

Keeping our Focus: Compliance Summary for Customers and Health Care Professionals

Understanding the Olympus
Health Care Compliance Code of Conduct

OLYMPUS[®]

Your Vision, Our Future



Introduction

Olympus Corporation of the Americas (“Olympus”) is subject to laws, regulations, and ethical standards, some of which are unique to the health care and life sciences areas of our business. These laws, regulations, and ethical standards are addressed in detail in our Health Care Compliance Code of Conduct (“Compliance Code”).

Our Compliance Code governs our interactions with our customers and health care professionals (“HCPs”). It also helps define our commitment as a corporation and as individuals to abide by the laws and industry standards that apply to our day-to-day interactions with our customers and with HCPs. It is essential that Olympus representatives, HCPs performing services for Olympus, as well as our customers and the HCPs we interact with understand and follow our Compliance Code.

We have summarized our Compliance Code in this guide for your reference. We hope you and your facility find this summary guide helpful. We expect you will embrace and follow the laws, regulations, and ethical standards in it in your interactions on behalf of Olympus and with Olympus representatives.

Please note as used in this guide, the terms “customer” and “HCP” encompass the individuals (whether clinical or non-clinical, including physicians, physician assistants, nurses, technicians, purchasing managers, and office staff) and entities (including hospitals and group purchasing organizations) that directly or indirectly purchase, lease, recommend, use, prescribe or arrange for the purchase or lease of any Olympus product or service.

Our Fundamental Principles

Our Health Care Compliance Code is based on three fundamental principles:

1. Medical decisions should be focused on the best interests of patients.
2. Products must be promoted in a manner consistent with the Food and Drug Administration's (FDA) approved uses (indications) as listed in the product labeling.
3. Training HCPs and others how to utilize our products and services in a safe and effective manner is important to enhance the well-being of the patients they serve.

These principles are grounded in the important laws that regulate the life sciences industry in the U.S. and other nations where companies with substantial U.S. operations may conduct business:

1. **The U.S. Anti-Kickback Statute** prohibits providing payments or other value to HCPs or customers to influence the use, prescription, purchase or lease of federally reimbursed products or services.
2. **The U.S. False Claims Act** prohibits knowingly submitting or causing someone else to submit a fraudulent claim for reimbursement to a government-funded health care program. This law may intersect with the Anti-Kickback Statute when product orders are placed as a result of improper inducements and later reimbursed by a federally funded health care program.
3. **The U.S. Federal Food, Drug, and Cosmetics Act** requires manufacturers to secure the approval or clearance of their products by the FDA before marketing and promoting them. Prior to marketing or promoting a product, the manufacturer must provide the FDA with evidence validating the safety and effectiveness of the product for a specific use or uses. The product receives FDA approval or clearance on the basis of this evidence, and the approved uses (indications) are listed in the product labeling. Although physicians can lawfully prescribe or use products for unapproved (or off-label) indications, companies may not promote products for off-label indications and are restricted in how they communicate about these uses.
4. **The U.S. Physician Payments Sunshine Act** requires life sciences companies to track and report certain expenses related to interactions with physicians and teaching hospitals. Importantly, Olympus representatives may not pay for anything with their own funds that would be otherwise reportable by Olympus under this law. Tracking and visibility is critical, as all data will be reported on a website maintained by the federal government.
5. **The U.S. Health Insurance Portability and Accountability Act – (HIPAA)** provides federal protections for personal health information and gives patients specific rights regarding this information. In the course of completing your job responsibilities you may have access to this information. You must maintain the privacy and security of any protected health information in accordance with HIPAA, related laws, and Olympus' policies and procedures.

These laws are sweeping and overlapping. One single act of misconduct can raise issues under a number of statutes. The consequences can be severe and include large monetary fines and the possibility of imprisonment. Furthermore, the government can impose sanctions that exclude a company's products from the list of approved devices that are reimbursable under federal and state health care programs, such as Medicare and Medicaid.

In addition to national laws, a number of U.S. states, such as Vermont and Massachusetts, have restrictions and outright prohibitions on certain interactions with HCPs licensed in those states, such as bans on meals, limitations on places where meals can be consumed, and restrictions on the provision of certain items of value. Some states also require life sciences companies to report to state agencies certain information about permitted interactions with HCPs.

