The Right Course

Everyday
Health Care
Compliance

An
Introductory
Guide for
Our Employees

Worldwide Office of Health Care Compliance & Privacy
The Chairman’s Message on Health Care Compliance

Johnson & Johnson is known the world over for innovative, life-saving medical products and for the values we embrace in making these products available to serve patient needs. Our Credo, Policy on Business Conduct, and Health Care Compliance guidelines communicate our commitment to putting patients first.

The Johnson & Johnson Health Care Compliance guidelines, like the laws and industry codes they reflect, are intended to serve patients by safeguarding medical decision-making from both the appearance and the fact of undue and improper financial influence. When we follow these guidelines, we stay on The Right Course—enabling us to advance patient care while protecting our customers, our employees, and our Company.

I am proud of our Health Care Compliance Program and what it says about our respect for patients and the professionals who oversee their care.

William C. Weldon
Chairman, Board of Directors, and Chief Executive Officer
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This guide is meant to serve as an introduction to the Johnson & Johnson Health Care Compliance guidelines and is not intended as a comprehensive presentation of these guidelines or to provide definitive guidance on any specific customer transaction or relationship. Each Johnson & Johnson company has detailed processes and procedures covering the areas discussed in this guide. Some state laws impose additional or different standards than described here. If you have questions about the information presented here or compliance with current state laws, please contact your company’s Health Care Compliance Department or the Johnson & Johnson Law Department. You may also visit the Worldwide Office of Health Care Compliance & Privacy (WWOHCC&P) website (http://wwohccp.jnj.com/) or the Johnson & Johnson Law Center website (http://law.jnj.com/).
Introduction

Staying on the Right Course

The Right Course is intended to enhance your understanding of the Johnson & Johnson Health Care Compliance guidelines for the United States. These guidelines help to define our commitment as a corporation and as individuals to abiding by the government laws and industry standards that apply to our day-to-day interactions with health care professionals. In the broadest sense, Health Care Compliance is about adhering to three fundamental principles:

- Keeping medical decision-making free of improper industry influence.
- Lawful promotion of products regulated by the US Food and Drug Administration (FDA).
- Disclosing accurate pricing information to assure appropriate government reimbursement.

We believe in these principles and in upholding the regulations that support them. To this end, our Health Care Compliance guidelines are founded on our understanding and application of relevant federal and state statutes and industry codes of ethics. They are consistent with the responsibilities and values defined in Our Credo and Policy on Business Conduct, and they are the underpinnings for key elements of an effective Health Care Compliance program, as defined by the US Department of Health and Human Services Office of Inspector General. All employees of Johnson & Johnson, who interact in any way with health care professionals, or with customers, who purchase health care products, must understand and abide by our Health Care Compliance guidelines.

What’s at Stake?

The laws that apply to Health Care Compliance are far-reaching and overlapping. As a result, single acts of misconduct can raise issues under multiple statutes. Punishments can be severe, resulting in multimillion-dollar civil penalties and criminal convictions that involve major fines and, in some cases, imprisonment. In addition, there are government sanctions that can potentially devastate an entire health care organization by excluding its products from the lists of medications and devices that are reimbursable by the government.

Under federal and state laws, all parties who engage in an illegal activity may be held accountable. This means that customers, along with companies and their employees, can be prosecuted for violations. In adhering to the regulations that govern Health Care Compliance, we protect our customers, our companies, and ourselves.
SEVEN ELEMENTS FUNDAMENTAL TO AN EFFECTIVE COMPLIANCE PROGRAM

1. Written policies and procedures for compliance
2. A designated compliance officer and committee
3. Effective training and education for employees
4. Effective lines of communication
5. Internal monitoring and auditing procedures
6. Enforcement of standards through disciplinary guidelines
7. Prompt responses to detected problems and implementation of corrective actions

Using the Guide

This guide contains discussions of the three fundamental principles of Health Care Compliance along with examples of our corporate guidelines for upholding them. Each of these principles is supported by existing government laws and industry codes, which are presented in detail in the Appendix.

The terms “customer” and “health care professional,” as used here, encompass the individuals, institutions, and other entities that prescribe, recommend, or acquire medical products and services or influence the recommendation, prescription, or acquisition of those products and services. Examples include physicians, nurses, and pharmacists, as well as institutions and organizations such as hospitals, group purchasing organizations, and managed care organizations.

An interaction with a Customer can be anything from a brief product-related discussion between a sales representative and a physician, to a pricing contract with a managed care organization, to an agreement with an institution on the terms of a research grant. All interactions with Customers—no matter how brief or how informal—must be conducted in accordance with existing laws, industry standards, and the Johnson & Johnson Health Care Compliance guidelines.

