Medical Device

PRECONFERENCE SESSION III

SPONSORED BY

THE PHARMACEUTICAL COMPLIANCE FORUM

Today's Agenda

Live Polling Instructions

- **Text Option Polling Instructions:**

1. Text Account Name **PC173** to **22333**
2. When a poll is shown, text your response.
3. Type “Leave” to exit the account. This must be done before you can enter a new one.

- **Guidebook Polling Tool Instructions:**

1. Download the conference app using the instructions on the cover of your agenda.
2. Select **Live Polling** from the menu in the conference app.
3. Enter username **PC173** and click join
4. When a Poll appears, select your response.

What industry are you representing?

dical device manufacturer

Pharmaceutical manufacturer

Law firm

Consulting firm

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Introductions

Jonathan Glazier

Senior Legal Counsel, US Compliance Lead
Philips Electronics North America

William Hrubes

Vice President, Chief Compliance Officer
ACell, Inc.

Andrew Van Haute

Associate
Sidley Austin LLP

Matt Wetzel

Vice President and Assistant General Counsel
AdvaMed

Becky Osowski

Senior Manager, Fraud Investigation & Dispute Services, Life Sciences
EY

Recent Enforcement Trends

t primary source does your organization use to stay current on indu developments and/or emerging enforcement trends?

Internal Law Department

OIG Fraud Alerts

External Law Firm

Industry Organizations
, AdvaMed, MedTech)

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Sampling of AKS Enforcement Against Device Manufacturers

Manufacturer	Alleged Activities	Settlement Amount	Date
Shire / Advanced BioHealing	Paid kickbacks to doctors and hospitals in the form of meals, entertainment, and travel; free product; consulting arrangements, etc.	$350 million	January 2017
Hollister and Byram Healthcare	Paid unlawful kickbacks to supplier to induce supplier to conduct marketing promotions and conversion campaigns designed to refer patients to the manufacturers' products.	$20.9 million	April 2016
Olympus	Paid kickbacks to doctors and hospitals in the form of free equipment, grants, consulting arrangements, etc.	$646 million	March 2016
Coloplast	Paid kickbacks to medical suppliers in the form of cash incentives, known as "spiffs", in return for marketing promotions and conversion campaigns.	$3.6 million	December 2015
Ev3	Advised hospitals to use its Silver Hawk Plaque Excision System on an inpatient basis, thereby enabling them to bill Medicare for more money	$1.25 million	February 2015
Biotronik	Paid kickbacks to physicians, caused hospitals and ambulatory surgery centers to submit false claims to Medicare and Medicaid for the implantation of Biotronik pacemakers, defibrillators and cardiac resynchronization therapy devices	$4.9 million	November 2014

Key Areas of Government Concern

- Consulting relationships in all forms
- Meals, travel, entertainment for physicians
- Co-Marketing activities
- Equipment loans and free devices
- “Sham” data fees and royalties
- Gifts to physicians and their family members
- Sponsored product training and conferences
- Charitable donations

Enforcement: 2016 Olympus Settlement

- In March 2016, Olympus Corp. of the Americas ("Olympus"), agreed to settle with the U.S. Department of Justice ("DOJ") for $646 million, including $623.2 million to resolve criminal and civil allegations that Olympus violated the Anti-Kickback Statute ("AKS")
  - Olympus also entered into a 3-year deferred prosecution agreement ("DPA") and a Corporate Integrity Agreement ("CIA") with the Department of Health and Human Services, Office of Inspector General ("OIG")
- To induce customers to purchase Olympus products, Olympus offered and/or paid illegal remuneration to customers in the form of:
  - Free equipment and devices and service agreements
  - Consulting payments
  - Sham "honorarium" and "speaker" arrangements
  - Grants to physicians
  - Meals and entertainment, facilitated by significant stipends to sales representatives

Key Areas of Government Concern

- Significantly, the criminal complaint alleges that the improper payments occurred during a time when Olympus lacked training and compliance programs that were commonplace at other medical and surgical products companies

"The Department of Justice has longstanding concerns about improper financial relationships between medical device manufacturers and the health care providers who prescribe or use their products…Such relationships can improperly influence a provider's judgment about a patient's health care needs, result in the use of inferior or overpriced equipment, and drive up health care costs for everybody."

