Health Care Compliance Communiqué

Q3 2016

MedTech Code of Ethical Business Practice

The now-decided Brexit vote has left considerable uncertainty in its wake among companies with operations in the UK and/or EU member states about the multiple rules and regulations under which they operate.

Those questions aren't likely to be answered anytime soon, given the apparent reluctance of UK officials to trigger the two-year stopwatch of EU-required action. Notwithstanding any uncertainty about future rules, companies have no option but to continue to comply with the regulations currently in place.

Medical device companies have a more immediate potential challenge in their compliance with the recently released MedTech Europe's Code of Ethical Business Practices. In 2015, a single Code of Ethical Business Practices was created to replace the two different, inconsistent codes of two organizations - the European Diagnostics Manufacturers Association (EDMA) and the European Medical Technology Industry (Eucomed). This Code is set to become effective on January 1, 2017, with one controversial exception. According to the Code, "After the end of the Transition Period on 31 December 2017, Member Companies shall no longer provide financial or in kind support directly to individual Healthcare Professionals to cover costs of their attendance at Third Party Organised Educational Events ...".

Bottom line, "This means that support of individual Healthcare Professionals to attend Third Party Organised Educational Events ... shall no longer be permitted under the Code."

The Role of the MedTech Europe Code

The Code does not carry the weight of government regulation. In fact, the Code specifically states, "The Code sets out the minimum standards appropriate to the various types of activities carried out by the Members. The Code is not intended to supplant or supersede national laws or regulations or professional codes (including company codes) that may impose more stringent requirements upon Members and all Members should independently ascertain that their activities comply with all current national and local laws, regulations and professional codes." The Code continues, "Furthermore, Member Companies must be mindful of the fact that they may be liable for the activities of third party intermediaries who interact with Healthcare Professionals or Healthcare Organizations in connection with the sale, promotion or other activity involving Member Companies' products." Specifically, MedTech Europe highlights the need for compliance with laws and regulations related to safety, quality and performance; advertising and promotion; data protection; anti-corruption; environmental health and safety; and competition.

UL is updating our Eucomed Code course to reflect the MedTech Code -- this self-paced course will be available in Q4 2016 to all subscribers of our Medical Device Sales & Marketing Library. To sign up for a free demo of the course, contact Pat Thunell at ***pat.thunell@ul.com***

Complimentary Webinar on September 27th: The New MedTech Code: Compliance Program Best Practices

This webinar will identify some recommendations and successful tactics for implementing the Code and conducting compliant interactions with Healthcare Professionals (HCPs) in today's ever increasing regulatory environment.

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The Code is broken down into three parts. The first part contains guidelines on the interactions with healthcare professionals and healthcare organizations. The second and third parts focus on dispute resolution and definitions of terms used in the Code. While the resolution of disputes and a clear understanding of terms are both essential to an understanding of the overall Code, it is the nine chapters of Part 1 that provide the scope and depth of the Code. The nine chapters are:

- General Criteria for Events
- Third Party Organised Educational Events
- Company Events
- Grants and Charitable Donations
- Arrangements with Consultants
- Research
- Royalties
- Educational Items and Gifts
- Demonstration Products and Samples

The Code is specific, laying out principles and criteria that will apply to events related to the interactions with healthcare professionals and healthcare organizations. Each chapter contains specific attention to a variety of events surrounding the stated activity or action. For example, Chapter 1 (General Criteria for Events), includes restrictions on the event program, its location and venue, guests, reasonable hospitality, travel and transparency. Similarly, Chapter 2 (Third Party Organised Educational Events) is equally specific for third party organized educational conferences and third party organized procedure training meetings. The third-party organized educational conference section contains provisions for educational grants, promotional activities and satellite symposia.

The Code in Context

Although the MedTech Code does not carry the weight of law, it does set a baseline standard for companies in its Member organizations in their interactions with healthcare professionals and healthcare organizations. There is growing public and regulatory concern about even the appearance of any influence by the medical technology and pharmaceutical industries on healthcare professionals and organizations. With this new Code, MedTech has taken those concerns on by providing guidance on virtually every aspect of the interactions between the industry and medical community.

Does Your Compliance Message Hit Its Mark?

Even before the US Sentencing Guidelines and the DOJ/SEC FCPA Guidance enumerated the elements of effective compliance, companies had crafted Codes of Conduct, policies and procedures, training programs and compliance communications tools.

Despite these near-universal compliance programs, companies – even those with widely respected compliance programs – have found themselves caught in the crosshairs of US enforcement agencies or their global counterparts for often-serious violations of anti-corruption laws.

There is universal agreement about the elements of an effective compliance program and near-universal acceptance that having a plan is worthless unless it is put into action. Our experience with clients across the business spectrum confirms that understanding. Unfortunately, that experience has also uncovered too many instances in which "implementation" falls short because the corporate message is dated, uninspiring or incompatible with the technologies on which employees and third parties increasingly rely. The company's stated compliance and ethics message simply gets lost between the corporate plan and its intended audience.