The Johnson & Johnson Health Care Compliance guidelines define our commitment as a corporation and as individuals to abiding by the government laws and industry standards that apply to our day-to-day interactions with Health Care Professionals.
I. Keeping Medical Decision-Making Free of Improper Industry Influence
I. Keeping Medical Decision-Making Free of Improper Industry Influence

Patients undergoing medical treatment share the expectation that decisions made on their behalf are guided by objective medical knowledge and experience and are free of improper influence. A growing number of laws, guidelines, and corporate policies have been introduced to help preserve the independence of medical decision-making. They limit and regulate giving or offering anything of value to Health Care Professionals to avoid improperly influencing choices made in the interest of patient care. Industry guidelines and corporate policies also are intended to limit even the appearance of improper influence.

Our Guidelines for Customer-Based Activities

Johnson & Johnson is committed to protecting treatment choices from improper financial inducements. Our guidelines, which reflect this commitment, are based on two important laws and the industry codes derived from these laws:

- The federal Anti-Kickback Statute, which prohibits companies from providing cash or other value to Health Care Professionals or Customers to influence the use, prescription, or purchase of federally reimbursed products.
- The federal False Claims Act, which prohibits a person from 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.
- The Pharmaceutical Research and Manufacturers of America (PhRMA), which represents research-based pharmaceutical and biotechnology companies, and the Advanced Medical Technology Association (AdvaMed), which represents medical device manufacturers, have established
codes of ethics intended to protect medical decision-making from improper financial incentives. The PhRMA and AdvaMed codes contain key points pertaining to providing meals and gifts to Health Care Professionals as well as guidelines about awarding grants and other funding.

Entertainment and Gifts

Johnson & Johnson companies are expected to adhere to industry standards for providing hospitality, meals, and gifts to Health Care Professionals.

Entertainment

Key Criteria for Compliance

- Sales calls and meetings with Health Care Professionals are limited to settings conducive to the exchange of information related to the company and its products.
- Companies may occasionally offer a modest meal, consistent with the standards of the applicable industry code of ethics, as part of a discussion about scientific or clinical information related to the company’s products.
- Recreational or entertainment events are not permitted in conjunction with Health Care Professional interactions.
- Attendance by spouses, children, or guests is not permitted.

Gifts

Key Criteria for Compliance

- J&J companies are prohibited from providing to Customers items that do not advance disease or treatment education or are otherwise not designed primarily for the education of patients or Customers. (Includes practice-related items, such as pens, notepads, mugs, other reminder items, and stethoscopes.)
- Items designed primarily for the education of patients or Customers must not offer value to the Customer outside of his or her professional responsibilities. Examples of appropriate items include anatomical models, textbooks, informational sheets and brochures, patient self-assessment and tracking tools, or written materials that inform patients about adherence to medications, healthy lifestyle choices, or the availability of patient assistance programs.
- Cash or cash-equivalent gifts are prohibited.

Some states sharply limit the value of certain gifts to Health Care Professionals or may require manufacturers to report the value of these gifts. Consult your Health Care Compliance Department for more information on this subject.
Fee-for-Service Agreements

Johnson & Johnson companies are permitted to occasionally enter into agreements with physicians and other Health Care Professionals who provide services (e.g., clinical research, advisory board participation, product development, and promotional speaking engagements) that are of *bona fide* value to the company.

**Key Criteria for Compliance**

- Services relate to an area of legitimate interest to the company.
- Compensation is consistent with fair market value.
- The agreement is clearly documented in a signed contract outlining the individual’s responsibilities, the duration of the arrangement, the terms of compensation, and the requirement for documentation of completion of the work.
- Recreational or entertainment events are not permitted in conjunction with Health Care Professional interactions.

Promotional Speaker Programs

Promotional speakers present information pertaining to a company’s products or services.

**Key Criteria for Compliance**

- Speakers receive payments consistent with fair market value and may be reimbursed for modest meals and reasonable travel and lodging expenses incurred in the fulfillment of their agreements.
- Expenses of program attendees are not reimbursed.
- Speakers are required to disclose potential conflicts of interest to the audience. Speakers must clarify that the programs are distinct from CME.
- Product-related scientific information is limited to approved labeling.
- Program content undergoes formal copy review.
- Companies may occasionally offer a modest meal, consistent with the standards of the applicable industry code of ethics as part of a discussion about scientific or clinical information related to the company’s products.
- Attendance by spouses, children, or guests is not permitted.
Educational Grants and Fellowships

Companies may provide grants to support legitimate educational activities directed toward Health Care Professionals or patients. Examples include grants to accredited continuing medical education (CME) providers, funding for speaker programs, fellowships at teaching institutions and support for grand rounds, and other educational endeavors.