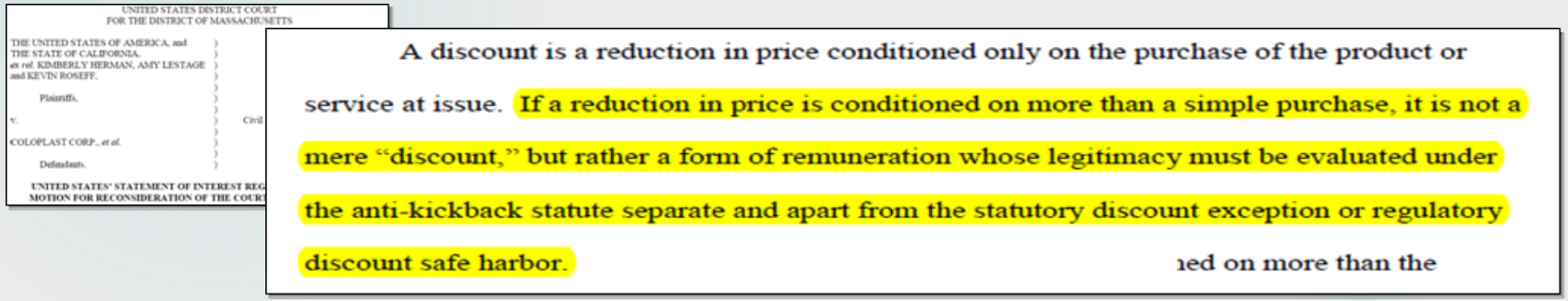
Principal Deputy Assistant Attorney General Mizer (Mar. 2016)

Recent Enforcement Trends: Areas to Watch

- Narrowing view of discount safe harbor
- Value-based arrangements
- Email monitoring requirements in CIAs

Recent Enforcement Trends: Discounts

- Coloplast/Hollister/Byram: 2012 FCA complaint alleged kickbacks in the form of "illegal price reductions" to DME suppliers
- While the government has not intervened, it has submitted statements of interest on several issues, including what does—and does not—constitute a discount under the AKS safe harbor



UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA, and
THE STATE OF CALIFORNIA,
ex rel. KIMBERLY HERMAN, AMY LESTAGE
and KEVIN ROSEFF,

Plaintiffs,

v. Civil

COLOPLAST CORP., *et al.*

Defendants.

UNITED STATES' STATEMENT OF INTEREST REG
MOTION FOR RECONSIDERATION OF THE COURT

A discount is a reduction in price conditioned only on the purchase of the product or service at issue. If a reduction in price is conditioned on more than a simple purchase, it is not a mere "discount," but rather a form of remuneration whose legitimacy must be evaluated under the anti-kickback statute separate and apart from the statutory discount exception or regulatory discount safe harbor. ıed on more than the

Recent Enforcement Trends: Value-Based Arrangements

- Government has expressed enthusiasm for value-based arrangements, but has not provided guidance instructing manufacturers how to structure them
- No public enforcement in this area; new safe harbors requested by industry
- OIG Advisory Opinion 17-03 (August 18, 2017)

[3] Although this arrangement does not fall within the definition of "written warranty," we note that a product could "fail to meet the specifications in the undertaking" for many reasons, including failure to meet quality standards or failing to achieve patient clinical results specified as targets at the time of sale. In such circumstances, the warranty safe harbor could apply, if other conditions of the safe harbor were met.

Recent Enforcement Trends: CIA Requirements

- Recent CIAs entered into by device manufacturers (e.g., Olympus, Cardiovascular Systems, EndoGastric) require monitoring of internal emails of sales personnel

> 2. *Records Reviews*. As a component of the FFMP, CSI shall also review various types of records to assess field sales representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations. For each

> These Records Reviews shall include the monitoring and review of (1) records and systems associated with field sales representatives' interactions with HCPs (including records relating to Co-Marketing Activities, consulting arrangements, travel and entertainment, expense reports, any payments to HCPs, and sales communications from managers); (2) field sales representative notes or other records from sales calls with HCPs, (3) field sales representative emails and other electronic records, and (4) recorded results of the Observations of field sales representatives, coaching guides, and manager notes.

Industry Perspectives

f asked, how would you rate your organization's monitoring efforts

Effective

Just scratching the surface

Needs work

What monitoring program!

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Building a monitoring program

- Where do we start?
  - As a Covered Manufacturer, we are all likely reporting transfers of value to the Government
    - The Government has the ability to mine that data, compare it with other data and identify trends
    - Being proactive in the identification of potential fraud, waste and abuse helps to better prepare the organization

Building a monitoring program

- The Philips story
  - 18,000 expense reports per month; 175,000 distinct events
  - Targeted three areas as a start:
    - Business meals
    - Interactions with Government Officials
    - Sunshine reporting
  - Leverage reporting systems (e.g., Concur) to begin to generate reporting

Building a monitoring program

- The low hanging fruit has value
  - Focus on accuracy of the data
    - Use of data mining and key word searches to identify data inconsistencies
  - Data reporting to flag transactions for review
    - Venue
    - Excess spend / over the meal limit
    - Split expenses
    - Outlier data – top spenders, top recipients, top entities (# and $)
- Expand to other payment sources
  - Evaluation equipment, clinical research, donations, etc.

s your organization currently perform keyword searches or utilize
mining/data analytics to help inform the monitoring program?

