

ZIMMER BIOMET

Moving You Forward.™

U.S. and Canada Sales Distributor and Direct Territory Compliance Manual

Direct Questions to:

Compliance.AMER@ZimmerBiomet.com

Contents

Introduction....4

Key Definitions....5

PART 1: General Compliance Principles....7

Fundamental Elements of an Effective Compliance Program....7

Element 1: Implement Written Policies, Procedures, and Standards of Conduct....7

Element 2: Designate a Compliance Officer and Compliance Committee....8

Element 3: Conduct Effective Training and Education....8

Element 4: Develop Effective Lines of Communication....9

Element 5: Enforce Standards through Well Publicized Disciplinary Guidelines....9

Element 6: Conduct Internal Monitoring and Auditing....9

Element 7: Respond Promptly to Detected Offenses through Corrective Action....10

PART 2: Zimmer Biomet Compliance Requirements....11

A. Employee and Sales Representative Screening....11

B. Conflict of Interest Disclosures....11

Disclosing Conflicts of Interest....11

Avoiding a Conflict of Interest....12

Sales Personnel with Active Medical License....12

Conflict of Interest with an HCP....13

C. Document Retention....14

Accurate Books and Records....14

PART 3: Interactions with HCPs and Public Officials....15

A. Prohibited Arrangements....15

Gifts and Entertainment....16

B. Meals and Transportation....16

HCP Meal....16

HCP Dinner Meal Limit Increase for Certain High-Cost Cities....17

Group and Business Meal Expense Payments....17

HCP Transportation....17

C. Product Support Materials and Educational Items....18

Journal Reprints....19

Anatomical Models....19

Etched Samples / Demonstration Products....19

Textbooks 20
D. HCP Consultant Identification and Selection 20
E. Zimmer Biomet Medical Education 20
F. Sales and Product Support Activities 21
Cadaveric Practice Workshop 21
HCP Consulting at Product Support Activities 21
Product Support Location and Timing 21
Product Support Meals 21
Medical Institution Training – Product Support Requests 22
G. Evaluation Products 23
PART 4: Commercial Sponsorships, Charitable Donations and Educational and Research Grants 23
Commercial Sponsorship and Exhibit Booth Space Purchases 23
Badge and Registration Fees 25
Journal Clubs and Grand Rounds 25
Charitable Donations and Promotional Sponsorships 25
Examples of Permitted Charitable Contributions 26
Charitable Product Donations - US 27
Charitable Product Donations – OUS (Medical Missions) 27
Educational Grants and Research Grants 27
PART 5: Advertising 28
PART 6: Social Media Guidelines 29
PART 7: Payer Reimbursement and Coding Guidance 29
Specialty Distribution Channels 30
PART 8: Privacy and Confidentiality 30
PART 9: Transparency Reporting 32
PART 10: State Law Restrictions 33
Part 11: Zimmer Biomet Compliance Monitoring and Auditing 34
Part 12: Non-Compliance 34
Appendix A : Compliance Contact Information 35
Appendix B: HCP Dinner Meal Limit Increase for High-Cost U.S. Cities 36

Introduction

This U.S. and Canada Sales Distributor and Direct Territory Compliance Manual (the "Manual") explains Zimmer Biomet's compliance requirements and expectations for anyone who contracts with or works on behalf of Zimmer Biomet in connection with the promotion or sale of its products within the United States and Canada.

Zimmer Biomet is committed to maintaining exemplary corporate conduct and the highest ethical standards. Zimmer Biomet developed this Manual to ensure that Distributors, Direct Territories, their employees, and sales representatives/agents adhere to the same ethical standards that we have established for Zimmer Biomet.

Each Direct Territory and Distributor is required to abide by this Manual and Zimmer Biomet's Code of Business Conduct and Ethics. Direct Territories and Distributors must ensure new personnel (*e.g.*, employees and sales representatives) complete required Code of Conduct training/certification within sixty (60) days of commencing employment or affiliation with the Distributor. A copy of the Code of Conduct can be found on the Zimmer Biomet website. Training will be issued via the electronic learning system ILEARN.

On an annual basis, Direct Territories, Distributors and their personnel will be asked to certify in writing or electronically that they have received, read, understood, and shall abide by this Manual and the Zimmer Biomet Code of Conduct. The final page of this Manual serves as a certification page that Direct Territory/Distributor must complete and return to Zimmer Biomet. Direct Territories and Distributors acknowledge receipt of this Manual and certify that all personnel will abide by the requirements within it by completing the certification page.

If any of the compliance requirements in the Manual are inconsistent with the terms and conditions of the agreement between the Zimmer Biomet Distributor (inclusive of employees, sales agents, or independent contractors) and Zimmer Biomet, or if a conflict exists between the Manual and an applicable law, regulation, or industry code, the most restrictive requirement will apply. If you have questions about the Manual, please contact Zimmer Biomet Compliance using the contact information provided in Appendix A. If any exception to the Manual is needed, such exception must be approved in writing by Zimmer Biomet Compliance prior to any deviation for the Manual requirements. To request an exception or if you have questions, please contact the Global Compliance Team at globalcompliance@zimmerbiomet.com. Please indicate specific details regarding the nature and business necessity for the request.

Zimmer Biomet, in its sole discretion and at any time, reserves the right to amend, modify, or otherwise change this Manual as needed and will provide notice of relevant changes to Distributors and their Compliance Liaisons.

The information contained in this Manual does not constitute legal advice. Each Distributor is responsible for staffing decisions, training and management of its personnel, and for ensuring (and for determining the means and manner for achieving) their organization's compliance with Zimmer Biomet policies, procedures, applicable industry codes, and any applicable federal/state/local laws.

Key Definitions

The definitions provided are not intended to and do not provide a comprehensive explanation of all criteria, factors, or regulations pertaining to any given term. The definitions are supplements to and must be used in conjunction with the appropriate explanations set forth with the Manual.

Close Family Member: Includes parents, siblings, spouses or partners, children, grandparents, grandchildren, step or half-relatives, in-laws, or any other individuals who reside in the same household or have a close relationship (*i.e.*, girlfriend, boyfriend, etc.).

Demonstration Product: A no-charge not for human use product (typically unsterilized) or replica that is used for HCP and patient education and awareness.

Distributor: An independent sales entity that promotes and sells Zimmer Biomet products.

- Distributor personnel may include:
    - Distributor Owner(s) and Officers
    - Distributor Employees (office administration, direct sales representatives, etc.)
    - 1099 Independent Sales Representative(s) and other agents of Distributor

  "Distributor" and "Distributor personnel" may be used interchangeably throughout this Manual.

Direct Territory: A sales entity directly managed by Zimmer Biomet employees that promotes and sells Zimmer Biomet products.

- Direct Territory personnel may include:
    - Zimmer Biomet Territory General Manager
    - Zimmer Biomet Office Manager
    - Zimmer Biomet Sales Representative(s)
    - 1099 Independent Sales Representative(s)

  "Distributor" and "Direct Territory" are collectively referred to as "Distributor". Any relevant differences associated with the two sales models are highlighted in the applicable sections within this Manual.

Evaluation Product: A no-charge consumable or durable product provided to an HCP, typically for patient care, to allow the HCP to assess the appropriate use and functionality of the product and/or technology. Durable products are typically multiple-use products, such as capital equipment and instruments which must be returned to Zimmer Biomet within an evaluation time period that does not exceed 90 days.

Healthcare Professional ("HCP"): An individual, entity, or employee of such entity, within the continuum of care of a patient, which may purchase, lease, recommend, use, prescribe, or arrange for the purchase or lease of Zimmer Biomet products and services.

Public Official: Any officer, agent, employee, or any person acting for or on behalf of: (1) a government, including any legislative, administrative, or judiciary branch of such government; (2) any department, agency, or instrumentality of a government, including wholly or majority state-owned or controlled enterprises; (3) any public international organization, such as the United Nations or World Health Organization; (4) a political party (including the political party itself); or (5) any candidate for political office. In many instances, HCPs who work at or are otherwise affiliated with public hospitals or universities may be considered Public Officials.

Zimmer Biomet Products: Any implants, instruments, equipment, services, supplies or consumable products that are manufactured, sold, leased, rented or distributed by Zimmer Biomet or any of its affiliates.