All requests for educational funding must be reviewed by a multidisciplinary committee, staffed by representatives from various departments, including Medical/Clinical, Regulatory, Health Care Compliance, and Law.

Under the Johnson & Johnson Health Care Compliance guidelines, educational grants cannot be contingent on product purchases or favored formulary positioning, nor can they be awarded as a substitute for price concessions.

Independent Educational Programs

Independent educational programs are intended to benefit patients and Health Care Professionals through the dissemination of information that advances the practice of medicine. Johnson & Johnson companies may provide grant support for these programs but cannot be involved in the development of the content or the selection of speakers or authors. Examples include continuing medical education (CME) activities accredited by the Accreditation Council for Continuing Medical Education (ACCME) and other accredited educational programs.

Key Criteria for Compliance

- Funding is consistent with the nature and scope of the program, and the source of the grant is disclosed.
- Speakers or authors disclose conflicts of interest.
- Speakers’ travel and other expenses are reimbursed by the institution or association conducting the program, not by the involved Johnson & Johnson company.
- Attendees’ expenses are not reimbursed.
- The content is non-promotional, balanced, educationally focused, and developed without input or guidance from the company providing the funding.
- The terms of the grant are clearly documented in a written agreement.
Customer-Sponsored Educational Programs

Customers—such as teaching institutions or hospitals, medical societies or associations, or a patient advocacy groups—may request educational grants to support bona fide, non-promotional educational functions. Examples include speaker programs or grand rounds, which are meetings held by institutional Customers to discuss clinical cases and issues.

Key Criteria for Compliance

- The grant is consistent with the nature and scope of the program and is made directly to the institution or association conducting the program.

- The grant is designated for a specific educational purpose (e.g., honoraria, audiovisual support, etc.).

- The terms of support are clearly documented in a written agreement.

- Speakers disclose conflicts of interest, such as a financial relationship with a Johnson & Johnson company, to the institution or association conducting the program.

- Speakers’ travel and other expenses are reimbursed by the sponsoring institution and not by the involved Johnson & Johnson company.

- Attendees’ expenses are not reimbursed.

- Content is limited to FDA-approved product labeling, is non-promotional, and is focused on education.

JOHNSON & JOHNSON IS COMMITTED TO PROTECTING TREATMENT CHOICES FROM IMPROPER FINANCIAL INDUCEMENTS.
Fellowships
Fellowships are grants to institutions or professional societies dedicated to medical education. The funding enables Health Care Professionals to gain additional knowledge and training in a medical specialty.

**Key Criteria for Compliance**

- Funding is consistent with the nature and scope of the fellowship and is issued to the institution (e.g., hospital or other educational association) rather than to an individual instructor or fellow.

- Recipients are chosen by the institution or association without any involvement on the part of the involved Johnson & Johnson company.

- Distribution of fellowship funds is at the sole discretion of the institution receiving the grant.

- The terms of the fellowship are clearly documented in a written agreement.

- The institution awarding the fellowship is solely responsible for the instructional content.

Charitable Contributions and Patient Assistance Programs

Charitable Contributions
Charitable contributions are limited to organizations that focus on health and human services, community needs, or educational programs related to medicine and health care.

**Key Criteria for Compliance**

- Organization has tax-exempt status.

- Requests are submitted in writing and specify how the donation will be used.

- Terms of the contribution are consistent with corporate guidelines on corporate giving.
Patient Assistance Programs
Patient Assistance Programs provide medically necessary prescription medicines and medical devices.

Key Criteria for Compliance

- Patients meet established income eligibility criteria, lack third-party coverage, and have no access to the required product.
- The Customer using or dispensing free product and the patients who receive it agree in writing not to submit reimbursement claims for the product.
- Patients retain the freedom to select their practitioners.
- The program satisfies requirements for protecting patients’ privacy.

Product Evaluation and Sampling
Johnson & Johnson companies may furnish Customers with free product samples to familiarize physicians, Customers, and patients with a product.

Drug Sampling

Key Criteria for Compliance

- All sampling is conducted in accordance with the Prescription Drug Marketing Act, which prohibits the sale, purchase, or trade of any drug sample.

- Samples may be distributed to licensed physicians, hospital pharmacies, and other institutional health care entities, but only in response to a written request from a licensed physician.
- Recipients of free product are informed that it is illegal to bill for product samples.
- Companies maintain detailed records of sampling and file reports as required by the Prescription Drug Marketing Act.