Yes

No

Not yet, but we have plans to implement in within the next 3-6 months

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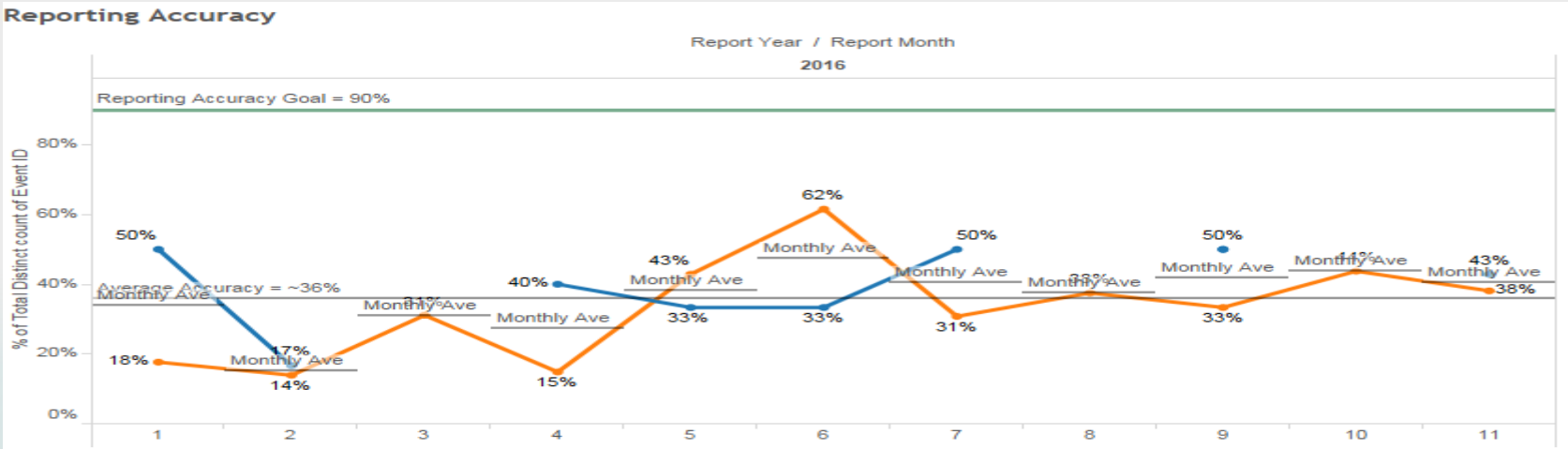
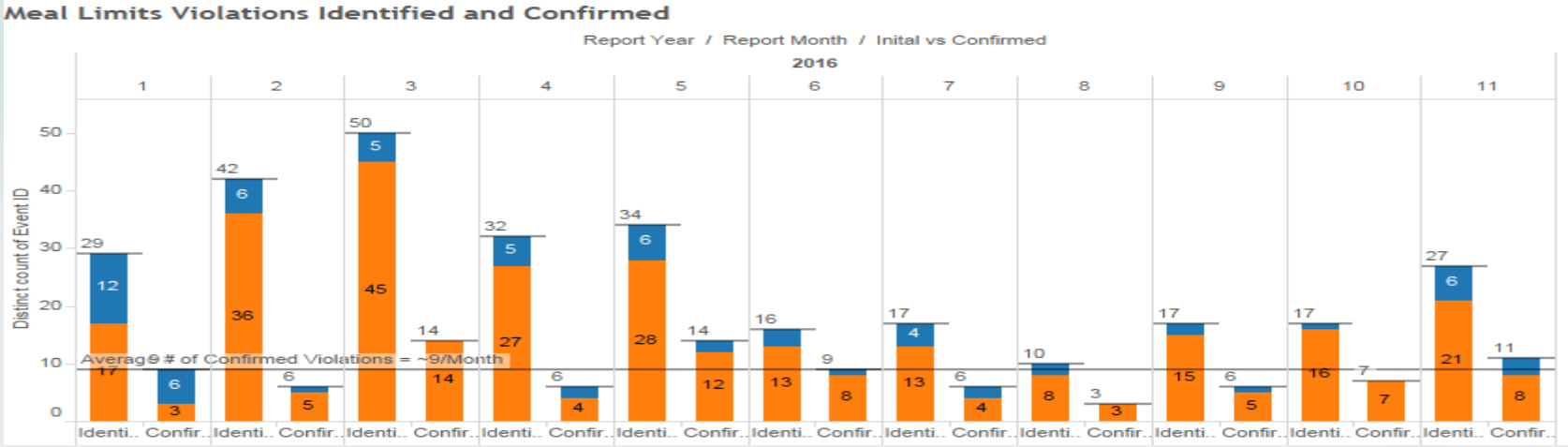
Example Monitoring Report