Value-Add Item[1]: An item that includes anything of value – including products, services, and funding of any nature – that is offered at no charge or at a discount as part of a tender submission, in addition to and apart from the Zimmer Biomet Products and services that are subject to the tender.

[1] Applies to Canada only

PART 1: General Compliance Principles

Zimmer Biomet Direct Territories and Distributors are required to conduct and maintain operations in strict compliance with all applicable laws, regulations, and industry codes and in a manner consistent with the highest standards of honesty, integrity, fair dealing, and ethical conduct. This section provides Direct Territories and Distributors with tools to establish a Compliance Program that fosters a culture of compliance and encourages ethical conduct in the promotion and delivery of Zimmer Biomet products and services.

Fundamental Elements of an Effective Compliance Program

The Office of the Inspector General within the Department of Health and Human Services has identified seven (7) fundamental elements of an effective compliance program. The seven (7) fundamental elements are described as follows:

1) Implement written policies, procedures, and standards of conduct;

2) Designate a compliance officer and compliance committee;

3) Conduct effective training and education;

4) Develop effective lines of communication;

5) Enforce standards through well-publicized disciplinary guidelines;

6) Conduct internal monitoring and auditing; and

7) Respond promptly to detected offenses through appropriate corrective action.

Zimmer Biomet's Corporate Compliance Program encompasses these seven (7) elements. Each Distributor is encouraged to build their own Distributor Compliance Program based on the elements of an effective compliance program, the general principles and policy statements set forth in this Manual, and the Zimmer Biomet Code of Conduct.

Element 1: Implement Written Policies, Procedures, and Standards of Conduct

A Distributor Compliance Program should include policies and procedures designed to operationalize this Manual and reflect local laws, practices, and regulations. Distributor policies or procedures, such as those pertaining to expense reimbursement, may not contradict or minimize the effectiveness of any portion of this Manual. Distributor certification to this Manual is the foundation of a Distributor Compliance Program.

This Manual is not intended to be comprehensive of all federal, state, and local laws and regulations. Distributors should consult with qualified independent legal counsel for further questions regarding a Distributor's obligations and responsibilities under federal, state, and local laws and regulations.

Direct Territories must collaborate and seek guidance directly from Zimmer Biomet Legal and Compliance regarding obligations and responsibilities under applicable federal, state, and local laws and regulations.

Element 2: Designate a Compliance Officer and Compliance Committee

Each Direct Territory and Distributor must designate a **Compliance Liaison** and **Spend Gatekeeper** on the Compliance Program Certification form located at the end of this Manual. The Compliance Liaison and Spend Gatekeeper are the foundation to establish a compliance officer and compliance committee for a distributorship.

The name, title and contact information for the Compliance Liaison and Spend Gatekeeper should be provided to Zimmer Biomet Compliance upon nomination, approval, or change.

The Compliance Liaison and Spend Gatekeeper may be the same person.

Compliance Liaison

A **Compliance Liaison** is an individual appointed by the Distributor principal or Territory General Manager to manage the entity's compliance program and serve as the primary point of contact for Zimmer Biomet Compliance. A Compliance Liaison is also expected to stay informed about and reinforce Zimmer Biomet Compliance policies and procedures.

Spend Gatekeeper

A **Spend Gatekeeper** is an individual responsible for managing, tracking and disclosing to Zimmer Biomet all relevant transfers of value provided to HCPs and healthcare institutions in accordance with applicable federal and state transparency reporting laws.

Element 3: Conduct Effective Training and Education

The Distributor and Compliance Liaison will ensure that all owners, employees, sales representatives, independent agents and their subcontractors (*i.e.*, Distributor personnel) working on its behalf complete required Zimmer Biomet compliance training made available through:

- Zimmer Biomet websites (*i.e.*, The Circle, SalesHub)
- Learning management systems (*i.e.*, iLearn)
- Webcasts (*i.e.*, Compliance Roundtables, New Sales Representative Onboarding Calls)
- In-person meetings (*i.e.*, distributor site visits from Zimmer Biomet Compliance)
- Compliance bulletins
- Guidance documents
- Any other medium provided by Zimmer Biomet Compliance and/or relevant functional corporate departments.

Training Records and Roster: Direct Territories and Distributors should maintain appropriate records of completion of training, as well as training materials. Distributors must frequently review their roster of Distributor personnel and promptly communicate the names of new Distributor personnel to Zimmer Biomet for inclusion in applicable Zimmer Biomet rosters, trainings, communications, and learning management system records.

New Distributor Personnel Training: Direct Territories and Distributors should ensure all personnel undergo the required new distributor personnel compliance training within sixty (60) days of employment or affiliation with the Distributor. During that initial sixty (60) day period, new distributor personnel must be trained on this Manual and the Zimmer Biomet Code of Business Conduct.

Element 4: Develop Effective Lines of Communication

An effective compliance programs will prevent, detect and remediate compliance risk. Territory Managers, Distributors, Compliance Liaisons, and Spend Gatekeepers are all responsible for ensuring effective lines of communication, both with Zimmer Biomet Compliance and among distributor personnel. This responsibility includes communicating any updates to Distributor Personnel to Zimmer Biomet and consistently communicating and enforcing Zimmer Biomet Compliance policies and procedures with all Distributor personnel. Access to this Manual and other applicable Zimmer Biomet policies, procedures and guideline documents should be made available to all Distributor Personnel through Distributor designated communications and information repositories.

Direct Territory personnel can access applicable Zimmer Biomet policies, procedures, and guideline documents through Zimmer Biomet's established information repositories (*e.g.*, The Circle).

Element 5: Enforce Standards through Well Publicized Disciplinary Guidelines

Each Distributor is encouraged to develop, adopt, and follow their own set of disciplinary and/or corrective action guidelines. It is imperative that each Distributor carefully documents these guidelines and enforcement of the guidelines.

Direct Territory personnel are required to escalate non-conformances and disciplinary matters to Zimmer Biomet Legal, Compliance and/or Human Resources.

Element 6: Conduct Internal Monitoring and Auditing

Distributors should review their business practices related to the promotion and sale of Zimmer Biomet products. The Compliance Liaison should review areas of compliance including, but not limited to:

- Training
- Credentialing
- HCP Interactions
- Product Promotion
- Product Support/Activities
- Product Orders/Paperwork
- Product Evaluations/Demonstration Product
- Charitable Donations
- Exhibit/Promotional Fees
- Facility Fees
- Privacy and Confidentiality
- Conflicts of Interest
- Travel and Expense Reimbursements
- HCP Spend/Transparency Reporting

Direct Territory personnel are required to report review findings to Zimmer Biomet Compliance and/or Legal in a timely manner.

Element 7: Respond Promptly to Detected Offenses through Corrective Action

Detection and Corrective Action

The Distributor, Compliance Liaison, and Spend Gatekeeper are responsible for prompt detection of violations of ethical issues and taking appropriate corrective actions to address the same.

Reporting Detection to Zimmer Biomet

Distributors must notify Zimmer Biomet of any known or suspected violations of any law pertaining to the operations of the Distributor's business. Distributors must also notify Zimmer Biomet of any known or suspected violations of any healthcare or medical device regulation, industry code, government health care program requirement, Zimmer Biomet's Code of Conduct, or the requirements in the Manual, either through Zimmer Biomet Compliance or the Speak Up Hotline (see Appendix A).

Confidentiality

To the extent allowed by applicable laws and regulations, reports of violations will be treated as confidential and be used only for the purpose of addressing the specific matter reported.

Prohibition Against Retaliation

Zimmer Biomet prohibits retaliation against anyone who makes a good faith report of a known or suspected concern. "Good Faith" does not mean that the individual has to be right, but it does mean that the individual believes he or she is providing truthful information. Individuals who believe they have been subjected to retaliation by Zimmer Biomet should report the situation to Compliance or through the Speak Up Hotline.

Cooperation with Internal Investigations

Distributors and Direct Territory personnel must cooperate with internal investigations by responding to requests for information; making owners, employees, sub-distributors, agents and representatives involved in Zimmer Biomet business available for interviews; implementing controls and internal financial policies; and providing certifications as may be required by Zimmer Biomet.