Device Evaluation and Sampling

Key Criteria for Compliance

- Durable equipment provided for an evaluation is returned or purchased at the end of a limited evaluation period.
- Single-use products or supplies are provided in limited quantities sufficient to familiarize professionals and patients with their use.
Scientific Research

Company-Sponsored Research

Johnson & Johnson companies are committed to the development of new products and technologies, and they maintain research programs that assist them in fulfilling that objective.

Key Criteria for Compliance

- Investigators are selected on the basis of their expertise on the subject studied.
- Johnson & Johnson companies disclose to FDA, as required, any potential conflicts of interest between study sponsors and clinical investigators, such as an investigator’s investment in the product being studied.
- Prior to beginning research, investigators sign a written contract describing the study design, the method of reporting results, ownership of intellectual property, terms of compensation, and other relevant items.
- The Johnson & Johnson company sponsoring the study owns the data generated by the study.
- Study subjects are provided written informed consent documents.
Investigator-Initiated Studies

Johnson & Johnson companies occasionally receive requests from investigators seeking funding to conduct scientific or clinical studies.

**Key Criteria for Compliance**

- Research is in an area of legitimate interest to the company.
- The grant recipient agrees to share all research findings with the company.
- The grant request is reviewed, managed, and funded through the Johnson & Johnson company’s Medical/Clinical Department to ensure the methodology and protocol are valid and appropriate.
- The terms of the grant request are clearly documented in a written agreement.

Interactions with Government Employees

As a rule, the standards that apply to interactions with government employees are more restrictive than those pertaining to interactions with commercial Customers.

**Key Criteria for Compliance**

- The Health Care Compliance Department is involved in all decisions related to hiring government Health Care Professionals as consultants.
- Johnson & Johnson companies abide by the conditions set forth by government health care facilities, including their restrictions on gifts, meals, and entertainment.
- Support for medical education programs is in accordance with the policies of the government health facility and provided through appropriate channels.
II. Lawful Promotion of FDA-Regulated Products
II. Lawful Promotion of FDA-Regulated Products

The US Food and Drug Administration (FDA) oversees the public health by assuring the safety and effectiveness of drugs and medical devices marketed in the US. In fulfilling this responsibility, FDA regulates how these products can be labeled and promoted.

Health care companies are bound by federal law to secure the approval or clearance of their products by FDA. Prior to marketing or promoting a product, the manufacturer provides 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 cannot promote products for off-label indications and are restricted in how they communicate with Health Care Professionals and other Customers about these uses.
Our Guidelines for Customer-Based Activities

Adherence to Product Labeling

Johnson & Johnson companies must adhere to federal requirements for the marketing and promotion of products—drugs, biologics, and medical devices—solely for the indications approved by the FDA and listed in the product labeling.

Key Criteria for Compliance

- The company's business plan is directed toward driving sales growth for approved indications.

- Promotional discussions and materials pertaining to FDA-approved products are consistent with product labeling.

- Sales representatives and other commercial field-based staff, including third-party agents contracted for these roles, undergo training in appropriate promotional practices.

- When feasible, compensation plans for commercial sales forces are based on sales of products for FDA-approved uses.

- All promotional, marketing and sales-training materials are reviewed and approved by the Johnson & Johnson company’s Promotional Review Committee, which typically includes representatives from various departments, such as Medical/Clinical, Regulatory, Marketing, and Law.

Educational Programs

Johnson & Johnson companies support educational programs, as well as promotional speaker programs, to convey information about the safety and efficacy of products, the treatment of diseases, and other topics related to health care. Educational funding requests are reviewed by a multidisciplinary committee, which usually includes representatives from the Medical/Clinical, Regulatory, Health Care Compliance, and Law Departments.

Under the Johnson & Johnson Health Care Compliance guidelines, educational grants cannot be contingent on product purchases or favored formulary positioning, nor can they be awarded as a substitute for price concessions.
Promotional Speaker Programs

Promotional speakers present information pertaining to a company’s products or services.

**Key Criteria for Compliance**

- Speakers receive payments consistent with fair market value and may be reimbursed for modest meals and reasonable travel and lodging expenses incurred in the fulfillment of their agreements.

- Expenses of program attendees are not reimbursed.

- Speakers disclose conflicts of interest, clarify that the programs are distinct from CME.

- Product-related scientific information is limited to approved labeling.

- Program content undergoes formal copy review. If the content includes information pertaining to reimbursement or practice management, it is also reviewed by the Johnson & Johnson Law Department.

- Companies may occasionally offer a modest meal, consistent with the standards of the applicable industry code of ethics, as part of an educational presentation or a business discussion.

- Attendance by spouses, children, or guests is not permitted.

