



| **A PASSION** FOR INTEGRITY

Every Day Health Care Compliance

Code of Conduct



Health Care Compliance Is Everyone's Responsibility

Johnson & Johnson Pharmaceutical Affiliates are 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. The Johnson & Johnson Credo, Policy on Business Conduct and Health Care Compliance guidelines communicate our commitment to putting patients first.

Johnson & Johnson Pharmaceutical Affiliates are committed to compliance with all laws that apply to federal health care programs, such as Medicare and Medicaid, and FDA requirements that govern how we market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products. This means that officers, directors, employees, sales associates and third parties that provide certain promotional, product and managed health care related services to Johnson & Johnson Pharmaceutical Affiliates are required to certify that they have read, understood and will abide by this Code of Conduct. This Code, the Health Care Compliance Framework and 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.

I am happy to be part of Johnson & Johnson, a company that embodies the commitment to shape and improve the quality of care for patients around the world.

A handwritten signature in black ink that reads "Sujata T. Dayal". The signature is written in a cursive style with a large initial 'S'.

Sujata Dayal

VP Health Care Compliance, Pharmaceutical Sector



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

Adapted from the US Department of Health and Human Services Office of Inspector General: Publication of OIG Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry. *Federal Register* 64 (128):36368, July 6, 1999, and the US Department of Health and Human Services Office of Inspector General: OIG Compliance Program Guidance for Pharmaceutical Manufacturers. *Federal Register* 68 (86):23731, May 5, 2003.



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If you have questions about the information presented here or compliance with current state laws or regulations, please contact the Compliance Officer or the Law Department. You may also visit the Pharmaceutical Sector Health Care Compliance (PGHCC) website (<http://pharmportal.jnj.com/portal/jnj/pharmportal/healthcarecompliance>) or the Law Center website (<http://lawcenter.jnj.com>).





Following the Code

This Code of Conduct is intended 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.

You are required to follow these principles and uphold 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.

Employees must report to their designated Compliance Officer or other appropriate company personnel suspected violations of any federal health care program or FDA requirements, or of Johnson & Johnson Pharmaceutical Affiliates' policies and procedures. Employees are required to disclose to the company any conduct or proceedings that would result in their becoming debarred or excluded from doing business with the government. Failing to immediately disclose such conduct or proceedings is considered a serious policy violation and will result in appropriate corrective action.

All employees of Johnson & Johnson Pharmaceutical Affiliates who interact in any way with health care professionals, or with customers, who purchase health care products, will be trained to understand and abide by this Code and our Health Care Compliance guidelines. Completion of this training and certification is considered a mandatory job requirement. Failure to comply with this job

requirement is considered a serious policy violation and will result in the appropriate corrective action.

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 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 company and ourselves.

Using the Code of Conduct

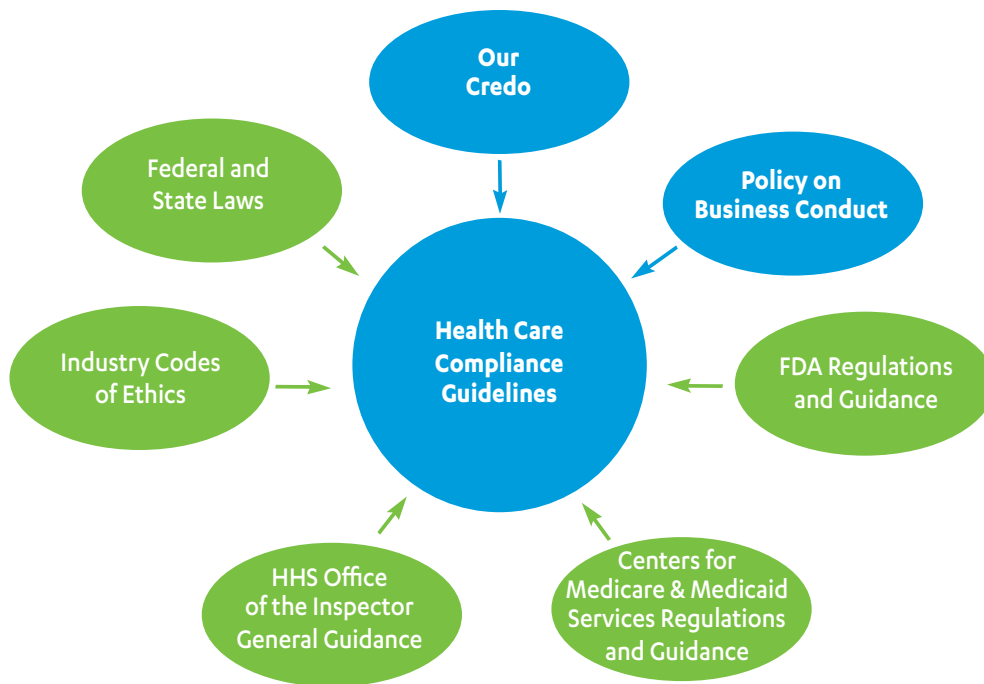
This Code contains discussions of the three fundamental principles of Health Care Compliance along with examples of our corporate guidelines for upholding them. Each of these principles is supported by existing government laws and industry codes, which are presented in detail in the Appendix.