PART 2: Zimmer Biomet Compliance Requirements

A. Employee and Sales Representative Screening

Direct Territory	Excluded Parties Screening for **W2 employees** is conducted by **Zimmer Biomet Corporate HR** as part of the employee background check process. **1099 Sales Representatives** are screened as part of the Zimmer Biomet **Accounts Payable Process** (TIN Check Payee Verification). Such screening includes checking to ensure the name of the individual does not appear on: • HHS – OIG's List of Excluded Individuals and Entities at Exclusions | Office of Inspector General | U.S. Department of Health and Human Services (hhs.gov) • General Services Administration Excluded Persons List System at SAM.gov | Exclusions
Distributor	Excluded Parties Screening for **all Distributor personnel and Sales Representatives** should be conducted by the Distributor **prior to contracting** with distributor personnel. Such screening includes checking to ensure the name of the individual does not appear on: • HHS – OIG's List of Excluded Individuals and Entities at Exclusions | Office of Inspector General | U.S. Department of Health and Human Services (hhs.gov) • General Services Administration Excluded Persons List System at SAM.gov | Exclusions

If it is determined, pursuant to this Section, that an individual or entity has been convicted, excluded, debarred, suspended, sanctioned, or is otherwise ineligible to participate in a Federal Healthcare Program or Governmental procurement or non-procurement program, the Direct Territory or Distributor may be required to terminate the employee or independent contractor. At a minimum, the Distributor shall immediately notify Zimmer Biomet Compliance, remove such individuals or entities from all responsibilities relating to any of Zimmer Biomet's business operations and terminate the affiliation of any such individual or entity with Zimmer Biomet.

B. Conflict of Interest Disclosures

Disclosing Conflicts of Interest

A conflict of interest may arise when Distributor personnel personal interests have the potential to influence, interfere with, or appear to interfere with his/her ability to carry out his/her obligations under the Manual and/or his/her agreement with Zimmer Biomet. During the term of the business relationship between the Distributor and Zimmer Biomet, Distributor and Distributor

personnel must disclose and mitigate any direct or indirect activity in which an actual or potential conflict of interest might arise.

Direct Territory	Direct Territories must report all possible conflicts of interest to Zimmer Biomet Compliance. Conflict of interest disclosures should occur prior to hiring; re-screening/updated disclosures must be conducted annually. Conflict of interest disclosures should be documented, and Zimmer Biomet may periodically audit the results of these screenings and disclosures. All W2 sales personnel are required to disclose conflicts each year within the annual iLearn Training Module. Any 1099 sales personnel must report conflicts using the Conflicts of Interest Disclosure Form. Disclosures should occur annually using the disclosure form. Distributor personnel should reach out to Zimmer Biomet Compliance if uncertain as to whether a conflict of interest exists in a particular situation.
Distributor	Distributors are required to ask all personnel to disclose potential conflicts of interest. Conflict of interest disclosures should occur prior to hiring; re-screening/updated disclosures must be conducted annually. Conflict of interest disclosures should be documented, and Zimmer Biomet may periodically audit the results of these screenings and disclosures. All 1099 sales personnel must report conflicts using the Conflicts of Interest Disclosure Form Disclosures should occur annually using the disclosure form. Distributor personnel should reach out to Zimmer Biomet Compliance if uncertain as to whether a conflict of interest exists in a particular situation.

Avoiding a Conflict of Interest

To avoid potential conflicts of interest when engaging Distributor personnel or other vendors, Distributor must (at a minimum) abide by the following guidelines:

- Any business relationship with any Distributor personnel or other vendor must be memorialized in advance by written agreement, specifying the particular services to be provided and containing other appropriate provisions sufficient to ensure Distributor and Distributor Personnel compliance (and vendor, as applicable) with the obligations set forth in this Manual.
- If Distributor or any Distributor personnel promote or sell items other than Zimmer Biomet's products, the individual will not condition any discount on any such other item on the purchase of Zimmer Biomet's products.
- Distributor may not have HCP ownership. ***(See Part 3: Interactions with HCPs and Public Officials)***
- Distributor may never hire or engage (or otherwise engage or participate in any sort of investment, commercial or other business relationship with) an HCP, or any other Distributor personnel or other vendors for the implicit or explicit purpose of inducing sales.

Sales Personnel with Active Medical License

Sales personnel may maintain an active medical license obtained prior to joining Zimmer Biomet. If a sales employee holds an active medical license, the following requirements apply:

- The individual may hold an active license but must not be actively practicing and must have no direct affiliation with a customer.
- Upon hire, the individual must complete a *Conflict of Interest (COI) disclosure*, identifying their HCP status and any actual or potential conflicts. If remediation is required, Compliance will work directly with the distributor to establish an appropriate plan.
- This disclosure must be completed annually to capture any changes.
- Compensation for the role must not include commissions or incentives tied to direct selling activities.
- ***Disclosure is required if sales personnel hold an active medical license – and is therefore considered a healthcare professional (HCP).***

Conflict of Interest with an HCP

Zimmer Biomet **strongly discourages** Distributors from hiring or otherwise engaging Distributor personnel or other vendors who have a **Close Family Member** who is an HCP. Where Distributor personnel have a Close Family Member who is an HCP, the Distributor personnel's private interest (which includes the interests of that family member) may interfere with his/her ability to carry out his/her obligations under the Manual and/or his/her agreement with Zimmer Biomet. Family or other close relationships may never be used to unduly influence purchasing decisions by HCPs and Public Officials.

If a Distributor chooses to hire or otherwise engage Distributor personnel or other vendors who have a Close Family Member who is an HCP, Distributor should consider, among other factors, (i) whether the Distributor personnel or other vendor has the requisite skills for the position or job,

(ii) whether the Distributor personnel or other vendor is the most qualified applicant or bid for the position or job, (iii) whether the Distributor personnel or other vendor's compensation is commensurate with the required duties or assignment, and (iv) whether the related HCP was involved in recommending the employee, independent agent, or vendor.

If after conducting the analysis above, a Distributor decides to hire or otherwise engage Distributor personnel who have a related HCP, Distributor may never allow the Distributor personnel to (i) promote or sell Zimmer Biomet products to, or for the use of the related HCP, if the related HCP is in a position to influence, opine, or make decisions regarding Zimmer Biomet products, or (ii) receive any compensation in connection with such sales.

The Distributor must not permit the Distributor personnel related to an HCP or an HCP's Close Family Member to promote or sell Zimmer Biomet products to any members of the related HCP's practice group unless approved by Zimmer Biomet Compliance in writing.

C. Document Retention

Distributors must maintain all records that may relate to the sale and promotion of Zimmer Biomet products, any topics covered in the Distributor Compliance Program, and/or any documents required under this Manual.

Distributors must maintain the following documents:

- Expense Reimbursement forms, receipts, and other supporting documentation;
- Distributor Compliance Program Manual and Certification;
- Training Records;
- All forms and related correspondence for approved financial arrangements (*e.g.*, contributions to non-profits, charitable fundraising, booth space, and badge fees with the applicable supporting documentation;
- All payment records of any kind relating to financial arrangements (*e.g.*, credit card statements, ledger entries, invoices, receipts);
- Monthly HCP Spend documentation (agendas, presentations, sign-in sheets, receipts with line item detail, etc.);
- Complete documentation related to exclusion screening of Distributor personnel;
- Complete documentation related to conflict of interest disclosures and screenings;
- Documentation from any review activities;
- Documentation related to investigation of potentially non-compliant activities and corrective actions.

Direct Territories are required to follow Zimmer Biomet document retention policies.

Accurate Books and Records

As a regular part of its global corporate compliance program and pursuant to its contractual audit rights, Zimmer Biomet periodically conducts audits and monitoring activities of its Distributors.

In addition to the documents listed above, Distributors must maintain books and records that accurately and fairly reflect in reasonable detail all transactions relating to Zimmer Biomet business and provide Zimmer Biomet, or a third party designated by Zimmer Biomet, access during ordinary business hours and as may be reasonably necessary to perform audit or monitor activity work.

Books and records related to Zimmer Biomet business include, but are not limited to, documents and information relating to:

- Marketing, promotion, and/or sale of Zimmer Biomet products;
- Any type of payment to and relationship with any HCP and/or third party relating to or benefitting the Zimmer Biomet business; and
- Anything of value provided to any HCP, customer, and/or third party in relation to the Zimmer Biomet business.