Taking it Global

- Objective:
  - To create a Group-wide **Monitoring of Business Interactions and Sample Testing** program in order to identify, detect and prevent fraud, waste and abuse among the identified risk areas globally
    - Use risk-based approach to prioritize resources and areas of focus
    - Leverage and significantly improve existing infrastructure
    - Use US monitoring experience as basis for pilot
    - Based on pilot learnings and local needs, further deploy market-per-market

Taking it Global

Domains

- Anti-Bribery & Anti-Corruption
- Healthcare Compliance

Identified in risk assessment as priority areas for monitoring program via available data*

- Data Privacy
- Antitrust

Identified as secondary focus area. Monitoring in next phase based on learnings from phase 1

- Export Control & Sanctions

Area where hard controls are already strongly embedded in processes

Data Sources

- T&E (Concur)
- Purchase Data (SAP, Ariba, Salesforce)
- Contracting Data (iCon)
- Training Data (Philips University)

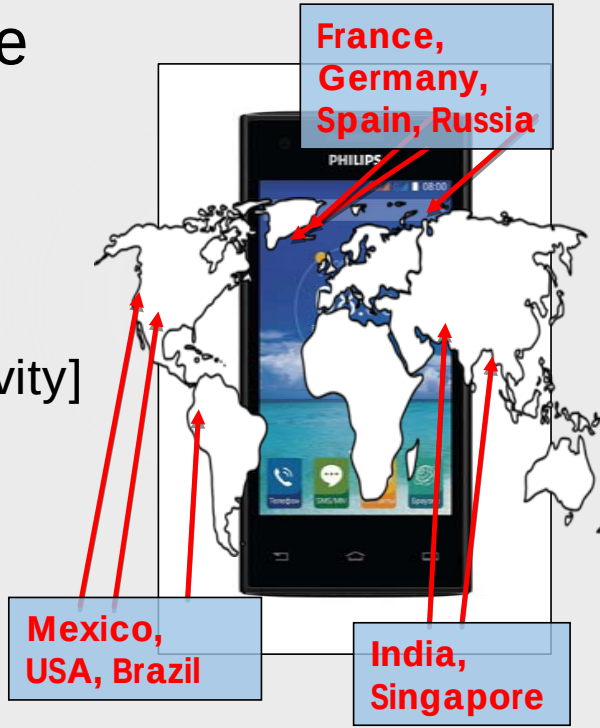
Monitoring is one the fundamental elements of any compliance program and the goal is to understand and lower Philips risk exposure by focusing on the highest impact areas.

Use of technology

- Global Legal Compliance App
  - Provides general guidance:
    - Code of Conduct
    - Antitrust
    - Privacy
    - Export Controls
    - Anti-bribery / Anti-corruption
  - Available for download on Android, Apple and Windows platform devices on Philips and personal mobile devices

Use of technology

- Enhancements to address Healthcare Compliance
  - Pilot launch in 10 countries
  - Content available in 10 languages
  - Users answer questions like:
    - I would like to engage an HCP licensed in [country] in [activity]
  - Content includes guidance from regional codes of conduct (e.g., COCIR, MedTech, AdvaMed China)
  - Cost effective alternatives:
    - AdvaMed App
    - Decision Trees
    - Flow Charts
    - If/Then



s your organization have a role in the consulting engagement proc

Yes

No

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t role does your compliance department play within your organizat

Advisor

Policy owner

Periodic monitoring

Approval role for certain transactions

N/A, not in an industry compliance role

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KOL consultant engagement

- Evolution of compliance (small/med/large)
- Role of Commercial versus Compliance
- KOL consultant engagement management
  - Role of Compliance in the engagement and payment process
  - Pharma versus Med Device
  - R&D, Clinical, MSL

Updates from AdvaMed

Who is AdvaMed?