Independent Educational Programs

Under specific circumstances, educational grants can be provided for programs that include scientific information related to both approved and unapproved uses of a product. Examples include continuing medical education (CME) activities accredited by the Accreditation Council for Continuing Medical Education (ACCME) and other accredited programs in which the involved Johnson & Johnson company does not take part in content development or selection of participants or audience.

**Key Criteria for Compliance**

- Content is non-promotional, balanced, and educationally focused.

- The Johnson & Johnson company remains “hands off” in regard to program content unless information on reimbursement or practice management is included, in which case this information must be reviewed by the Johnson & Johnson Law Department.

- Funding is consistent with the nature and scope of the program, and the source of the grant is disclosed.

- Speakers and authors disclose conflicts of interest. In the case of a CME program, the disclosure must comply with ACCME guidelines.
 Speakers’ travel and other expenses are reimbursed by the institution or association conducting the program, not by the Johnson & Johnson company. Attendees’ expenses are not reimbursed, with the exception of a modest meal offered in connection with the program.

The terms of the grant are clearly documented in a written agreement.

Customer-Sponsored Educational Programs
Customers (other than CME providers) frequently request grants from Johnson & Johnson companies to support educational speaker programs or other activities. The Customer (e.g., teaching institution or hospital, medical society or association, or patient advocacy group) must have a bona fide interest in advancing education in an area of legitimate interest to the Johnson & Johnson company.

Key Criteria for Compliance

- The program content is limited to FDA-approved product labeling, is non-promotional, and is focused on education.
- The grant is awarded directly to the institution or association and is designated for a specific educational purpose (e.g., honoraria, audiovisual support, etc.).
- The Johnson & Johnson company remains “hands off” in the development and control of program content unless information on reimbursement or practice management is included, in which case this information is reviewed by the Johnson & Johnson Law Department.

Funding is consistent with the nature and scope of the program. Speakers’ travel and other expenses are reimbursed by the sponsoring institution and not by the Johnson & Johnson company. Attendees’ expenses are not reimbursed, with the exception of modest meals provided in connection with a grand rounds program.

The terms of support are clearly documented in a written agreement.

JOHNSON & JOHNSON COMPANIES MUST ADHERE TO FEDERAL REQUIREMENTS FOR THE MARKETING AND PROMOTION OF PRODUCTS—DRUGS, BIOLOGICS, AND MEDICAL DEVICES—SOLELY FOR THE INDICATIONS APPROVED BY FDA AND LISTED IN THE PRODUCT LABELING.
Patient/Provider Educational Materials

In certain circumstances, Johnson & Johnson companies can provide grants to Customers, such as hospitals or medical associations, to develop or disseminate patient education or professional education materials describing medical conditions and their treatments.

**Key Criteria for Compliance**

- The content is limited to FDA-approved product labeling, is non-promotional, and is focused on education.
- The grant request is appropriate for the nature and scope of the project, and the terms of support are clearly documented in a written agreement.

Providing Product Information to Customers

Manufacturers cannot promote products for unapproved indications and are restricted in how they communicate with Customers about these uses.

**Key Criteria for Compliance**

- Unsolicited Customer requests for medical information about off-label uses received by sales representatives or other members of the commercial staff are referred to the company’s designated Medical/Clinical Department.
- The company’s designated Medical/Clinical Department has processes in place to ensure the information provided is current, comprehensive, objective, scientifically sound, and free of promotional influence. This department must also disclose that the information being provided is outside the approved labeling.

Responding to Unsolicited Requests for Medical Information About Off-Label Uses

Each Johnson & Johnson company has a designated Medical/Clinical Department responsible for responding to unsolicited requests for information about the safe and effective use of its products, as well as information on unapproved, off-label uses.
Providing Technical Support During Patient Procedures with Medical Devices

Physicians sometimes request that a Johnson & Johnson company’s representative remain in the room during patient procedures for the purpose of answering technical questions about medical devices.

Key Criteria for Compliance

- The company representative providing technical support does not promote the device, or any of its features, for uses outside the approved product labeling.

- If a physician elects to use a device in a manner not described in the product labeling, the company representative limits 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.

- The company representative must not touch or make contact with the patient or, during the procedure, touch or operate instruments or equipment that delivers or regulates therapy to the patient.
Product Training

Johnson & Johnson companies have a responsibility to demonstrate the safe and effective use of medical devices to Health Care Professionals who—due to lack of familiarity with a device or its particular use or the need for a refresher course—clearly require such training. Product demonstrations can be conducted live or through a remote connection.

Key Criteria for Compliance

- Training is consistent with approved product labeling.

- Training venues may include a Johnson & Johnson company’s facility, an independent teaching center, such as a hospital, or another appropriate clinical setting.