PART 3: Interactions with HCPs and Public Officials

Distributors and Distributor personnel are obligated, through their association with Zimmer Biomet, to engage HCPs in an ethical and compliant manner. Such engagements must be conducted in accordance with Zimmer Biomet's Compliance policies, procedures, standards of conduct, the requirements and expectations outlined in this Manual, and the Distributor's agreement with Zimmer Biomet.

A. Prohibited Arrangements

Zimmer Biomet Direct Territories and Distributors may not offer, promise, provide, or authorize giving anything of value – directly or indirectly – to anyone (including HCPs and public officials) in exchange for an improper business advantage (*i.e.*, improper payment.) The term "improper payment" applies to: (1) anything that has value or is perceived to have value to the recipient; and (2) is used or intended to obtain or retain an improper business advantage. **Improper payments may take the form of, but are not limited to, direct or indirect financial payments, meals, travel, gifts, entertainment, donations, grants, sponsorships, consulting arrangements, employment, and/or offers of employment.**

Zimmer Biomet's general prohibition on financial arrangements with HCPs and improper payments to HCPs is broad and is intended to prevent a violation of the federal Anti-Kickback Statute, False Claims Act, and/or other applicable codes, laws, rules and regulations.

By way of example, Direct Territory and Distributor personnel are prohibited from engaging in the following financial arrangements:

- Payments of any kind directly or indirectly to an HCP or to a third party with the purpose of influencing or attempting to influence an HCP's purchasing, product referral or utilization decisions.
- Payments of any kind directly or indirectly to HCPs or HCP-owned entities that derive revenue from selling or servicing or arranging for the sale or servicing of medical devices ordered by their physician-owners or their partners for use in procedures the physician-owners or their partners perform on their own or their partner's patients at hospitals or ambulatory surgical centers. *(See e.g., Special Fraud Alert: Physician-Owned Entities, Office of Inspector General of the Department of Health and Human Services, (March 26, 2013).*
- Distributor/Direct Territory may not, whether directly or indirectly, grant any equity or other ownership or financial or operating interest, or employment rights, to any HCP or a Close Family Member of an HCP.
- Payments to fund fellowships, **educational grants**[2], and other financial support to a healthcare institution, individual HCP or private practice.
- Payments to assist HCPs in marketing or promoting their hospital or practice (*e.g.,* HCP private practice magazine or journals).

Gifts and Entertainment

Providing gifts and entertainment to HCPs is strictly prohibited. Gifts and entertainment are prohibited regardless of whether reimbursement is sought from Zimmer Biomet or not.

Gifts

Direct Territory and Distributor personnel may not provide gifts to HCPs, Public Officials, and/or their Close Family Members, partners, friends, or staff. This prohibition has no exception and applies to all circumstances and life events (*i.e.*, career milestone, wedding, funeral, etc.).

Gifts include, but are not limited to: Zimmer Biomet branded items, scrubs, scrub caps, x-ray bags, golf balls, wine, flowers, chocolates, gift baskets, tickets to sporting events, wedding presents, holiday presents, and gift cards. Personal greeting cards are not considered gifts and are allowable but should not include product or promotional information. Management should review and approve the expense for direct employees prior to purchase.

Entertainment

Direct Territory and Distributor personnel may not pay for and/or arrange entertainment or recreational activities for HCPs, Public Officials, and/or their Close Family Members, partners, or other guests. Prohibited entertainment includes but is not limited to: sporting events, theatre, skiing, hunting, fishing, movies, concerts, golfing, leisure trips, and other recreational activities.

B. Meals and Transportation

Providing business courtesies to HCPs and Public Officials, such as meals and transportation, is an accepted business practice under appropriate conditions.

HCP Meal

In providing any meal to an HCP or Public Official, Direct Territory and Distributor personnel should ensure that such meals are:

- For a bona fide presentation of scientific, educational or business information.
- Modest in perception and reasonable in price (never exceeding Zimmer Biomet's established HCP meal limits listed below);
- Provided occasionally;
- At an appropriate location conducive for discussing Zimmer Biomet business;
- Restricted to attendees directly involved in the related business discussions (*e.g.*, no invitation of and payment for family members, non-essential office or department staff, or other guests); and
- Attended by Zimmer Biomet Distributor or Distributor personnel for the duration of the meal.

[2] Educational grants provided by Zimmer Biomet Corporate typically support general meeting expenses such as audio/visual, venue costs, development, accreditation, cadaveric expenses, and occasionally HCP Honoraria and travel. Zimmer Biomet grant funding would not cover expenses such as gifts, entertainment, rewards, recognition plaques, building construction, etc.

Region	Location of Meal	HCP Meal Limits * (per person, including tax and gratuity)			
		Currency	*Breakfast*	*Lunch*	*Dinner*
Americas	Canada	CAD	50	75	150
	United States	USD	50	75	150

*Meal limits are inclusive of all beverages, taxes, gratuities, and other charges imposed by vendor (e.g., credit card surcharge), but they do not include room rental fees, catering fees, or other similar fees.

HCP Dinner Meal Limit Increase for Certain High-Cost US Cities

Zimmer Biomet hosts a significant number of HCP meals in certain high-cost cities. These cities are also the locations for some of our largest Medical Education meetings, corporate events, and industry events. Therefore, Zimmer Biomet has made an adjustment to the meal limits for meals hosted in the following high-cost cities.

Region	Location of Meal	High-Cost City HCP Meal Limits * (per person, including tax and gratuity)			
		Currency	*Breakfast*	*Lunch*	*Dinner*
Americas	Canada	CAD	**60**	**90**	**240**
	United States	USD	**60**	**90**	**240**

*Meal limits are inclusive of all beverages, taxes, gratuities, and other charges imposed by vendor (e.g., credit card surcharge), but they do not include room rental fees, catering fees, or other similar fees.

See ***APPENDIX B*** for the current list of U.S. high-cost cities. Additional high-cost cities could be identified and subject to the higher dinner limit in the future.

Group and Business Meal Expense Payment

The most senior team member present at the meal or event must pay and provide documentation for the entire bill, *unless* a location is hosting another location's team member(s) and in this case, the most senior team member of the hosting location can pay the bill. If circumstances require a subordinate to pay, then the team member's expense report will require the approval of the most senior team member's supervisor.

HCP Transportation

Direct Territory and Distributor personnel may arrange and pay for travel for the reasonable cost of a taxi service, ride share service, shuttle, or public transportation for an HCP or Public Official who requires ground transportation to attend an approved Zimmer Biomet Activity (contact Med Ed or Compliance for information on approved activities) or legitimate business activity. Zimmer Biomet Corporate Medical Education Team Members can support HCP travel only for approved Zimmer Biomet corporate medical training and education courses and activities (*e.g.*, Local/Regional meetings, bio-skill courses, and corporate sales training).

See Part 10: State Law Restrictions for meal, transportation, and other transfer of value restrictions that may apply in certain states.

Meals and travel payments with HCPs must be reported in the applicable Zimmer Biomet tracking database (MediSpend) for transparency reporting. Itemized receipts and other support documentation (*i.e.*, sign-in sheets, receipts and meeting agendas) must be tracked and maintained by the Distributor.

To ensure accurate reporting and alignment with the above meal limits and travel, receipts must not be split. It is a violation of Zimmer Biomet's policy to split meal expenses between attendees and submit separate expense reports for reimbursement. This includes splitting alcohol expenses and meal expenses for separate submission to circumvent the meal limits.

Direct Territory and Distributor personnel may not split payment of the meal with other attendees, themselves, or personally pay for all or part of the meal out of pocket, to prevent or conceal a meal limit violation. The only exception to the prohibition on splitting checks is when an HCP wants to split a check to pay for himself/herself and documentation is still required in this event.

C. Product Support Materials and Educational Items

Product Support Materials are informational and educational items that are designed to inform or educate HCPs and/or their patients regarding the musculoskeletal system and Zimmer Biomet products, services, techniques or instruments.

Product Support Materials may be provided to HCPs and patients when servicing a genuine educational or informational purpose related to Zimmer Biomet products if the Product Support Materials:

- are branded with Zimmer Biomet's name and/or logos;
- are product-specific;
- are ordered through approved Zimmer Biomet corporate channels; and
- do not have independent commercial value

Distributor personnel may never create or distribute home-grown Product Support Materials to patients or HCPs. Similarly, Distributors must not reprint, alter, modify or repurpose any Zimmer Biomet approved Product Support Materials, communications, or applicable documentation (*e.g.*, emails, bulletins, papers, etc.) in any way.