Advanced Medical Technology Association (AdvaMed)

- World's largest medical technology association
- Nearly 300 members with a global presence in countries including China, Europe, India, Brazil and Japan
- Advocate on a global basis for the highest ethical standards, timely patient access to safe and effective products and economic policies that reward value recreation
- Act as the common voice for companies producing medical devices, diagnostic products and health information systems

AdvaMed
Advanced Medical Technology Association

Is your organization a member of AdvaMed?

Yes

No

N/A, my organization is not a manufacturer of edical technologies

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AdvaMed Code of Ethics

- Originally launched in 2003
- Revised & Restated in 2009
  - 2007 Deferred Prosecution Agreements – orthopedics
  - Evolution in CIAs and Other Settlements
  - New Transparency and Marketing/Behavioral Restrictions
  - Updated with FAQs & Best Practices Guidance


AdvaMed

CODE OF ETHICS
ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

ADOPTED BY THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

I. Preamble: Goal and Scope of AdvaMed Code

The Advanced Medical Technology Association ("AdvaMed") represents companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities ("Medical Technologies") in order to enable patients to live longer and healthier lives (collectively "Companies," and individually "Company"). AdvaMed is dedicated to the advancement of medical science, the improvement of patient care, and, in particular, the contributions that high quality, innovative Medical Technologies make toward achieving these goals. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and those individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies in the United States ("Health Care Professionals").

Medical Technologies

Medical Technologies are often highly dependent upon "hands on" Health Care Professional interaction from beginning to end—unlike drugs and biologics, which act on the human body by pharmacological, immunological or metabolic means. For example, implantable Medical Technologies are often placed in the human body to replace or strengthen a body part. Surgical Medical Technologies often serve as extensions of a physician's hands. In other circumstances, Medical Technologies are noninvasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by Health Care Professionals. Some Medical Technologies work synergistically with other technologies, or are paired with other products that deploy devices in the safest and most effective manner. Many Medical Technologies require technical support during and after deployment.

Interactions with Health Care Professionals

The scope of beneficial interactions between Health Care Professionals and Companies is broad and includes interactions intended to:

- *Promote the Advancement of Medical Technologies.* Developing and improving cutting edge Medical Technologies are collaborative processes between Companies and Health

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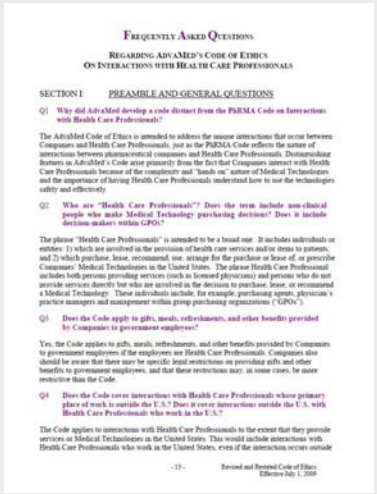
Revised and Restated Code of Ethics
Effective July 1, 2009


FREQUENTLY ASKED QUESTIONS

REGARDING ADVAMED'S CODE OF ETHICS
ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

SECTION I: PREAMBLE AND GENERAL QUESTIONS

Q1 **Why did AdvaMed develop a code distinct from the PhRMA Code on Interactions with Health Care Professionals?**

The AdvaMed Code of Ethics is intended to address the unique interactions that occur between Companies and Health Care Professionals, just as the PhRMA Code reflects the nature of interactions between pharmaceutical companies and Health Care Professionals. Distinguishing features in AdvaMed's Code arise primarily from the fact that Companies interact with Health Care Professionals because of the complexity and "hands on" nature of Medical Technologies and the importance of having Health Care Professionals understand how to use the technologies safely and effectively.

Q2 **Who are "Health Care Professionals"? Does the term include non-clinical people who make Medical Technology purchasing decisions? Does it include decision-makers within GPOs?**

The phrase "Health Care Professionals" is intended to be a broad one. It includes individuals or entities: 1) which are involved in the provision of health care services and/or items to patients; and 2) which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies in the United States. The phrase Health Care Professional includes both persons providing services (such as licensed physicians) and persons who do not provide services directly but who are involved in the decision to purchase, lease, or recommend a Medical Technology. These individuals include, for example, purchasing agents, physicians's practice managers and management within group purchasing organizations ("GPOs").

Q3 **Does the Code apply to gifts, meals, refreshments, and other benefits provided by Companies to government employees?**

Yes, the Code applies to gifts, meals, refreshments, and other benefits provided by Companies to government employees if the employees are Health Care Professionals. Companies also should be aware that there may be specific legal restrictions on providing gifts and other benefits to government employees, and that these restrictions may, in some cases, be more restrictive than the Code.

