

CLIENT ALERT November 2009

Read DuVal & Associate's 10-Point Physician-Consulting Compliance Checklist recently published in "Orthopedics This Week." Incorporate this list into your compliance program and share it with your consulting physicians so that you can keep your company in compliance and off the front page of the news.

INTRODUCTION

Physician relationships with industry have recently received attention in the media and from politicians like Senator Chuck Grassley (R-Iowa). Recently, Medtronic consultant Dr. David Polly was criticized for failing to disclose his relationship with Medtronic while testifying before Congress. Dr. Polly has responded strongly stating that he abided by the rules and the criticism of Senator Grassley is unfair. The bottom line is that with increased reporting and transparency, how will the public perceive your relationships with consultants?

When engaging physicians in a paid relationship, companies not only face exposure to the court of public opinion, but also to the Anti-Kickback Statute, False Claims Act and other laws. Paying physicians as consultants is not an unlawful practice. In developing and commercializing any product, gaining input from top notch medical consultants is paramount and is what society should expect of industry—get the very best advice. Industry needs physician input to provide ideas for new products, designing the ideas that are identified and in understanding how to clinically study them. Industry uses physicians to present their 510(k) submissions and PMAs to FDA and their advisory panels. Physicians participate on marketing focus panels and provide important feedback on messaging in advertising and promotion. Industry uses physicians on speaker's bureaus to teach peers, advisory boards, and in many other areas of product development and commercialization. The major concern is if the financial relationship is compromising a physician's medical decisions and the care of the patient, then the relationship is not compliant, and should be avoided. Additionally, even if the financial relationship is not compromising the care of the patient (in the vast majority of situations, this will be the case) could a perception be created that this bias exists?

This Client Alert presents tips on how physician-industry interactions can be kept in compliance. Sometimes physicians don't totally understand or even agree with the compliance efforts going on around the country. Industry is often in the position of debating consulting physicians who complain of too much government involvement in their profession. Ironically, in this debate, industry is trying to help these physicians protect themselves (and the company). We've created a 10-point physician consulting checklist that is useful not only to your company, but could also be handed out to your consulting physicians so they can understand your concern that your relationship be viewed as bona fide and paid at fair market value for the work they perform. These points provide some constructive thoughts/action steps for physicians to undertake to protect themselves. By following these guidelines, our hope is that the exposure physicians and companies face associated with consulting relationships can be managed more effectively and candidly.

10-Point Physician-Consulting Compliance Checklist

DuVal and Associates offers the following guidelines. This list was published in October by Walter Eisner in "*Orthopedics This Week*." Mr. Eisner interviewed Dr. Polly for the article titled "Surgeon in the Crosshairs." We commend this article to your reading. After reviewing the list, Dr. Polly referred to it as "spot-on." Although this list is written for physicians, it is equally applicable to company employees in executive management, marketing, clinical, engineering, and legal as well as other disciplines that contract with physicians for input on a regular basis.

1. ***Begin your consulting relationship with potential adverse publicity in mind***—ask yourself, how would my relationship look if it were on the front page of the newspaper or on the nightly news? Are you viewed as a product evangelist or prostitute for one company or product? It's acceptable to be an enthusiastic user/prescriber, but try to maintain some sense of balance.
2. ***Document your relationship with the Company***—the agreement must be in writing to qualify for protection from the government prosecution under the Personal Services Safe Harbor to the Anti-kickback Statute. Also document all that you bill a company with detail—the matter, time spent, work performed, mention names of people with whom you've dealt and/or products on which you've worked. Would the rate you are being paid meet an outsider's view of "fair market value" or is it a reflection of your ego?
3. ***Be scrupulous about meeting your institution's guidelines***—go above and beyond disclosure requirements if necessary. The more you can demonstrate transparency and openness; the better off you'll be and subject to less criticism. Consider disclosing all the money and other remuneration (stock, stock options) you make and making your time sheets available to your institution even if they do not require them to be disclosed. Remember to disclose on other occasions as well such as in a journal

article or speaking in front of a professional audience. Many organizations have disclosure guidelines and, if they don't, disclose anyway.

4. ***Use a third party*** (friend, mentor, colleague, institutional ethics officer) ***to serve as a sounding board about your financial relationships***—they don't need to have veto power, but they should be someone who can provide an independent perspective. It will make you think of things you might do along the way to protect your reputation.
5. ***Don't be greedy or too attached to one company***—be wary of doing business with companies that seem overly desperate for your assistance and sales of their product to you, your practice and/or any affiliated institutions. You are entitled to be paid for your time, but make sure that the time your bill does not appear to deprive your employer of your services during a work day and be careful when the cumulative hours billed in a day seems to be more than a normal human can bill in a day. Ensure that you do not appear to bill for every conceivable second and/or overbill for time spent on tasks that could be done in far less time than you've billed.
6. ***Know the AdvaMed Code, PhRMA Code, and the company's guidelines on interactions with health care professionals so you know the rules***—also abide by the AMA Code and your medical specialty society's rules if you are member.
7. ***Don't rely on your institution or the company with whom you've worked to protect you if times get tough***—they may be loyal, they may not be. It depends on how bad the publicity is and pressure gets. Make your own personal compliance your objective.
8. ***Remember the world has changed—it's no longer how it used to be, get over it.***
9. You are entitled to be paid for all the time you legitimately work, don't be an apologist for it, but ***view the public's perspective independently*** of your freedom to work and to be paid at fair market value for it. You may decide to take the risk of criticism, but do it knowingly and protecting yourself the best you can.
10. ***Most importantly, ask yourself always—have my financial relationships compromised or biased my medical decisions and the care of my patient?***

HOW DOES THIS CHECKLIST RELATE TO MY COMPLIANCE PROGRAM?

Government oversight of relationships with physicians is becoming more intense. With it comes greater pressure to maintain compliance. Therefore, it is crucial that companies understand the responsibilities that come with physician relationships and comply with the laws which govern them. Thought also needs to be put into designing a code on interactions with health care professionals to manage these relationships when they are hired as consultants. Have you taken some time to simply reflect as a management team on what you do and don't have in place and are you potentially engaged in conduct that

might draw prosecutorial attention or even the attention of a whistleblower (in-house or a competitor)?

HOW CAN WE HELP?

Our firm has put together compliance programs covering the company's code of conduct, AdvaMed Code (if the company is a signatory to it), Anti-kickback Statute, False Claims Act, advertising and promotion under the Food, Drug and Cosmetic Act, and HIPAA (for sales reps) for over 60 companies and trained management and field sales forces for years in fun and interesting ways to help them understand, not just what they can't do, but what they can do in the field in their relationships with physicians.

We've also conducted attorney-client privileged and work product "reviews" (an abbreviated, far less expensive audit) that gives management a snapshot at how an outside prosecutor might look at their firm's sales and marketing activities.

We also have developed a package of materials to help you make the reports required to be sent to the State of Massachusetts.

Finally, we help counsel firms day to day on practical issues like how to properly discount, bundle products or consign their product or offer reimbursement guarantees or conduct referral seminars or pay physicians for properly constructed retrospective chart reviews, or how to engage a consulting physician lawfully, among many other programs, without violating the Anti-kickback Statute. We also counsel on how to provide reimbursement advice without violating the False Claims Act. And we review promotional programs and ad copy for compliance with FDA's advertising and promotion regulations. We can help you strategize how to conduct lawful pre-approval communications or post-marketing programs.

In sum, we have comprehensive long-standing experience into how products are marketed and the laws that affect what you want to do to make your product a success. We want to help you get there and to be appropriately aggressive, but still compliant.