Acceptable and Prohibited Product Support Materials

ACCEPTABLE	PROHIBITED
• Zimmer Biomet surgical technique guides • Zimmer Biomet Consumer Materials • Zimmer Biomet Marketing Collateral • Zimmer Biomet white paper or industry journal reprints • Anatomical models • Etched samples/demonstration product obtained through the established sample/demonstration product program • Textbooks • Zimmer Biomet product templates • Zimmer Biomet Patient ID cards • Zimmer Biomet product information CDs, DVDs, or memory sticks	• X-ray bag • Generic X-ray markers • Subscriptions to Medical Journals • Blank media devices (jump drives/memory sticks) • Office supplies • Clothing/Scrubs • Clip Boards • Goniometer (not instrument grade) • Pens • Unused Generic Sawbones • HCP Referral cards or similar collateral • Product information loaded onto iPads, electronic notebooks, etc.

Journal Reprints

All papers or journal reprints provided by Distributor/Direct Territory personnel must be on label. If an HCP has a request to review literature outside of a product's FDA approved/cleared indications, refer the HCP to Zimmer Biomet Regulatory/Clinical/Medical Affairs personnel.

Anatomical Models

Direct Territory and Distributor personnel may provide HCPs with a reasonable quantity of anatomical bone models for use in patient education and awareness at no charge. They may provide only model types that are relevant to the HCP's practice and are specific to Zimmer Biomet systems. In addition, all Direct Territories and Distributors should keep documentation of the number of bone models given to each HCP and justification for the number given. Zimmer Biomet Bone Models can be purchased via www.zbmarketsmart.com, the central location for patient-focused tools. Questions related to consumer marketing can be directed to marketing.operations@zimmerbiomet.com.

Etched Samples / Demonstration Products

Etched samples/demonstration products may not be left with an HCP. Demonstration product use must comply with Zimmer Biomet's loaner bank or Business Unit specific policies, procedures, and/or guidance.

Textbooks

Direct Territories and Distributors are permitted to purchase textbooks for residents or fellows subject to the following conditions:

- May provide only one (1) textbook per resident or fellow per calendar year;
- Any textbook provided by Distributor/Direct Territory must primarily contain content affiliated with the therapeutic areas supported by Zimmer Biomet (*i.e.*, A textbook on hip/knee replacement would be appropriate whereas a textbook on medical terminology for healthcare professions would not).
- Must have the resident/fellow sign the Zimmer Biomet letter of agreement prior to receiving a textbook. Distributor/Direct Territory must keep a copy of this agreement on file for audit purposes;
- Must provide the textbook directly to the resident/fellow recipient; and
- Distributor/Direct Territory must track and report all textbook transfers of value to Zimmer Biomet in accordance with transparency requirements.

Most product support materials and educational items provided to HCPs must be reported in the applicable Zimmer Biomet tracking database (Medispend**) for transparency reporting.** Itemized receipts and other support documentation must be tracked and maintained by the Distributor. See Part 10: Transparency Reporting.

D. HCP Consultant Identification and Selection

Appropriate Zimmer Biomet corporate personnel identify and select HCPs for various consulting services (*e.g.*, Training and Education, Product Development, Clinical Research, etc.) in accordance with its corporate Compliance Program. Direct Territory and Distributor involvement is very limited, and sales personnel may only provide information about potential HCP consultants in response to a request from Zimmer Biomet corporate personnel outside the sales and/or marketing functions(s).

Direct Territory and Distributor personnel may not otherwise solicit, influence, or attempt to influence, the engagement of an HCP as a Zimmer Biomet consultant.

E. Zimmer Biomet Medical Education

Zimmer Biomet Corporate Medical Education organizes educational activities to train HCPs on the safe and effective use of Zimmer Biomet products. Medical Education generally includes surgical skills training, didactic presentations, sawbones workshops, and surgeon-to-surgeon activities.

Direct Territory and Distributor personnel may not organize or lead Medical Education events; however, their personnel may provide information to the Medical Education teams to assist in the identification of product training needs for HCPs.

Direct Territory and Distributor personnel are prohibited from soliciting or agreeing to allow HCPs to teach, proctor, or provide training and education consulting services for Zimmer Biomet and for local Distributor product training or education events, whether paid or pro-bono.

F. Sales and Product Support Activities

Direct Territory and Distributor personnel product support activities are distinct and separate from Zimmer Biomet Corporate Medical Education Activities. Product support activities allow Direct Territory and Distributor personnel to inform HCPs about the features and benefits of Zimmer Biomet's products, instrumentation, and other general information.

Product support activities may include, but are not limited to:

- Product and/or instrument demonstrations;
- Distribution of product brochures, surgical technique videos, guides and other approved information about Zimmer Biomet products;
- ZBI Cadaveric Practice Workshops

Cadaveric Practice Workshops

Cadaveric Practice Workshops (CPW) provides local healthcare professionals with an opportunity to practice using ZB products, in accordance with product indications and surgical techniques in an approved laboratory setting using anatomical material. Contact Medical Education with questions on CPWs.

CPW REQUEST FORM LINK

HCP Consulting at Product Support Activities

HCPs may not host, proctor or serve as faculty at a distributor-led product support activity. HCPs may not be utilized as speaker or proctor at a distributor-led event, regardless of if the service is pro-bono.

Zimmer Biomet Medical Education may use HCPs to support Local/Regional meetings/events, but all HCP use must be approved and coordinated through the Medical Education teams.

Product Support Location and Timing

Product support may occur at a location that is conducive to the exchange of relevant product information. Product support activities can generally occur at any time, but some CME conferences prohibit Zimmer Biomet Product Support Activities while that CME conference is occurring (*e.g.*, AAOS prohibits companies from holding events with HCPs during the hours of AAOS).

Product Support Meals

Modest and reasonable meals provided to HCPs in connection with product support activities are generally permissible. Meals must not exceed the per-person meal limits established by Zimmer Biomet. Attendees must be recorded for transparency reporting purposes.

Medical Institution Training – Product Support Requests

Third Parties, such as Medical Institutions and Medical Education Conference providers sometimes approach Zimmer Biomet, as well as its Direct Territory and Distributor Personnel, to help support third-party driven training or education activities that include Zimmer Biomet products.

Distributors who are solicited to support third-party directed product training using Zimmer Biomet products must:

- Assess the scope of the proposed third party activity;
- Assess the availability of on-hand product, equipment, or instruments;
- Escalate concerns to Zimmer Biomet AVPs/Territory Managers, etc.;
- Require the requestor to agree to and sign the Zimmer Biomet Third Party Training Support Product Agreement;
- Retain responsibility for: (i) providing Third-Party with Support Product that is in good working condition, (ii) Support product delivery, set-up, and recovery, and (iii) providing Third-Party personnel with Support Product assistance during the Third-Party training;
- Ensure that the Third-Party receives no fees in connection with facility access and placement or removal of the Support Product.
- Confirm acknowledgement that the Product cannot be used for live patient use; and
- Abide by the prohibition on the use of products outside of the applicable FDA or Health Canada approved/cleared product indications.

Third-party product support requests are for ZB products ONLY. If the third-party requests anything other than product, as described in the agreement, such as a C-Arm, Specimen, or other third-party event expenses, the Direct Territory/Distributor cannot go forward with product support, and instead must contact Medical Education to determine if the Direct Territory/Distributor can participate in the event.

Direct Territories and Distributors are **prohibited** from supporting product or instrument requests that are not associated with Zimmer Biomet products. These requests may be addressed to Convention Services.

G. Evaluation Products

Evaluation products provide HCPs with an opportunity to evaluate safe and effective use of Zimmer Biomet products during live patient care. Direct Territories and Distributors may provide a limited quantity of approved no charge evaluation products to eligible HCPs in accordance with the guidelines below.

Evaluation Products may be used only in the following situations:

- A surgeon is new to the technology and has not used the product in a live surgery or procedure; and/or
- A healthcare institution or facility has a "free trial" requirement as part of their product procurement process.