Q4 **Does the Code cover interactions with Health Care Professionals whose primary place of work is outside the U.S.? Does it cover interactions outside the U.S. with Health Care Professionals who work in the U.S.?**

The Code applies to interactions with Health Care Professionals to the extent that they provide services or Medical Technologies in the United States. This would include interactions with Health Care Professionals who work in the United States, even if the interaction occurs outside

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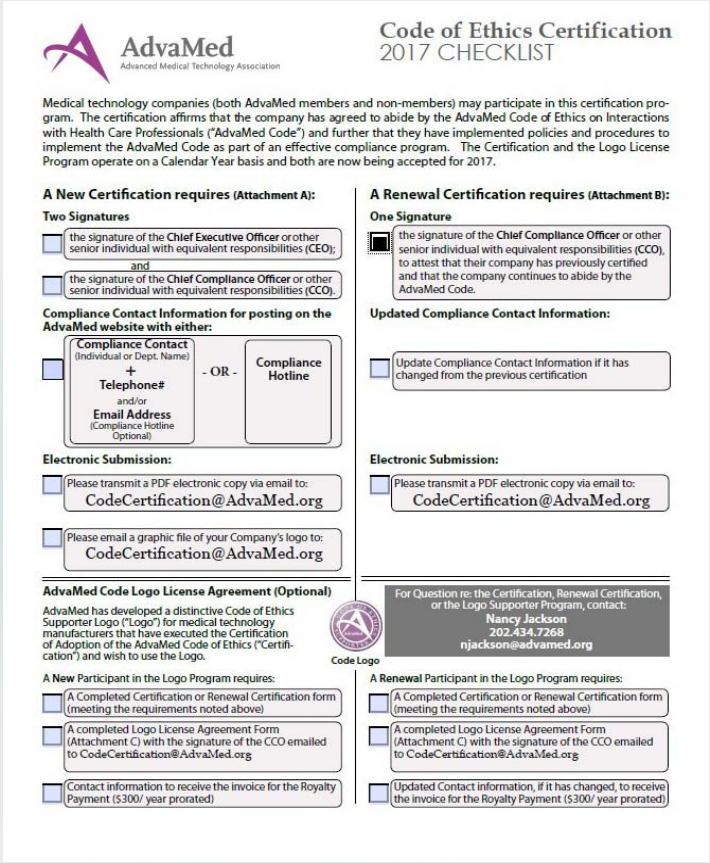
Revised and Restated Code of Ethics
Effective July 1, 2009

THE PHARMACEUTICAL COMPLIANCE FORUM

AdvaMed Code of Ethics



AdvaMed
Advanced Medical Technology Association

Code of Ethics Certification
2017 CHECKLIST

Medical technology companies (both AdvaMed members and non-members) may participate in this certification program. The certification affirms that the company has agreed to abide by the AdvaMed Code of Ethics on Interactions with Health Care Professionals ("AdvaMed Code") and further that they have implemented policies and procedures to implement the AdvaMed Code as part of an effective compliance program. The Certification and the Logo License Program operate on a Calendar Year basis and both are now being accepted for 2017.

A New Certification requires (Attachment A):

Two Signatures

☐ the signature of the **Chief Executive Officer** or other senior individual with equivalent responsibilities (**CEO**);
and
☐ the signature of the **Chief Compliance Officer** or other senior individual with equivalent responsibilities (**CCO**).

Compliance Contact Information for posting on the AdvaMed website with either:

☐ **Compliance Contact** (Individual or Dept. Name) + **Telephone#** and/or **Email Address** (Compliance Hotline Optional) - OR - **Compliance Hotline**

Electronic Submission:

☐ Please transmit a PDF electronic copy via email to: CodeCertification@AdvaMed.org

☐ Please email a graphic file of your Company's logo to: CodeCertification@AdvaMed.org

A Renewal Certification requires (Attachment B):

One Signature

☑ the signature of the **Chief Compliance Officer** or other senior individual with equivalent responsibilities (**CCO**), to attest that their company has previously certified and that the company continues to abide by the AdvaMed Code.

Updated Compliance Contact Information:

☐ Update Compliance Contact Information if it has changed from the previous certification

Electronic Submission:

☐ Please transmit a PDF electronic copy via email to: CodeCertification@AdvaMed.org

AdvaMed Code Logo License Agreement (Optional)

AdvaMed has developed a distinctive Code of Ethics Supporter Logo ("Logo") for medical technology manufacturers that have executed the Certification of Adoption of the AdvaMed Code of Ethics ("Certification") and wish to use the Logo.