- Health Care Professionals who attend training sessions may be reimbursed for reasonable travel and modest lodging costs but may not receive an honorarium or other compensation for time spent in training.
III. Disclosing Accurate Pricing Information for Government Reimbursement
III. Disclosing Accurate Pricing Information for Government Reimbursement

Health care costs are continuing to increase, with the US government paying the largest share through programs such as Medicare and Medicaid. Because of its significant financial stake in health-related acquisitions and reimbursements, the government has a vested interest in seeing that resources are allocated to the provision of necessary and appropriate products and services and that reimbursement is based on accurate pricing information.

Multiple federal laws are in place to protect the government from overpaying for health care and from receiving fraudulent claims for medical products and services.

**Our Guidelines for Customer-Based Activities**

Johnson & Johnson companies are allowed to support accurate and responsible billing to government programs and other third-party payors by providing accurate reimbursement information to Health Care Professionals regarding Johnson & Johnson companies’ products.

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**Reimbursement**

**Key Criteria for Compliance**

- Generally, representatives of Johnson & Johnson companies do not participate in the preparation or submission of claims to any third-party payor.

- Johnson & Johnson companies make every effort to assure that reimbursement information supplied to Customers, patients, and others is accurate, complete, and timely. All reimbursement-related sales and marketing materials are reviewed through a formal review process.

- Customers and patients are advised to review and confirm any information provided to them prior to submitting claims or making any purchasing decision.

- Reimbursement assistance supplied by representatives of a Johnson & Johnson company is limited to identifying appropriate coverage, coding, or billing related to the company’s products or to procedures using those products. Health Care Professionals and patients are responsible for reviewing and confirming applicable billing, coverage, and payment policies with third-party payors.
Discounts and Pricing

All discounts, rebates, credits, and other price-related concessions to Customers must meet specific criteria and must be approved by the company’s pricing committee.

Key Criteria for Compliance

- Appropriate documentation is provided to enable the Customer to establish the net cost of acquisition for products purchased by the Customer.
- The Johnson & Johnson company advises Customers that they may be required to report the value of the discount.

Medicare Part D

Medicare, a federally funded insurance program for senior citizens and persons with certain disabilities who meet specific criteria, has multiple parts with different benefits. The newest addition, Part D, covers prescription drugs.

Part D, which is a voluntary program available to all Medicare beneficiaries, operates like a private health insurance plan. The Centers for Medicare and Medicaid Services (CMS) contracts with private insurance companies to cover the cost of prescriptions filled by commercial pharmacies and approves the formularies, or lists of drugs, covered under Part D.

Ensuring compliance with Part D involves monitoring a wide range of company activities that relate to this program. Examples include procedures for getting products added to formularies, interactions with Pharmacy and Therapeutics (P&T) committees that make formulary decisions, as well as interactions with physicians and promotional activities. In addition, the company must ensure that its Patient Assistance Programs are in compliance with Part D requirements.

Key Criteria for Compliance

- CMS rules for Part D and other Medicare benefits are followed.
- Requests for inclusion on Part D formularies are consistent with company policies and procedures for this process.
- Negotiations and agreements pertaining to commercial formularies are independent of negotiations and agreements pertaining to Part D formularies (and vice versa) to prevent inappropriate contracting practices that may result in increased costs to the government.
- Discounts, rebates, and other price concessions are disclosed to the Part D plan provider, and the provider is advised to report these concessions to CMS in accordance with Part D requirements.
- Interactions with P&T committee members are consistent with company policies and procedures.
Communications and Corrective Actions

Johnson & Johnson companies maintain an open environment in which employees can report, without fear of retaliation, any conduct they know to be or believe to be in violation of the Johnson & Johnson Health Care Compliance guidelines. All reports of misconduct are taken seriously and are thoroughly investigated. If irregularities are found, action will be taken to correct them.

Employees are required to make their concerns known to their supervisors, senior management, Human Resources Department, the Johnson & Johnson Law Department, or other responsible company personnel. Concerns may be presented verbally or in writing. For persons who prefer to remain anonymous or prefer to make a report by telephone, a hotline program is available 24 hours a day, year-round, with services offered in multiple languages.

**US Hotline Program: 1-800-371-2029**

Anonymous allegations can also be submitted online at www.credohotline.com. A list of global hotline numbers is also available on this website.

Conclusion

The Johnson & Johnson Health Care Compliance guidelines reinforce our commitment to adhering to all applicable federal and state laws and industry codes. If you have questions about any topic discussed in this guide, please consult your supervisor, your company’s Health Care Compliance Department, or the Johnson & Johnson Law Department.