Requirements:

- Evaluation products and quantities must comply with the approved Zimmer Biomet Approved Product and Quantity list (check with your local Sales Admin Team for lists).
- Some products require pre-approval.
- Sales personnel (Distributors, team members, etc.) must have eligible product evaluators (HCPs) and complete a product evaluation agreement by or before the surgery/patient procedure and/or within the period outlined in the agreement (*e.g.*, Capital Equipment).
- Distributors must be trained on Zimmer Biomet's product evaluation guidelines to be eligible for inventory reconciliation.
- Capital or other multi-use evaluation equipment not returned after 90 days will be charged to the facility and subject to transparency reporting.

Distributors who fail to comply with the product evaluation requirements may be subject to out-of-pocket inventory costs, prohibited from product evaluation requests, and/or other discipline prescribed by Zimmer Biomet Compliance.

PART 4: Commercial Sponsorships, Promotional Fundraising, Charitable Donations and Educational and Research Grants

Commercial Sponsorship and Exhibit Booth Space Purchases

A commercial sponsorship and exhibit booth space purchase is defined as payment or in- kind support provided to a third party in exchange for advertising or promotional opportunities for the Company (for example, a Company exhibit at a Third-Party Program).

Direct Territories	All exhibit/booth space payments connected to **Direct Territories** must be coordinated by the Zimmer Biomet Corporate Conventions Services Team, Meetings/Events Department, or other approved corporate designee. Direct territories must reach out to Corporate Conventions or submit the **US/Canada Exhibits, Commercial Sponsorship & Promotional Fundraiser Request Form**. The form will indicate whether compliance review and approval are required. Once approved, the Conventions Services Team will reach out for next steps.
Distributors	**Distributors** are permitted to purchase booth/tabletop exhibit space at third-party educational events (CME or non-CME). The process to do so is below: • To initiate an exhibit space or commercial sponsorship, gather relevant details to assess the event legitimacy (e.g. meeting details/organizer, HCP Control/affiliation, package inclusions/cost, prospectus, etc.). • Review the request and fill out the **US/Canada Exhibits, Commercial Sponsorship & Promotional Fundraiser Request Form.** The form will indicate whether compliance review and approval are required. • **The form must be completed in full and submitted to obtain proper approval.** • Choose "send me a copy of my responses" when submitting request form and file completed form with supporting documentation for future record. • A written agreement must be fully executed prior to paying for an exhibit space or commercial sponsorship. • Payment must be paid to the approved payee named in the written agreement and never to an individual HCP, HCP practice, or hospital department.

Examples of permissible and prohibited benefits:

List A (Permissible)	List B (Prohibited)
Table top exhibit	Zimmer Biomet branded, non-educational promotional items, (i.e., re-usable tote bags, pens, notepads, mugs, thumb drives, and other items with a Company or product name or logo)
Badges for team members	Tickets to HCPs for recreational or fundraising events
Advertisements and/or branding in event materials (e.g., programs, banners, apps, websites, keycards, lanyards)	Badges to HCPs for events
Advertisements and/or branding on physical conference spaces (e.g., elevators, benches, water fountains, charging stations)	Awards for HCPs
Ability to hand out routed and approved educational or sales materials	Raffles for items or gifts
Ability to talk about Zimmer Biomet products/services (when purchasing the opportunity)	Other non-educational/re-usable items offered by the third party organization (e.g., water bottles, tote bags, t-shirts)
Branded, non-reusable promotional items (e.g., coffee sleeve, napkins, paper cups, plastic bags)	
Attendee lists	
Exclusive or group sponsorship of a reception, meal, or coffee break (but requires transparency tracking and reporting)	

Badge and Registration Fees

Direct Territories	**Direct Territories must** consult Zimmer Biomet's Corporate Conventions Team, Meetings/Events Department, or other approved corporate designee for badge and registration support questions.
Distributors	Distributors are permitted to pay badge and registration fees for Distributor personnel to participate in third-party educational events (CME or non-CME), if all the following conditions apply: • Payment is not made to individual HCP, HCP practice or hospital department (*e.g.*, orthopedic or neurosurgery departments); • Fees are reasonable and consistent with fair market value for similar educational events (*e.g.*, Distributor should not knowingly pay more than other industry participants); • Payment receipt is provided; and • The event is not a large Healthcare Organization Meeting, such as AAOS, that is otherwise administered by Zimmer Biomet Corporate Conventions Team (in such case, Corporate would provide badges to Distributors). A letter of agreement is not required if the Distributor is purchasing only event badges, but Distributor should maintain all payment receipts and other supporting documentation in connection with third party event attendance.

Journal Clubs and Grand Rounds

Direct Territories and Distributors are permitted to support Journal Clubs and Grand Round meals, if all the following conditions apply:

- In addition to the display or exhibit of Zimmer Biomet product, Distributor is given time on the event agenda to conduct a product discussion. The distributor or direct territory must obtain a copy of the agenda to confirm adequate discussion time is provided;
- Payment for the meal is not made to individual HCP, HCP practice, or hospital department (*e.g.*, orthopedic or neurosurgery departments);
- Meal funding **does not include** facility rental or room fees (those fees are the responsibility of the third-party event organizer); and
- The meal must comply with Zimmer Biomet meal limits and venue restrictions and must be reported per the appropriate transparency reporting requirements.

Direct Territories and Distributors are prohibited from soliciting or engaging speakers of faculty (paid or pro-bono) in support of third-party Journal Club or Grand Round events.

Charitable Donations and Promotional Sponsorships

Charitable Donation is defined as monetary funding or in-kind charitable donations of product or equipment for charitable purposes such as indigent care, patient or public education. Donations and promotional sponsorship participation should be made for bona fide charitable purposes and should be made only to charitable organizations or other non-profit entities with bona fide and/or philanthropic purposes.

Direct Territories	**Direct Territories** must submit all HCP-related or medical institution related Charitable Donation requests to the ZB Philanthropy Team. • Resources: The Giving Office directed to Tabatha.mcdonald@zimmerbiomet.com For Promotional Sponsorships, Direct Territories must complete the **US/Canada Exhibits, Commercial Sponsorship & Promotional Fundraiser Request Form.** The form will indicate whether compliance review and approval are required. Once approved, the Philanthropy Team will reach out for next steps.
Distributors	Charitable contributions and promotional sponsorship participation by Distributors and Distributor personnel are permitted **if all the following conditions apply:** • Request is made in writing from an organization with 501(c)(3) or equivalent status on behalf of an organization raising funds for a cause which benefits the public interest, and not from an individual HCP, unless the HCP is acting in an official capacity on behalf of the organization. • Verify use of funds is only towards charitable or philanthropic purposes. Proceeds are used for patient or public education and/or indigent care (for HCP related charities) • Request does not exceed $7500 USD (requests exceeding $7,500 USD require approval from Zimmer Biomet Corporate Compliance); • Request is unrestricted; • Charitable contributions and/or charitable fundraising support to a particular organization occurs only occasionally; • Payment is not made to individual HCP, HCP practice, or hospital department (*e.g.*, orthopedic or neurosurgery departments); • A written agreement or invoice must be executed or received prior to paying for a charitable donation. For promotional sponsorship requests, Distributors and Distributor personnel are required to completed the **US/Canada Exhibits, Commercial Sponsorship & Promotional Fundraiser Request Form.** The form will indicate whether compliance review and approval are required. Once approved, the Distributor can move forward with execution if the above mentioned conditions are met. These seven requirements must be met for all charitable donations that will benefit a healthcare entity or cause. Charitable donations that are both a) not for the benefit of an HCP or other healthcare entity or cause, and b) not made at the request of an HCP or healthcare entity do not need to meet the seven requirements but should be transparent on the general ledger. **Examples of Permitted Charitable Contributions** • Requests from a hospital, hospital foundation or other third-party requestor for financial support for **indigent patients, patient education and/or outreach offerings;** • Galas and golf events to raise funds for patient education and indigent care (*e.g.*, local Arthritis Foundation Events and local Operation Walk Fundraisers); Note: A company may not pay or provide tickets to HCPs or their spouses or guests to attend charitable events, such as galas and golf outings; • Donations to local non-HCP charities such as youth athletic leagues, Red Cross, local races, etc.

Charitable Product Donations - US

Zimmer Biomet partners with two third-party organizations, Americares | Disaster Relief & Global Health Organization and Operation Walk USA, who facilitate donating Zimmer Biomet products to U.S. licensed physicians performing surgeries in the U.S. at no cost to patients who qualify for charitable assistance. Americares also manages Zimmer Biomet product donations for Operation Walk USA program.

