Device-specific guidance from HHS OIG would be a catalyst for enhanced compliance efforts within the industry.

Second, even modest efforts from regulatory agencies could have a major impact. The HHS OIG has tools at its disposal -- such as Special Fraud Alerts and Open Letters -- that the agency can and should use to provide specific guidance in areas of concern within the device industry. Bundling arrangements is a specific area where the OIG's prior guidance is spotty at best and where additional guidance would be useful.

Third, government agencies also could help by focusing some attention on the "demand" side of the compliance equation. They should increase their scrutiny of physicians who continue to solicit inappropriate payments or support from manufacturers. While manufacturers must resist such entreaties, a handful of high-profile investigations and (if the evidence warrants) prosecutions of physicians who solicit improper payments would send a powerful message. This would change the current dynamic between manufacturers and physicians in which manufacturers are forced to police their own customers. Further, "demand" side enforcement would promote greater compliance with applicable laws and industry and professional society codes of conduct.

RECOMMENDATIONS

The following recommendations highlight how various constituencies can promote regulatory compliance.

Government (FDA, HHS OIG and DOJ)

- Engage the industry on how the agencies can provide more specific guidance as to what sales and marketing activities and the types of manufacturer-customer relationships that do and do not comply with the law.
- Focus additional enforcement scrutiny on physicians who demand improper payments or services from manufacturers.
- Provide clear guidance regarding the benefits of self-disclosure and a high quality compliance program.
- Discuss with industry how to provide disclosure protections, particularly for responsible companies that engage in pro-active monitoring and auditing activities.

AdvaMed

- Expand the AdvaMed Code to address additional sales and marketing risk areas (e.g. educational and research grants, reimbursement support) and to provide methodologies for determining “fair market value.”
- Work with government agencies to develop more guidance on sales and marketing practices.
- Engage customer associations to educate members on industry ethics.
- Continue to work with member companies to promote the benefits of effective compliance programs that enhance the reputation of the member and the industry.
- Work with a handful of leading medical centers to develop model guidelines regarding interactions with healthcare professionals. These institutions command respect throughout the medical profession, and joint guidelines might increase physician awareness of, and compliance with, physician society and industry codes of conduct.

Customers

- Recognize that the environment has changed. Customers and their relationships with manufacturers must comply with the Code. Customers must undertake their own role in driving ethical business behavior.
- Include Ethics and Compliance training at all levels: medical schools, CME programs, and industry organizations to manage customer expectations.

Medical Device Companies

- Expand their sales and marketing policies to address risks beyond those currently in the AdvaMed Code, including grants, educational and research funding and reimbursement support. Companies would be more likely to take such steps if the AdvaMed Code were expanded to address these activities and thus provide a level compliance playing field.
- Develop more effective controls (beyond written policies) addressing consultants, speaker programs and educational and research funding.
- Create incentive compensation programs for sales personnel that are consistent with companies' compliance programs and values. Compliance officers need more input into incentive plans as a first step toward ensuring sales compensation, performance evaluations and accountability mechanisms that strike the proper balance between sales performance and compliance.
- Provide sufficient time and support for compliance officers to deliver adequate training to employees on the Code and to develop policies that drive compliance with the Code. Education and training programs need to become more sophisticated, moving beyond "basic" fraud/abuse training to more detailed training tailored to job function (e.g. pricing/contracting/discounting).
- Implement or expand compliance monitoring and auditing as part of their overall compliance programs.

SURVEY METHODOLOGY

The Survey authors developed a 30-question, on-line survey tool based on their knowledge and experience with the medical technology industry. They authors also obtained informal guidance on content and format from a number of in-house lawyers and compliance professionals.

The survey tool was distributed to several hundred in-house compliance professionals from a broad spectrum of medical device manufacturers, including large, medium and small manufacturers across multiple sectors of the device industry. Seventy-two officials from medical device firms filled out the survey.

The Survey was voluntary and anonymous -- no people or entities, including the authors, are able to link specific answers to specific respondents or companies. The authors believe this level of anonymity encouraged honest and candid answers and bolstered the quality of the data provided by respondents.

Respondents provided answers to the survey in late January-early February 2007.

ABOUT THE SURVEY AUTHORS

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