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 Pharmaceutical Affiliates Health Care Compliance guidelines.



The Health Care Compliance framework defines our commitment as a corporation and as individuals to abide 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

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 and increase transparency of our relationships with Health Care Professionals. 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 Pharmaceutical Affiliates are 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. It has established a code of ethics intended to protect medical decision-making from improper financial incentives. The PhRMA code contains 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 Pharmaceutical Affiliates 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

- Johnson & Johnson Pharmaceutical Affiliates 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, note pads, 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. Federal and some state laws require manufacturers to report certain payment transfer of value to Health Care Professionals. Consult your Health Care Compliance Department for more information on this subject.

Fee-for-Service Agreements

Johnson & Johnson Pharmaceutical Affiliates 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 Continuing Medical Education (CME).
- Product-related scientific information is limited to approved labeling.
- Program content to be used 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 the approved promotional speaker event.
- Attendance by spouses, children, or guests is not permitted.

Educational Grants and Fellowships

Johnson & Johnson Pharmaceutical Affiliates 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, 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 Legal, as appropriate.

Under the 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 Pharmaceutical Affiliates 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 any Johnson & Johnson Pharmaceutical Affiliates.

- 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.

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inducements.

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.

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 any Johnson & Johnson Pharmaceutical Affiliates.
- 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.

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

A Johnson & Johnson Pharmaceutical Affiliate 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 and is done only to HealthCare Professionals in an approved Company call plan.
- Samples may be distributed to HealthCare Professionals licensed by law to prescribe and receive such drugs and only in response to a written request.
- 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.

Scientific Research

Company-Sponsored Research

Johnson & Johnson Pharmaceutical Affiliates 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

- Research pertains to a disease state of interest to the company and fulfills a legitimate scientific need.
- Company-initiated sponsorships for research studies are reviewed and approved by the company's designated Medical/Clinical Department.
- Investigators are selected on the basis of their expertise on the subject studied.
- Johnson & Johnson Pharmaceutical Affiliates 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.

- Johnson & Johnson Pharmaceutical Affiliates own the data generated by the study and has full rights to it.
- Study subjects are provided written informed consent documents.

Investigator-Initiated Studies

Some Johnson & Johnson Pharmaceutical Affiliates 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 Johnson & Johnson Pharmaceutical Affiliates' 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.

Clinical Trial Results Disclosure

We are committed to transparent and ethical disclosure of the results of our company-sponsored clinical research. In that regard, we support the overall principles of greater clinical trial data transparency, including registration and disclosure of clinical trial results in external registries, and publication of results in peer reviewed journals, as outlined below.

Registration and Disclosure of Clinical Trial Results

- Johnson & Johnson Pharmaceutical Affiliates publicly discloses information about their clinical trials in external public registries, such as clinicaltrials.gov. Accordingly, we will register and post results of company-sponsored clinical trials conducted in patients (Phase 1b through phase 4) on clinicaltrials.gov in accordance with specified timelines and other applicable legal requirements.

Publication of Clinical Trials Results in Peer-Reviewed Journals

- We seek to publish, in peer-reviewed journals, results from all company-sponsored pharmaceutical studies in patients, as well as medically or scientifically important pharmaceutical research

from discontinued clinical research programs, prospective observational studies including registries, analyses from subscribed databases and health economics and outcomes research programs.

Publications and Authorship

We must abide by established codes of ethics, only present information that is complete, timely and accurate and ensure scientific rigor in all our activities.

Key Criteria for Compliance

- Adhere to the scientific method, be objective and scientifically balanced and present support and balanced conclusions
- Be non-promotional
- Disclose all relevant contributions to content and conflicts of interest, and may not utilize “ghost writers”

- Adhere to International Committee of Medical Journal Editors (ICMJE) requirements for authorship including: substantial intellectual contributions, participation in article drafting or critical revision and final version approval.
- Disclosure of financial support provided by a Johnson & Johnson Pharmaceutical Affiliate.

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

- Health Care Compliance Department is involved in decisions related to hiring government Health Care Professionals as consultants.

- Johnson & Johnson Pharmaceutical Affiliates 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.

Johnson & Johnson Pharmaceutical Affiliates are committed to the development of new products and technologies.



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 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 Pharmaceutical Affiliates must adhere to federal requirements for the marketing and promotion of products—drugs and biologics—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 Promotional Review Committee, which typically includes representatives from various departments, such as Medical/Clinical, Regulatory, Marketing and Legal, as appropriate.

Educational Programs

Johnson & Johnson Pharmaceutical Affiliates 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 and Health Care Compliance Departments, and the Law Department, as appropriate.

Under the Health Care Compliance framework, 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 Continuing Medical Education (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 Law Department, as appropriate.
- 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 Johnson & Johnson Pharmaceutical Affiliates do not take part in content development or selection of participants or audience.