Direct Territories and Distributors are **prohibited from donating or authorizing the donation** of any Zimmer Biomet products without express authorization from Zimmer Biomet. For more information review program details at Americares Medical Outreach or contact the ZB Philanthropy Team.

Charitable Product Donations – OUS (Medical Missions)

Zimmer Biomet accepts requests for product donations to non-profit organizations supporting medical mission trips outside the U.S. and Canada. The non-profit organization must submit an application as well as all required documents at least ninety (90) days prior to the date product is needed to be considered for this type of charitable product donation.

Direct Territories and Distributors must direct organizations to the Charitable Donations Portal to submit an application to start the request process. For more information, please contact the ZB Philanthropy Team.

It is never permissible to contribute to any organization (including a non-profit) or charitable fundraising effort with the intent to influence a product decision (*e.g.*, purchase, referral, or utilization), or if the request is from an HCP requesting funding for their personal benefit/interest.

Charitable donations do not include funding for non-charitable purposes such as research, educational or in-kind educational product grants (see section on educational grants and research grants.)

Educational Grants and Research Grants

A grant is defined as monetary funding or Zimmer Biomet in-kind Product to support legitimate third-party medical education or research activities, including medical education events, educational conferences, research initiatives, and patient and public educational initiatives.

Direct Territories and Distributors	**Direct Territories and Distributors must** consult the Medical Education team, Compliance Team or other approved corporate designee for information regarding the grants process. All organizations must apply through Zimmer Biomet's Grants Portal. ***Grants Portal Website & Grants Manual: Our Impact (zimmerbiomet.com)***

Grants and in-kind product donations may not be contingent upon, or related to, the past, present, or potential future recommendation, use, prescription, purchase, lease, or procurement of Zimmer Biomet Products or services.

PART 5: Advertising

All advertising associated with Zimmer Biomet products must go through Corporate Brand Communication/Marketing department for pre-approval.

Payments for advertising to or on behalf of individual HCPs, including HCP practices, and musculoskeletal departments (*e.g.*, orthopedic or neurosurgery departments) are prohibited. This prohibition includes advertising in HCP or HCO publications (*e.g.*, magazines or journals) that are intended to benefit a particular facility, HCP, or practice group.

Distributors or Direct Territories who are interested in Co-Marketing and Promotional Programs conducted by or on behalf of Zimmer Biomet in conjunction with a Healthcare Professional should contact their Compliance and Marketing Business Partners to seek guidance on the requirements to conduct such an event.

It is important to note that Co-Marketing and Promotional Programs are different than the trainings Zimmer Biomet conducts to train and educate HCPs on the safe and effective use of its products and services. All Co-Marketing and Promotional Programs require an appropriate written agreement in accordance with compliance and marketing guidelines, as well as the use of routed and approved materials.

- **Co-Marketing** – The creation, dissemination, or display of advertising coordinated between an HCP and Zimmer Biomet, which contains both HCP and Zimmer Biomet images or information.
- **Promotional Programs** – Events jointly conducted by Zimmer Biomet and a Program Partner to educate Patients, which contain both Zimmer Biomet product and clinical disease information.
- **Program Partner** – An HCP who has the medical and scientific expertise to jointly develop and present patient education at a Promotional Program

PART 6: Social Media Guidelines

Direct Territory and Distributor personnel and sales associates whose job functions are at least partially controlled by Zimmer Biomet must follow all applicable Zimmer Biomet Social Media Policies set forth in MKTG 101 Employee and Company Agent Use of Social Media. This policy, owned by the Zimmer Biomet Marketing Department, sets parameters for permissible and impermissible work-related use of Social Media by Zimmer Biomet employees and Company Agents (distributors, contractors, vendors, third-party agents, and sales force).

Social media should never be used to endorse an HCP's skills or expertise, or refer patients to a particular surgeon (e.g., adding a comment on an HCP's LinkedIn post stating that the surgeon is a "Best in Class Surgeon!"). Sharing, liking, posting or reposting info by or about (HCPs) is permissible if it does NOT benefit the HCP in a way that violates the Anti-Kickback Statute or other relevant policies.

If you wish to recognize a surgeon milestone, please contact the Social Media team for approved language and guidance regarding recognition posts. The provision of gifts or in-kind support to surgeons in connection with milestones is prohibited.

- Contact the Social Media team or Compliance for a copy of the Social Media Policy.
- Questions related to this policy can be directly sent to socialmedia@zimmerbiomet.com

PART 7: Payer Reimbursement and Coding Guidance

The determination of appropriate reimbursement and coding guidance for customers, along with strategies related to negotiating reimbursement, pricing, coverage and payment policy with government healthcare agencies (*e.g.,* Medicare, Medicaid and TRICARE), third-party payers (*e.g.*, commercial insurance companies) and any other payer (*e.g.,* workers' compensation carrier, employer group or union sponsored benefit administrators, etc.) are functions within the exclusive authority and control of the Zimmer Biomet Corporate Market Access Department.
Direct Territory and Distributor personnel must not engage in negotiations or any other meetings with government or payers, unless specifically authorized by Zimmer Biomet Market Access Corporate personnel.

Direct Territory and Distributor personnel must not provide any reimbursement or coding guidance to customers or engage in detailed reimbursement discussions with providers and facilities unless authorized to do so by designated Market Access Team Members. Additionally, only Market Access approved reimbursement materials can be shared with or distributed to customers. It is not acceptable to create individualized reimbursement, cost or revenue/profitability/margin calculators or coding information in the field, or to share coding and/or reimbursement information from one provider to another.

Specialty Distribution Channels

For those products which involve distribution through specialty channels or intermediaries (*e.g.*, wholesalers or specialty pharmacies), Direct Territory and Distributor Personnel may not contact, engage, or negotiate with entities involved in the specialty distribution channels. Management of communication and relationships with specialty distribution channels are the responsibility of the Market Access group.

All customer inquiries regarding reimbursement or coding information should be directed to the Reimbursement Hotline at (866)-946-0444 or via the web at http://www.zimmerbiomet.com/reimbursement.

PART 8: Privacy and Confidentiality

Information about individuals and their health is protected under an array of laws, including federal, state and local (in the U.S.), and provincial and municipal (in Canada), that govern privacy and confidentiality. Such information (often referred to as "protected health information" in the U.S. and "personal information" in Canada) may include, but is not limited to, the following:

- Names (patient, relatives, household members, employers and caregivers);
- Dates (except for year): birth, death, admission, discharge, date of service, date of surgery,
- Diagnosis;
- Numbers: medical record, financial accounts, social security, device, telephone, VIN;
- Addresses: any geographic subdivision smaller than a U.S. State or Canadian province, and not just for the patient, but also relatives and employers (street, city, county, Zip/postal code), e-mail addresses, IP addresses;
- Graphics: photographs, radiographs (x-rays, MRI, etc.), video; and
- Any other unique number, characteristic or code that could reasonably be linked to a person (includes unique physical attributes).

Zimmer Biomet requires that all Distributors, their employees or sales agents comply with any and all applicable laws, including federal, state and local (in the U.S.), and provincial and municipal (in Canada) that govern privacy and confidentiality, including, but not limited to, legal obligations regarding transfers for processing.

For the purposes of Canadian privacy law, a Distributor is a third-party processor on behalf of Zimmer Biomet of any personal information received while distributing Zimmer Biomet products. As a third-party processor, a Distributor must only use personal information only for the purposes for which it was collected or transferred. Further, a Distributor must provide protection for such personal information that is comparable the level of protection the personal information would receive if it had not been transferred. Distributors must take all reasonable steps to protect any personal information in its control from unauthorized uses and disclosures and must ensure to have policies and processes in place, including training for its staff and effective security measures, to ensure that the personal information in its care is properly safeguarded at

all times.

Anytime a Distributor or Distributor personnel are working with protected health information, personal information or confidential information, the Distributor should apply the “minimum necessary” standard, which means only access, disclose or use the minimum amount of such information that required to complete responsibilities. Moreover, such information should be kept and stored securely and only for as long as necessary to satisfy the purpose for which it was collected. Distributors should have guidelines and procedures in place for retaining and destroying personal information or confidential information and should destroy, erase or render de-identified or anonymous such information that is no longer required for a permissible and identified purpose or to meet a legal requirement.