Three elements of a compliance program frequently emerge as the most vulnerable to messaging that fails to deliver on its intended purpose: Codes of Conduct, training, and two-way communications. Why do these elements fall short – and what can companies do to improve their performance? The answer can be found in three general areas: content, format and technology.

Updating and Upgrading Content

The Code of Conduct defines a company's philosophy, mission, priorities and expectations for itself as an organization and its people as individuals. It is the expression of a company's culture and is also the basis of an effective compliance and ethics program.

Too often, a company's Code is "set in stone" when it should be a dynamic, vibrant illustration of how the company's culture, ethics and compliance respond to the current challenges of the real world, a world in which discrimination, fraud, harassment, bribery, abuse and unfair advantage are regulated under constantly evolving laws in countries around the world. Simply sticking a section on China's current anti-bribery laws or the UK's anti-slavery law into an established Code may do nothing to dispel employees' perception that the Code is static and unresponsive to today's issues and challenges. A Code of Conduct must be continually updated with new content but, just as important, existing content must be updated to reflect the issues and challenges faced by the company, its employees and its third-party partners.

The same problem of outdated content is often present in a company's compliance training program. A globalized economy demands that employees and third parties understand laws and regulations that may appear to be outside their area of work. Consider, for example, an employee working with a company in Brazil. The employee knows that there are multiple, fast-changing anti-corruption laws being enacted in the country. He or she knows that the US FCPA may apply if a foreign government official is involved in the work of the employee or third party. But that same person may well roll his or her eyes when presented with a training lesson about the UK's Bribery Act, which applies to any company with operations in the UK. Training must be put into context that clearly ties the individual's responsibilities to the lessons presented. Given the number of laws that could apply to the business activities of a company, its corporate relatives or its third parties, it is essential that instruction about all the laws that may apply be covered.

Finally, a Code must reflect current culture. Even though the central message of ethics, integrity and compliance remain constant, the content used to communicate the company's culture should change with the times. Few of us would read a news report from 2014 to understand current political conditions. Learners should not be expected to approach a Code of Conduct or learning materials produced in 2014 with enthusiasm and confidence.

Multiple Formats

Companies can learn a substantial amount from the advertising world. Consider how many people see one billboard or one television commercial and race right out to buy the $40,000 SUV featured on the ad. Not many. Advertisers know that their message must be communicated in multiple formats. To make a sale, advertisers might use TV and magazine ads, corporate blogs, movie or TV placements, jingles or music, contests or famous spokespeople. Companies can use many similar tools to communicate their compliance message, not to outside buyers but to the most important "consumers" of all: their workforce.

Short bursts of information using different formats are particularly important for reinforcing a corporate message. The format can be a quick audible reminder delivered to a cellphone, a contest with rewards for employees who score highest on training for specific topics, corporate newsletters highlighting the accomplishments of employees in charitable or civic activities, a short text congratulating employees on their support of the company's culture ("Our new hires keep commenting on the strong ethics programs in our company. Congratulations for keeping our culture strong!") Even though these short bursts do not replace more traditional learning methods, they serve as important tools to reinforce knowledge and engagement of employees and third parties.

Embracing the Potential of Technology

Although desktop computers have retained a place in business, they are no longer the primary business tool they were just a decade ago. Instead, individuals inside and outside the corporate office rely on laptops, tablets and smartphones. Many of these newer technological tools are far more powerful and versatile than their predecessors but they also impose specific limits for corporate compliance communications. The Code's full-page corporate policy on respect in the workplace looks fine on a 23-inch desk-top monitor; it is eye-blurring on the screen of most tablets (regardless of resolution) and it is impossible on a smartphone notwithstanding the phone's powerful processor. Given that many employees and third-party learners spend the majority of their work time on the road with mobile devices, Codes of Conduct and training resources that fail to take into account the technology being used are likely to fail.

Companies can consider several approaches to match their compliance communication and learning needs with the reality of a mobile workforce dependent on mobile devices. Large documents such as a Code of Conduct can be broken into small, manageable chunks easily accessible through a dedicated, intuitive search engine. Companies may even want to incorporate a voice-activated "assistant" to locate needed information, similar to the "Ok Google" and "Cortana" tools used so often by everyone from child to grandparent. Consider the employee stuck in an airport who asks the question, "Which anti-corruption laws will apply to me in China?" A response of "six" or "eight" or "Where is your client headquartered?" can lead to a short answer that can be followed up onwhen the employee has adequate time or tools. Companies may also consider audible training models that employees can listen to when reading is not possible. While these audio lessons might not be appropriate for all training instruction, they can be especially useful for general topics or remedial training.

Keeping it Current

No company can be expected to trash these elements of its compliance program. In fact, very few companies should start from scratch. There is always something valuable in existing programs; often, the substance and style of an established program needs only minor adjustments, but every company can benefit from taking a hard look at how it is communicating its message.