Under many of the applicable laws, all parties that participate in illegal conduct may be held accountable. Accordingly, violations can result in criminal and civil penalties being imposed on manufacturers and their employees, as well as their customers, such as hospitals, physicians, or group purchasing organizations. **This means that Olympus personnel, and our customers, and HCPs that fail to comply with the law may individually be subject to prosecution and may face fines and criminal charges. Compliance is intended to protect you as well as our employees and our company.**

Overview of our Compliance Code

Our Compliance Code, our policies, and our procedures are consistent with the AdvaMed Code on Interactions with HCPs, as well as the Canadian MEDEC Code of Conduct on Interactions with HCPs, and the European Eucomed Guidelines for Interactions with HCPs. These documents are the underpinnings for key elements of an effective health care compliance program, as defined by the U.S. Department of Health and Human Services Office of Inspector General. All of our interactions with customers or HCPs, no matter how brief or informal, must be conducted in accordance with applicable laws, regulating industry standards, and our company's Compliance Code, policies, and procedures. Interactions might be anything from a brief, product-related discussion, to negotiating the terms of a pricing contract, to establishing the terms of a research grant.

Product Labeling

Olympus must adhere to applicable requirements for the marketing and promotion of products, including those that allow only marketing and promotion solely for the indications cleared by the FDA and listed in the product labeling.

Our Code

- Our promotional discussions with you and promotional materials pertaining to FDA-cleared products must be consistent with product labeling. This includes presentations by HCPs performing services for Olympus and other third parties serving as promotional speakers at Olympus events.
- Olympus representatives may only provide you with instruction, oral assistance or training, and answer your questions regarding the use of an Olympus product in a manner consistent with the product labeling.
- Olympus representatives and HCP consultants performing services for Olympus must direct any questions that potentially relate to off-label indications of a product to our Regulatory Affairs Department, which is responsible for responding to unsolicited requests for information about the safe and effective use of Olympus products, as well as information on unapproved, off-label uses.
- Olympus representatives may not be present for medical procedures at your facility in which they are aware the procedure will involve the off-label use of an Olympus product. Olympus representatives must excuse themselves from the operating room if a product is used in a manner inconsistent with its cleared indications.
- Olympus representatives must limit the discussion of product-related information to the device's labeled instructions for use, its operating principles, its performance specifications, and other technical aspects of the product, even if you, as a HCP, elect to use a device in a manner not described in the product labeling. An exception to this would be for certain appropriate conversations between you and representatives from our Regulatory Affairs Department consistent with Olympus policies.

Entertainment, Hospitality and Meals

Olympus must adhere to industry standards and applicable laws and regulations governing the provision of hospitality and meals and prohibiting entertainment for customers and HCPs.

Our Code

- Our interactions with you should be professional and facilitate the exchange of information that will benefit patient care.
- Provision or reimbursement by Olympus for your entertainment and/or recreational activities are prohibited, regardless of value, whether Olympus has engaged you as a speaker or other consultant, or whether the entertainment is secondary to an educational purpose.
- Your meals, when permissible in accordance with Olympus policies, must be incidental to a bona fide presentation of scientific, educational or business information, and must be provided in a setting conducive to informational exchange.
- Permissible meals provided to you must be occasional and modest in value.
- Apart from legitimate travel expenses, and permissible reimbursement incurred pursuant to a written agreement for services, Olympus may not provide a meal for you unless Olympus representatives are present, and we may not provide a meal to anyone that does not have a bona fide professional interest in the information being shared during the meeting, including your spouse or other guests.
- Olympus representatives are prohibited from using their own funds to pay for or supplement HCP-related expenses.

Educational Items of Value

Olympus must adhere to industry standards and applicable laws and regulations governing the provision of items of value to HCPs.

Our Code

- Items that benefit patients or serve a genuine educational function for HCPs may occasionally be provided to you. Such permitted items include educational brochures, starter kits, journal reprints, textbooks, and anatomical models.
- Items that do not benefit patients or serve a genuine educational function for HCPs are prohibited. This includes items such as cameras, pens, coffee mugs, calendars, wine, gift baskets, holiday gifts, cash, and cash equivalents (e.g., gift cards).

Product Training and Education

Olympus has a responsibility to demonstrate the safe and effective use of our products to HCPs requiring such training.