For protected health information or personal information in the course of work, Distributors have an obligation and responsibility to take reasonable efforts to protect and secure the information to avoid a breach (*i.e.*, loss or theft) or prevent an impermissible use or disclosure of such information. Protected health information, personal information and confidential information, regardless of format, should be safeguarded from destruction, loss, unauthorized disclosure, copying, use or alteration. If a Distributor becomes aware of a data breach, *e.g.*, protected health information or personal information that has been lost, stolen, hacked, or used impermissibly, or communicated or sent to those having no official need to receive it, the Distributor shall contact the Zimmer Biomet Global Privacy Officer, or Zimmer Biomet’s Legal or Compliance Departments immediately.

Distributors, their employees or sales agents who fail to comply with applicable laws that govern privacy are subject to disciplinary action, up to, and including termination of agreement and disqualification from representing Zimmer Biomet products. If a Distributor has a specific protected health information or personal information scenario to discuss, or questions about privacy obligations and responsibilities, please contact the Zimmer Biomet Global Privacy Officer or the Zimmer Biomet Legal or Compliance Departments.

Note: Often HCPs or healthcare institutions will require the signing of a confidentiality or non-disclosure agreement, or Business Associate Agreement. Please contact Zimmer Biomet Legal or Compliance for all requests pertaining to the signing of agreements.

PART 9: Transparency Reporting

For Zimmer Biomet to comply with federal and state transparency laws, all Direct Territory and Distributor personnel must completely and accurately report payments or other transfers of value provided directly or indirectly to HCPs, or at the request of HCPs, as directed by Zimmer Biomet Compliance.

Reportable payments or transfers of value to HCPs (including Teaching Hospitals and HCP-owned entities) include but are not limited to:

- Textbooks
- Journal Reprints
- Food and Beverages
- Travel Expenses
- Charitable Donations
- Charitable Fundraising Support
- Badges/Registration Fees
- Booth Space/Exhibit Space
- Facility Fees (leased or rented space)
- Advertising

The recording of transactions in the applicable tracking database (Medispend) must be performed by the tenth (10^{th}) calendar day of the month following the date of the transaction, unless specifically instructed otherwise by Zimmer Biomet Compliance.

Distributors must retain copies of all itemized receipts and supporting documentation, including any HCP spend from Distributor personnel. All itemized receipts should be included with each Medispend transaction record. This documentation must be maintained pursuant to the requirements set forth in this Manual.

When an individual leaves a Distributor's organization, Distributor must use best efforts to obtain any HCP spend the departing individual incurred.

HCP-related payments that are charged back to a Distributor will be tracked and recorded by corporate. Please do not report items that are charged back to Distributor as it will risk double reporting of those expenses.

Direct Territories: HCP meals that are reconciled in the Zimmer Biomet corporate instance of Concur will automatically flow through to Medispend for transparency reporting. All itemized receipts must be included in the Concur system.

PART 10: State Law Restrictions

The state laws of Massachusetts and Vermont restrict certain interactions between medical device manufacturers (and their Distributors) and HCPs. All Distributor personnel must understand the restrictions imposed by these laws.

Both states' requirements "follow" the HCP and apply even if the HCP is licensed or regularly practices in other states as well. For example, if a sales representative participates in a business meal in California with an HCP who is licensed in both California and Massachusetts, the restrictions imposed by Massachusetts apply.

HCPs are commonly licensed in more than one state and Distributor personnel should be knowledgeable about all state licenses for HCPs with whom they interact.

Massachusetts:

- Meals: All meals provided to Massachusetts HCPs must be both modest and educational in nature, and the location of the meal must be conducive to the bona fide educational purpose.
- Massachusetts HCPs can attend facility tours if travel is booked using the approved Zimmer Biomet Travel Agency.

Vermont:

- Meals: Distributor personnel may not provide meals to Vermont HCPs; a written agreement is required to provide any meals to Vermont HCPs.
- Support of Third-Party Educational Conferences: Zimmer Biomet and its Distributors may not provide sponsorship or payment for any third-party meeting in Vermont that does not meet the commercial support standards established by the ACCME or equivalent commercial support standards established by the relevant accrediting body.
- Zimmer Biomet and its Distributors may not provide any meals directly to a Vermont HCP at any third-party educational conference. This means that Biomet and its Distributors may not host a reception or meal at a third-party educational conference attended by Vermont HCPs, even if that reception or meal would be open to all conference attendees.
- Vermont HCPs can attend facility tours using the approved Zimmer Biomet Travel Agency, after the appropriate agreement has been executed.
- Evaluation and Demonstration Products: Any loan of multiple-use devices (capital equipment) for a short-term trial period to permit evaluation by a Vermont HCP may not exceed ninety (90) days.
- Charitable Donations: Under Vermont law, Distributor may not provide charitable donations to Vermont HCPs, hospitals, nursing homes, pharmacists, health benefit plan

administrators, or any other person authorized to dispense or purchase for distribution medical devices in Vermont unless the donation:

- is made to a hospital foundation that is organized as a non-profit entity separate from a hospital; or
- is made to a healthcare facility operated by a non-profit organization as a "free clinic."

Part 11: Zimmer Biomet Compliance Monitoring and Auditing

Zimmer Biomet's Compliance Monitoring and Auditing personnel may conduct Distributor/Direct Territory field visits that involve the following:

- Site visits;
- Books and Records assessments;
- HCP expense assessments;
- Ride-along;
- Local Distributor events;
- Industry events (*e.g.*, Society Meetings, third-party educational conferences, trade shows, etc.); and
- Other

The purpose of these visits is to ensure compliance with the Zimmer Biomet's compliance guidelines and expectations outlined in this manual.

Distributor/Direct Territory leaders and applicable Compliance Liaisons must cooperate with Zimmer Biomet personnel to successfully coordinate and support these visits.

Part 12: Non-Compliance

Direct Territories and Distributors must be proactive with engaging Zimmer Biomet Compliance with any business scenarios that may impact compliance with Zimmer Biomet policies and procedures.

Failure to comply with this Manual, agreements with Zimmer Biomet, and all affiliated Zimmer Biomet Compliance policies and procedures may subject the Direct Territory/Distributor and/or personnel to disciplinary action or disqualification from representing Zimmer Biomet products and services.

Appendix A: Compliance Contact Information

Zimmer Biomet Compliance Contact Information

General Compliance Questions: Compliance.AMER@ZimmerBiomet.com
Grants & Donations Questions: Grants.AMER@zimmerbiomet.com
Global Compliance Exception Request: globalcompliance@zimmerbiomet.com

Zimmer Biomet Speak Up Hotline

File a report online at zimmerbiomet.com/speakup. Country-specific phone numbers are located on the Speak Up website.

Potential or known compliance violations involving Zimmer Biomet team members and Distributors should be reported through this Speak Up Hotline, which is available twenty-four (24) hours a day, seven (7) days a week. Everything submitted to the hotline is considered confidential and submitters may choose to make an anonymous report, unless otherwise required by law.

Zimmer Biomet will investigate all reports. Retaliation against any individual who makes a report is strictly prohibited.

If the **suspected or alleged** compliance violation **involves competitor activity only** (*e.g.*, competitor company or competitor agents/representatives), consider the following options:

- Contact your Direct Territory/Distributor Compliance Liaison;
- Contact Zimmer Biomet Compliance or Legal;
- Report the concern through the Speak Up Hotline; or
- Contact the Office of Inspector General
    - Online: https://oig.hhs.gov/fraud/report-fraud/
    - Phone: 1-800-HHS-TIPS (+1 (800) 447-8477)

Zimmer Biomet Compliance Documents

For access to compliance policies, procedures, guidelines, and forms, please visit the Zimmer Biomet Circle or contact Compliance.AMER@zimmerbiomet.com.

APPENDIX B

HCP Dinner Meal Limit Increase for High-Cost U.S. Cities

Current Cities List

New York City, NY	Boston, MA
Washington, D.C.	Chicago, IL
Las Vegas, NV	San Francisco, CA
Los Angeles, CA	San Diego, CA
Miami, FL	Seattle, WA
Philadelphia, PA	Honolulu, HI
Scottsdale, AZ	Denver, CO

Current Canadian Cities List

Calgary	Montreal
Toronto	Vancouver
Halifax	Ottawa
Quebec City	