A New Approach to Meet Your Learning Needs

Corporate Compliance Essentials for Pharmaceutical and Medical Device companies

"We need to deliver multiple training events to our sales team on key compliance topics, such as anti-bribery, but we also need to stay within budget."

More than 100 Corporate Compliance teams within Pharmaceutical and Medical Device companies trust UL's Corporate Compliance courses to deliver "foundational" compliance training to sales teams, distributors, field service, senior management and other client-facing departments.

Our Quality & Compliance Essentials program enables many more Life Sciences organizations to gain affordable access to five of the most popular courses in our Corporate Compliance Library – for a single price.

The Corporate Compliance program includes:

- Basics of the PhRMA Code (Pharmaceutical)
- Basics of the AdvaMed Code (Medical Device)
- Global Anti-Bribery
- Physician Payment Sunshine Act
- Introduction to Pharmaceutical Compliance
- Recognizing and Avoiding Conflicts of Interest

Get Started

To learn more about the Corporate Compliance courses, **view a preview of the courses** or contact Pat Thunell at **pat.thunell@ul.com**.

Anti-Kickback Statute and Stark Law

The Anti-Kickback Statute (AKS) typically overshadows the Stark Law in compliance concerns in the world of healthcare and Life Sciences. That's understandable for Life Sciences companies since ASK poses the greater compliance risk in the marketing and sale of medical products. Conversely, the Stark Law applies directly to a Life Sciences company's clients – healthcare providers.

In general the Stark Law, or Physician Self-Referral Law, prohibits physicians from referring patients for Medicare- and Medicaid-covered health services to an entity in which the physician or close family member has a financial interest. The law is highly technical, with multiple exceptions and precise recordkeeping and documentation requirements. In late 2015, the Centers for Medicare and Medicaid Services (CMS) issued a final rule that revised the law, adding new exceptions and clarifying requirements such as the Law's written compensation agreements and one-year rental limitations. Even with its recent clarifications and CMS' stated goal of reducing the law's compliance burdens, the Stark Law remains technically demanding.

The Law has also become more interesting in the the US Department of Justice as highlighted in this brief review of several recent cases highlights the DOJ's enforcement perspective and actions.

- In October 2015, DOJ resolved a case with Tuomey Healthcare System for illegally billing the Medicare program for services that were referred by physicians with whom the hospital had improper financial relationships. The $237 million judgment

resolves the government's case against the healthcare system. According to Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of DOJ's Civil Division, "This case demonstrates the United States' commitment to ensuring that doctors who refer Medicare beneficiaries to hospitals for procedures, tests and other health services do so only because they believe the service is in the patient's best interest, and not because the physician stands to gain financially from the referral." As part of its settlement with the government, the hospital is required to retain an independent review organization to monitor any arrangements it makes with physicians or other sources of referrals under a five-year Corporate Integrity Agreement.

- In September 2015, DOJ resolved a case against Columbus Regional Healthcare System (CRHS) and one of its physicians for violations of the Stark Law and the False Claims Act (FCA). CRHS was alleged to have compensated its physician-employee in excess of fair market value and in excess of revenue received on the services the physician performed. The physician, in turn, allegedly billed for medical practitioners who were not physicians and were not properly certified under his provider number.

- In January 2016, Tri-City Medical Center agreed to pay more than $3 million to resolve allegations that it violated the Stark Law and FCA by maintaining financial arrangements with community-based physicians and physician groups that violated Medicare's requirement related to financial relationships between hospitals and referring physicians. According to DOJ's allegations, Tri-City maintained 97 financial arrangements with physicians and physician groups in violation of the Stark Law. These arrangements violated the law, in part, because the written agreements between physician and hospital were expired, missing signatures or could not be located. Tri-City self-disclosed the misconduct, which was acknowledged by DOJ in determining the settlement amount and conditions.

The Enforcement Risk

DOJ's interest in the Stark Law is part of a greater push. According to the agency, recent settlements illustrate "... the government's emphasis on combating health care fraud." That emphasis is supported by the Health Care Fraud Prevention and Enforcement Action Team (HEAT), which focuses on efforts to reduce and prevent Medicare and Medicaid financial fraud. Although the Stark Law does not apply directly to Life Sciences companies, it applies to the industry's customers and parallels the Anti-Kickback Statute in mission and risk of FCA prosecution. Being aware of the Stark Law is a "heads up" for Life Sciences companies in working with their customers.

About UL EduNeering

UL EduNeering provides knowledge and expertise that empowers Life Sciences organizations globally to accelerate growth and move from compliance to performance. Our solutions help companies enter new markets, manage compliance, optimize quality and elevate performance by supporting processes at every stage of a company's evolution. UL provides a powerful combination of advisory solutions with a strong modular SaaS backbone that features ComplianceWire®, our award-winning learning and performance platform.

UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 12,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

For more than 30 years, UL EduNeering has served corporate and government customers in the Life Sciences, Health Care, Energy and Industrial sectors. Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), EduNeering has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations.

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