Our Code

- All training programs must be consistent with the FDA-cleared product labeling of Olympus products.
- Programs must be conducted in settings or an appropriate facility conducive to the exchange of information.
- Olympus may not compensate a HCP for attending an educational program. In some circumstances, however, it may be permissible for Olympus to reimburse a HCP for reasonable travel expense related to attending an Olympus product training event.
- If a HCP is traveling for a program, Olympus may not host, fund or support the attendance of third parties (e.g., spouses or other guests) that do not have a bona fide professional interest in the program.

Consultant and Development Arrangements

Olympus is permitted to occasionally enter into agreements with HCPs and others who provide services (e.g., education and training, clinical research, product development, and marketing services) that are of bona fide value to the company.

Our Code

- Services must relate to a legitimate business and need to be identified prior to the engagement of the consultant.
- Consultants must be selected to provide services based on their qualifications and expertise. Consultants may never be selected based upon factors such as past or future purchases, referrals or recommendations of our products or services.
- The agreement must be clearly documented in a signed contract outlining the consultant's responsibilities, the duration of the arrangement, the terms of compensation, coverage/ reimbursement of expenses, and the requirement for documentation evidencing completion of the contracted services.
- Compensation must be consistent with the fair market value of the contracted services actually provided.
- Meetings with consultants must be held in venues conducive to informational exchange.
- If a consultant is traveling or otherwise attending any functions in conjunction with the performance of services, Olympus may not host, fund or support the attendance of third parties (e.g., spouses or other guests) that do not have a bona fide professional interest in the services.
- Royalty arrangements are only entered into with HCPs that make, or have already made, a novel, significant or innovative contribution to the development of a product, technology, process or method.

Educational Grants

The Olympus Grants Committee makes decisions pertaining to support of legitimate educational activities directed to HCPs or patients. Examples include grants to accredited continuing medical education (CME) providers, support for conferences of national medical associations, fellowships at teaching institutions, and support of other educational endeavors.

Our Code

- Educational grants cannot be contingent upon factors such as past or future purchases, referrals or recommendations of our products or services.
- Educational grants cannot be used to promote off-label use of Olympus products.
- Educational grants may be paid only to organizations with a genuine educational function and for genuine educational purposes.
- Educational grants must be formalized in an appropriate document between Olympus and the grant recipient.
- Olympus sales and marketing representatives may provide input about the suitability of a proposed grant recipient or program, but sales and marketing representatives must not control or unduly influence the decision of whether a particular HCP or institution will receive a grant or the amount of such grant.
- All decisions regarding requests for grants will be made solely by the Olympus Grants Committee, independent from Olympus' sales and marketing operations, in compliance with the federal Anti-Kickback Statute and related state statutes, and consistent with the AdvaMed Code of Ethics. Accordingly, Olympus sales and marketing personnel may not (i) initiate grant requests on a requestor's behalf; (ii) assist a HCP in applying for a grant (e.g., such personnel cannot fill out the form for the requestor); or (iii) create any expectations regarding grant approvals, denials or amounts. The Olympus Grants Committee maintains discretion to deny requests or modify the requested support as it deems appropriate.

If you are interested in requesting medical educational grants, you are invited to submit a written application exclusively through the online application portal located at olympusconnect.com/GrantApplication. Applications not submitted through the online application portal will not be considered. Please note, all applications must be complete at least sixty (60) days prior to the date of the event for which the grant support will be used.

Research Grants

Olympus occasionally receives requests from investigators seeking funding to conduct scientific or clinical studies. The Olympus Grants Committee, in appropriate circumstances, may provide monetary funding or a product donation to support legitimate, independent medical research that has scientific or clinical merit related to Olympus products or in disease states pertinent to Olympus.

Our Code

- Research grants cannot be contingent upon factors such as past or future purchases, referrals or recommendations of our products or services.
- Research must be in an area of legitimate interest to our company.
- Research must have well-defined objectives and milestones and may not be linked directly or indirectly to the purchase of Olympus products.
- The terms of the grant must be clearly documented in a written agreement.
- Olympus sales and marketing representatives may provide input about the suitability of a proposed research grant recipient or program, but sales and marketing representatives must not control or unduly influence the decision of whether a particular HCP or institution will receive the grant or support. HCPs should not engage in discussions about these matters with Olympus sales and marketing representatives.

Charitable Donations

The Olympus Grants Committee may provide charitable contributions to organizations that focus on health and human services, community needs or educational programs related to medicine and health care.