Key Criteria for Compliance

- Content is non-promotional, balanced and educationally focused.
- Johnson & Johnson Pharmaceutical Affiliates remain "hands off" in regard to program content unless information on reimbursement or practice management is included, in which case this information is reviewed by the Law Department, as appropriate.
- 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 a Johnson & Johnson Pharmaceutical Affiliates. 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 Pharmaceutical Affiliates 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 a Johnson & Johnson Pharmaceutical Affiliate.

Key Criteria for Compliance

- The program content for Johnson & Johnson Pharmaceutical Affiliates products 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.).

- Johnson & Johnson Pharmaceutical Affiliates remain “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 Law Department, as appropriate.
- 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 a Johnson & Johnson Pharmaceutical Affiliates. 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.

Patient/Provider Educational Materials

In certain circumstances, Johnson & Johnson Pharmaceutical Affiliates 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.

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

Some Johnson & Johnson Pharmaceutical Affiliates have 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. Johnson & Johnson Pharmaceutical Affiliates maintain a database that tracks these requests and the company reviews these requests regularly.

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.





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, that reimbursement is based on accurate pricing information and that the government pays the right price for products it purchases.

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 Pharmaceutical Affiliates 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 Pharmaceutical Affiliates' products.

Reimbursement

Key Criteria for Compliance

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

Customers that they may be required to report the value of the discount.

Government Pricing Calculations

Johnson & Johnson Pharmaceutical Affiliates submit pricing calculations to the US Government on a monthly and/or quarterly basis for Medicare Part B covered drugs, Medicaid and other Government pricing programs. These calculations are based on pricing and discounting information associated with commercial sales transactions. The Government relies on this information to determine reimbursement rates and to obtain rebates or to establish pricing for our products.

Key Criteria for Compliance:

- Johnson & Johnson Pharmaceutical Affiliates accurately calculate and report all required pricing calculations.
- Johnson & Johnson Pharmaceutical Affiliates charge Government entities an amount for our products that strictly adheres to the requirements of the applicable programs.
- Johnson & Johnson Pharmaceutical Affiliates pay all rebates due to government entities in a timely manner

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.



Johnson & Johnson Pharmaceutical Affiliates maintain an open environment in which employees must report, without fear of retaliation, any conduct they know to be or believe to be in violation of Health Care Compliance framework or any federal health care program or FDA requirements. All reports of misconduct are taken seriously and are thoroughly investigated. If irregularities are found, action will be taken to correct them. No one may be punished for making a good faith report about possible compliance violations.

Employees are required to make their concerns known to their supervisors, senior management, Human Resources Department, the Law Department, or other responsible company personnel. Concerns may be presented verbally or in writing. You may report violations to the Health Care Compliance Office by calling your designated HCC officer. For persons who prefer to remain anonymous, a hotline program is available 24 hours a day, year-round, with services offered in multiple languages.

US Employee Hotline:
1-800-371-2029. A list of global hotline numbers is available at www.credohotline.com.
Anonymous allegations can also be submitted online at this website.



CONCLUSION



The Johnson & Johnson Pharmaceutical Affiliates Code and 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, the Health Care Compliance Department, or the Law Department.



Johnson & Johnson Pharmaceutical Affiliates must adhere to Federal requirements for the marketing and promotion of products—drugs and biologics—solely for the indications approved by FDA and listed in the product labeling.





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 the 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 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 Pharmaceutical Affiliates 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](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 Code and DTC Guiding Principles

Johnson & Johnson Pharmaceutical Affiliates adhere to the code of ethics and Direct to Consumer (DTC) guidelines established by the Pharmaceutical Research and Manufacturers of America (PhRMA).

The PhRMA code is intended to protect medical decision-making from improper inducements. It contains 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 DTC Guiding Principles

DTC communications must comply with FDA regulations. In general, the FDA requires all DTC information:

- To be accurate and not misleading.
- To make claims only when supported by substantial evidence.
- To reflect balance between risks and benefits.
- To be consistent with the FDA-approved labeling.

Beyond this, key points for DTC advertisements pertain to the following:

- Increasing awareness about diseases.
- Educating patients about treatment options.
- Motivating patients to contact their physicians and engage in a dialogue about health concerns.
- Increasing the likelihood that patients will receive appropriate care for conditions that are frequently under-diagnosed and under-treated.
- Encouraging compliance with prescription drug treatment regimens.

Patient Protection and Affordable Care Act of 2010

Physician and Teaching Hospital Payments Sunshine Act

Effective August 2013, pharmaceutical manufacturers were required to track and report to the US Department of Health and Human Services payments and other transfers of value to physicians and teaching hospitals and ownership or investment interests held by physicians in the manufacturer, other than through publicly traded shares.

Anything of Value: The law requires manufacturers to report certain transfers of value to physicians or teaching hospitals and contains specific exclusions. These exclusions include, but are not limited to product samples intended for patient use, certain educational materials and indirect payments where the manufacturer does not know the identity of the physician or teaching hospital, to name a few.

Publication of Specific

Information: In 2014, the US Department of Health and Human Services made the information reported by manufacturers publicly available through a searchable website. This information included many elements reported by manufacturers, such as the recipient's name and address, the date and amount of the payment and a description of the form of payment or transfer of value.

Resources

Our Credo

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 (www.oig.hhs.gov)

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

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

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