**IN ADHERING TO THE REGULATIONS THAT GOVERN HEALTH CARE COMPLIANCE, WE PROTECT OUR CUSTOMERS, OUR COMPANIES, AND OURSELVES.**
Appendix: Laws and Codes Applicable to Health Care Compliance
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Laws and Codes Applicable to Health Care Compliance

**Government Regulations**

**Federal Anti-Kickback Statute**

The Anti-Kickback Statute protects government-funded health care programs (e.g., Medicare and Medicaid) from fraud and abuse. This law prohibits a health care company from providing remuneration in the form of cash or other value to Health Care Professionals in order to induce them to use, prescribe, or purchase its federally reimbursed products or to refer patients to others to use its federally reimbursed products. For example, a sales representative cannot offer a physician a research grant in exchange for the physician’s recommendation that a product be added to a hospital formulary.

**Allowable Activities (Safe Harbors):**

The Anti-Kickback Statute includes several safe harbors, which allow certain marketing and promotional activities despite their potential for violating the statute. Examples of two safe harbors important to our business are the following:

- **Discount Safe Harbor:** Permits companies to discount the prices of products to Customers if the discounts are fully documented and disclosed.

- **Personal Services Safe Harbor:** Protects legitimate fee-for-service agreements (e.g., consulting or training) with physicians and other Health Care Professionals.

**Federal False Claims Act**

**Related Penalties & Provisions**

The False Claims Act is a powerful weapon used by law enforcement agencies to combat health care fraud and abuse. This act prohibits a person from knowingly submitting or causing someone else to submit a fraudulent claim for reimbursement to a government-funded health care program. Manufacturers have been held accountable under the False Claims Act even though the Health Care Professional, rather than the manufacturer, submits the claim to the government.

The False Claims Act has a broad application and has been invoked in cases involving allegations of kickbacks and off-label marketing and promotional activities. Examples of violations include the submission of claims that result in greater payments than are justified, claims for treatments or products that are not administered, and claims for items or services that are not medically necessary.
State Laws

While some states rely on federal laws to govern Health Care Compliance activities within their borders, several states have enacted their own anti-kickback statutes and other regulations that prohibit the giving or offering of anything of value to induce the purchase, prescription, or use of a specific product. In addition, many states have enacted their own laws similar to the federal False Claims Act, which may apply either to state programs or, more broadly, to commercial insurance programs. If you are uncertain about the statutes in a specific state, consult your supervisor or your company’s Health Care Compliance Department.

FDA Regulations for Product Labeling and Promotion

Product Labeling: The term “product label” refers to all printed information (wording and graphics) on the exterior packaging, the product container, and the prescribing information (“PI” or package insert) enclosed with pharmaceutical products or the IFU (instructions for appropriate and safe use) enclosed with medical devices.

Product Promotion: All materials used to promote or advertise pharmaceutical products must be truthful and not misleading and must provide “fair balance” (statements about potential risks or side effects).

Adherence to Approved Indications:
When FDA approves, or clears, a product for marketing, the approval is based on scientific information relating to the treatment of a specific condition or conditions. These conditions are known as “approved indications.”

Health Insurance Portability and Accountability Act (HIPAA)

HIPAA (also known as the Health Insurance Reform Bill of 1996) established new guidelines in many areas related to patient care and individual health insurance coverage. Several elements of this act significantly affect how medical product manufacturers conduct their business.

The Privacy Regulation

Implemented by the US Department of Health and Human Services, the privacy regulation guards the confidentiality of patient health information by restricting how “covered entities” (e.g., physicians, hospitals, and health insurance carriers) can disclose and use this information. Johnson & Johnson companies are committed to cooperating with Customers in their efforts to protect patient confidentiality. (For more information on this topic, please consult the Privacy website (http://privacy.jnj.com).
Health Care Fraud and Abuse Control Program
This program is administered by the US Attorney General and the US Department of Health and Human Services. It coordinates federal, state, and local law enforcement activities in identifying and prosecuting individuals responsible for violations of health care fraud and abuse. Examples of practices found to be illegal include billing for a more expensive procedure than the one actually performed, billing twice for the same procedure, and falsifying diagnoses to obtain reimbursement for a non-reimbursable product. As mentioned in the discussion of the False Claims Act, manufacturers have been found liable for engaging in any activity that results in or influences the filing of a fraudulent claim.

Civil Monetary Penalties
This provision substantially increased the civil monetary penalties and damages for filing false claims with federally funded health care programs.

Centers for Medicare and Medicaid Services (CMS) Programs

Medicaid “Best Price”
Medicaid is a state and federally funded program that provides assistance to low-income individuals and typically reimburses pharmacies directly for filling patient prescriptions for drugs and devices. Medicaid programs cover inpatient and outpatient hospital services as well as physician, laboratory, and nursing home services. Manufacturers must sign a rebate agreement with the Secretary of Health and Human Services in order for their products to be covered by Medicaid. Under this agreement, manufacturers must pay rebates to state Medicaid programs based on the “best price” offered to private purchasers or retail pharmacies.