Code Logo

For Question re: the Certification, Renewal Certification, or the Logo Supporter Program, contact:
Nancy Jackson
202.434.7268
njackson@advamed.org

A New Participant in the Logo Program requires:

☐ A Completed Certification or Renewal Certification form (meeting the requirements noted above)

☐ A completed Logo License Agreement Form (Attachment C) with the signature of the CCO emailed to CodeCertification@AdvaMed.org

☐ Contact information to receive the invoice for the Royalty Payment ($300/ year prorated)

A Renewal Participant in the Logo Program requires:

☐ A Completed Certification or Renewal Certification form (meeting the requirements noted above)

☐ A completed Logo License Agreement Form (Attachment C) with the signature of the CCO emailed to CodeCertification@AdvaMed.org

☐ Updated Contact information, if it has changed, to receive the invoice for the Royalty Payment ($300/ year prorated)

- Impact of self-regulation
  - Requires companies to take a hard look at both policies and practices
  - Mitigates risk of government enforcement through reasonable rules and behavioral restrictions
  - Demonstrates industry-wide commitment to acting with ethics & integrity
  - Grounds all customer interactions in pragmatic compliance principles
  - Preserves objectivity and patient-centric decision-making
  - Enhances industry and individual company reputations
  - Supports innovation and development of cutting-edge technologies
  - Provides industry with credibility in other contexts (e.g., transparency)

AdvaMed Code of Ethics

Developing an Effective Compliance Program

- Foundation for strong policies, training, and tone
- Certification process focuses company attention on effectiveness of compliance program

Company-Conducted Product Training & Education

- Appropriate trainers
- Venue & location
- Travel & lodging expenses
- Provision of modest meals

Supporting Third-Party Educational Conferences

- Educational grants to conference organizers
- Support for HCPs-in-Training
- Providing meals and refreshments to conference attendees

AdvaMed Code of Ethics

Sales & Promotional Meetings

- Appropriate venue & location
- Travel & lodging expenses
- Provision of modest meals

Consulting Arrangements with HCPs

- Written agreement
- Legitimate need for services; legitimate need for consultant
- Fair market value
- Venue & location of meetings
- Sales personnel input
- Payment of royalties

Modest Meals

- Incidental to bona fide presentation of information
- Setting/location
- Appropriate participants
- Ban on entertainment & recreation

AdvaMed Code of Ethics

Educational Items; Ban on Gifts	Health Economics Information	Research Grants/Charitable Donations	Evaluation & Demonstration Products
• OK to provide educational items or patient benefit items up to $100 (exception: textbooks & anatomical models) • No branded promotional items • No items capable of personal use • No gifts	• Objective • Accurate • No unlawful inducement	• Objective criteria and procedures for review • Can't account for volume/value of purchases • Limited sales involvement • Bona fide recipient	• Single Use/Disposables (reasonable number of samples) • Multiple Use/Capital (reasonable evaluation period, objective processes) • Demonstration Products (unsterilized, mock-ups)

Global Compliance Efforts

- Code Harmonization
  - Efforts underway to develop harmonized code principles around the world
  - Launch of Inter-American Coalition on MedTech Ethics
  - Approval of Bogota Principles – principles for business ethics in Latin America to be embedded in country-specific codes

Global Compliance Efforts

- APEC Distributor Guidelines
  - Asia-Pacific Economic Cooperation (APEC) Business Ethics for Small- and Medium-Sized Companies – Sept 2017 forum in Hanoi
  - Leaders from over 150 public, private and civil society organizations
  - Release of APEC guidance for ethical third-party intermediary relationships in the medical sector – guidance to help ensure that third parties sales & marketing intermediaries adhere to ethical business practices

our organization currently fund direct sponsorships to attend third educational conferences?