Our Code

- The organization must be a bona fide charitable organization with tax-exempt status.
- Terms of the contribution must be clearly documented in a written agreement and require that the funds be used consistent with the charitable purposes of the organization.
- All donations must fall within an approved budget.

Patient Privacy

In the course of certain interactions with HCPs, Olympus representatives may be exposed to, come into contact with, or have a need to receive a patient's information, such as patient records. Olympus is committed to maintaining the privacy of protected health information and supporting our customers' efforts to comply with applicable privacy laws and regulations including the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH").

Our Code

- Olympus makes commercially reasonable efforts to ensure that the protected health information is treated in a confidential manner.
- Olympus representatives are expected to make reasonable efforts to limit their access and exposure to the minimum amount of protected health information necessary to provide necessary products and services to our customers.

Product Evaluation, Demonstration and Sampling

Olympus may furnish products to customers without charge in reasonable quantities and/or for a reasonable amount of time to allow them to evaluate the appropriate use and functionality of the products, and for patient awareness, education, and training purposes.

Our Code

- Olympus must provide documentation and disclosure that instructs a HCP from inappropriately billing any patient, third-party payor or other person or entity, for use of any evaluation or demonstration product furnished without charge.
- The number of products provided without charge to a HCP should be limited to the amount reasonably necessary for the HCP to adequately evaluate or demonstrate the products under the circumstances and must be documented and returned (if capital equipment) in accordance with Olympus' policies.
- Capital equipment should be furnished only for a reasonable period sufficient for an evaluation, and after the evaluation period, it must be returned if not leased or purchased by the customer.

Coverage, Reimbursement and Health Economics Information

Olympus may provide coverage, reimbursement and health economics information regarding our products that is accurate and objective. This includes coverage, coding and billing options, changes in coverage or reimbursement payments, and the efficient use or installation of products or technology.

Our Code

- Olympus representatives must not suggest mechanisms for billing services that are not medically necessary or for engaging in unlawful practices to achieve inappropriate payment.
- Olympus must not provide any assurances to a HCP that any coding or coverage determination is correct, that a product will be reimbursed by an insurer or that the product will be reimbursed at any particular amount.
- Reimbursement assistance supplied by Olympus representatives is limited to identifying appropriate coverage, coding or billing related to the Olympus products or to procedures using those products, as they have been documented or explained by appropriate third-party authorities. HCPs and patients are responsible for reviewing and confirming applicable billing, coverage and payment policies with third-party payors, and for making all billing and reimbursement decisions.

Interactions with Government Officials and Employees

As a company that conducts business around the world, Olympus is committed to complying with all laws and regulations that govern its interactions with government officials and employees, including all elements of the U.S. Foreign Corrupt Practices Act and other applicable anti-bribery laws and regulations. Generally, the standards that apply to interactions with government officials and employees are more restrictive than those pertaining to interactions with non-government customers. The term “government official” includes all employees of, or those with privileges at, government-owned or operated health care facilities.

Our Code

- Olympus representatives are prohibited from offering or making a payment or any other inducement to any person with the intent to corruptly influence official conduct by a government official or employee, including purchasing decisions.
- Olympus abides by the conditions set forth by government health care facilities.
- All interactions with government officials and employees, of any nation, must be conducted in a manner that does not violate the laws or regulations of the nation for which the government official or employee works.

Compliance with this Guide and the Olympus Health Care Compliance Code

Olympus strives for compliant and ethical behavior. Olympus representatives and HCP consultants performing services for Olympus are expected to report, without fear of retaliation, any conduct they know to be or believe to be in violation of our Compliance Code, any state or federal laws, any health care program or any FDA requirement.

If you have any compliance concerns, they can be submitted in writing or in person to the Olympus Compliance Officer in our Compliance Department at 484-896-4GRC (4472) or via email at compliance@olympus.com.

Any person preferring to remain anonymous may make a report through our third-party Integrity Hotline by calling 1-844-277-1698 or olympusamerica.ethicspoint.com. The Integrity Hotline is secure, confidential and anonymous, and is available 24 hours a day, year-round, with services offered in multiple languages.

U.S., Canada & Puerto Rico: 1-844-277-1698
Canada: French 1-855-350-9393
Costa Rica: 0800-011-1248

Mexico: 001-855-232-1301
Brazil: 0800-892-0649