Medicare
Medicare is a federally funded insurance program for senior citizens with sufficient years of employment, the permanently disabled, and other select groups of individuals. The program includes multiple parts with different benefits.

Part A, known as “hospital insurance,” covers inpatient hospital care, home health care, skilled nursing facility care and hospice services, as well as the cost of drugs and devices within those settings.

Part B is medical insurance that covers physician services, outpatient hospital services, and injectable and intravenous prescription drugs related to a physician service, as well as supplies and durable medical equipment.

Part C provides for a managed care option known as “Medicare Advantage.” Under this program, private managed care plans offer benefits covered by Parts A and B.

Part D covers prescription drugs.
**How Part D Works**

Part D—a voluntary program available to all Medicare beneficiaries—is set up like a private health insurance plan. CMS contracts with private insurance companies to cover the cost of prescriptions filled by commercial pharmacies.

There are two types of Medicare Part D plans: prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA-PDPs). PDPs only cover Medicare prescription drugs and are used with an individual’s traditional “fee-for-service” Medicare. MA-PDPs are managed care plans that cover Medicare prescription drugs in addition to providing all the benefits of Medicare Parts A and B. Once enrolled in a Part D plan, most individuals are responsible for paying a monthly premium, a yearly deductible, and a portion of the price of each prescription filled. Low-income individuals enrolled in Part D may receive additional financial assistance from the government.

Each Part D plan develops a formulary that lists the drugs covered by the plan, and the formulary has to be approved by CMS. Part D plans are expected to solicit manufacturer discounts and rebates for covered drugs and to reflect these discounts in their charges to the government.

**Federal Guidance**

**Office of Inspector General (OIG) Compliance Program Guidance**

In 2003, the US Department of Health and Human Services Office of Inspector General issued guidance for manufacturers to foster an environment of compliance. This initiative, titled “Compliance Program Guidance,” is an “effort to engage the health care community in preventing and reducing fraud and abuse in federal health care programs.” The program contains seven elements recognized as fundamental to a company’s internal Health Care Compliance program:

- The development of written policies and procedures for compliance.
- The appointment of a designated compliance officer and committee.
- The development and implementation of regular education and training programs for all employees.
- The creation and maintenance of open and effective lines of communication between the compliance committee and employees.
- The use of internal monitoring and auditing procedures to identify problem areas.
- The enforcement of standards through well-publicized disciplinary guidelines.
- The development of procedures for prompt response to detected problems and implementation of corrective action.
Industry Codes of Ethics

PhRMA and AdvaMed Codes

As a corporation that encompasses both pharmaceutical and medical device companies, Johnson & Johnson companies adhere to the codes of ethics established by the Pharmaceutical Research and Manufacturers of America (PhRMA), representing research-based pharmaceutical and biotechnology companies, and the Advanced Medical Technology Association (AdvaMed), representing medical device manufacturers.

The PhRMA and AdvaMed codes are intended to protect medical decision-making from improper inducements. Both the PhRMA Code and the AdvaMed Code contain key points pertaining to the following:

- Informing Health Care Professionals about products.
- Providing meals and gifts to Health Care Professionals.
- Providing support to sponsors of continuing medical education (CME), medical conferences, and other forums where scientific information is exchanged.
- Recruiting and training speakers for company-sponsored speaker bureaus.
- Providing scholarships and other educational funds.
- Compensating consultants.

Points Specific to the AdvaMed Code

The training requirements for Health Care Professionals who prescribe and use medical devices are often extensive. Therefore, the AdvaMed Code includes guidance for activities such as facility visits, medical equipment demonstrations, and training.
Resources

Our Credo

Policy on Business Conduct

US Health Care Compliance Framework

Health Care Compliance Regulatory Guidance Documents

Worldwide Office of Health Care Compliance & Privacy (http://wwohccp.jnj.com/)

Johnson & Johnson Law Center Website (http://law.jnj.com/)

Accreditation Council for Continuing Medical Education (www.accme.org)

American Medical Association (www.ama.assn.org)

Centers for Medicare & Medicaid Services (www.cms.hhs.gov)

The Department of Health and Human Services Office of Inspector General
OIG Compliance Program for Pharmaceutical Manufacturers (http://www.oig.hhs.gov)

The US Food and Drug Administration (www.fda.gov)

Pharmaceutical Research and Manufacturers of America (www.phrma.org)

Advanced Medical Technology Association (www.advamed.org)