Yes

No

N/A, my organization does not fund direct sponsorships

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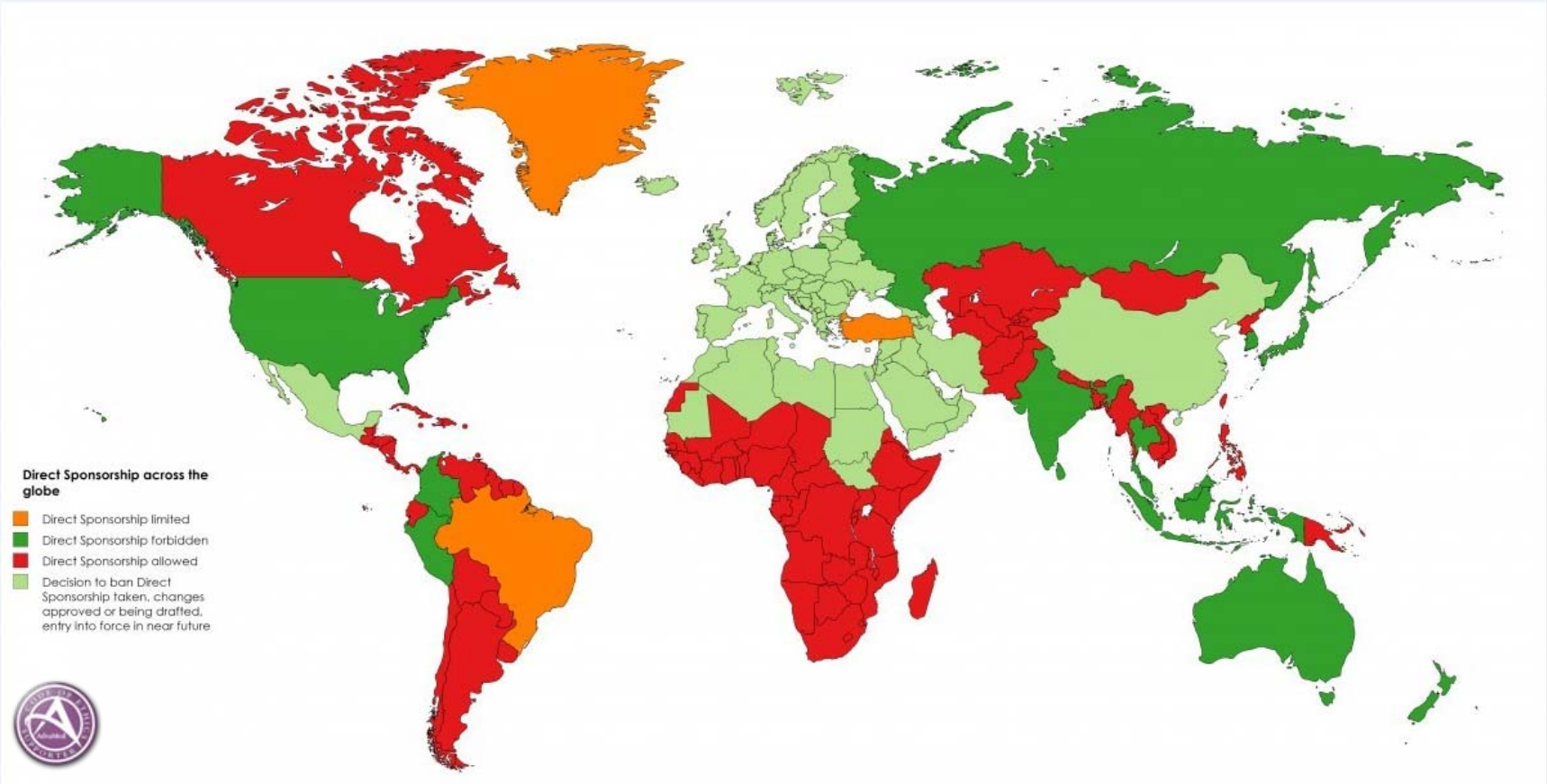
Global Compliance Efforts

- Phase-out of Direct Sponsorships
  - Effective January 1, 2018
  - AdvaMed – China
  - MedTech Europe – Europe, Middle East, Africa
  - APACMed – Asia Pacific
  - Companies can no longer pay directly for HCPs' costs incurred to attend third-party educational conferences
  - Move to an educational grant model around the world

Global Compliance Efforts



Other Compliance Initiatives

- Value-Based Health Care
  - Moving from fee-for-service model to risk-sharing model
  - Seeking legislative or regulatory solutions – expanded safe harbors, OIG guidance
- Dental Compliance
  - Building coalition of AdvaMed members and non-AdvaMed members to raise the dental sector's compliance profile
  - Dental Is Not Different!

Other Compliance Initiatives

- Physician-Owned Distributors
  - Ethical concerns; fraud & abuse risks
  - Hospital policies disproportionately impacting start-ups
  - Sunshine Act – Fill the GPO Loophole!
  - Stark Law – Potential Recommendations from MedPAC to eliminate availability of indirect compensation exception

Other Compliance Initiatives

- U.S. Physician Payments Sunshine Act
- Global transparency requirements – need for uniform legislation?
- Cleaning up Open Payments System Issues
- Need for greater clarity and context
- Acquisition payments; debt forgiveness; evaluation equipment; other
- Expansion to other practitioner types