



**U.S. & Canada Sales  
Healthcare Compliance Manual  
Spine and EBI**

Please direct any questions about this Manual to the ZimVie Healthcare Compliance Team.

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## Introduction

ZimVie is committed to maintaining exemplary corporate conduct and the highest ethical standards. This U.S. and Canada Sales Healthcare Compliance Manual (the “Manual”) explains ZimVie’s compliance requirements and expectations for anyone who is employed by or contracts with ZimVie in connection with the promotion or sale of its products within the United States and Canada (“Sales Personnel”). Sales Personnel include ZimVie employees, Distributors, distributor employees, sales agents, and anyone else who may engage in sales activities on behalf of ZimVie.

All Sales Personnel are required to abide by ZimVie’s Code of Business Conduct and Ethics (“CoBCE”) and this Manual. On an annual basis, Sales Personnel must certify in zLearn that they have received, understand, and shall abide by this Manual and the ZimVie CoBCE.

ZimVie, 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 Sales Personnel.

### *Additional Guidance for ZimVie Sales Employees (e.g., W-2 Sales Employees)*

This Manual does not cover all relevant compliance policies applicable to performing your job function as an employee of ZimVie. ZimVie employees are responsible for adhering to all policies and procedures applicable to their role within the organization and completing any associated training, as required.

### *Additional Guidance for Distributors and Contracted Sales Agents*

If any of the compliance requirements in this Manual are inconsistent with the terms and conditions of the agreement between the ZimVie Distributor (inclusive of employees, sales agents, or independent contractors) and ZimVie, 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 ZimVie Healthcare Compliance. If any exception to the Manual is needed, such exception must be approved in writing by ZimVie Healthcare Compliance prior to any deviation for the Manual requirements.

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 particular means and manner for achieving) their organization’s compliance with ZimVie policies, procedures, applicable industry codes, and any applicable federal/state/local laws.

Distributors and other third party sales contractors must ensure new personnel complete required training/certification on the CoBCE and the Manual within sixty (60) days of commencing affiliation with ZimVie. A copy of the CoBCE can be found on the ZimVie Corporate website. Training and certification will be issued via the electronic learning system.

## Using the Manual

Many topics covered in this Manual apply to all Sales Personnel, regardless of whether employed directly by ZimVie or through a third party relationship, such as a Distributor.

- Anything that applies to “Sales Personnel” applies to all employees, Distributors, distributor employees, sales agents, and anyone else who may engage in sales activities on behalf of ZimVie.
- Anything that applies to “ZimVie Employees” only applies to individuals who are direct sales employees of the company (i.e., ZimVie W-2 employees).
- Anything that applies to “Distributors” only applies to Distributors (and their personnel) and other contracted sales agents. The term “Distributor” is used throughout this manual to identify where obligations exist for independent third parties.
- If you are unsure of which policies apply to you based on your relationship with ZimVie, please contact ZimVie Healthcare Compliance for clarification.

## 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 the Manual.

**Close Family Member:** Includes parents, siblings, spouses or partners, children, grandparents, grandchildren (whether adopted or by birth), 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.

**Distributor:** An independent sales entity that promotes and sells ZimVie 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.*

**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 ZimVie 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 ZimVie products and services.

**Public Official:** Any officer, agent, employee, or 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.

**Sales Personnel:** Anyone who engages in sales and promotional activities on behalf of ZimVie. This includes employees of ZimVie, distributor principals, distributor representatives, and any other third party sales agents or organizations that may engage in promotional activities.

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

**Value-Add Item:** 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 ZimVie Products and services that are subject to the tender. Value-Add Items are only applicable in Canada.

## PART 1: General Compliance Principles

ZimVie Sales Personnel are required to conduct and maintain operations in 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.

### 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.

ZimVie's Corporate Compliance Program encompasses these seven (7) elements.

- **ZimVie Employees** - Must operate within the Healthcare Compliance framework established by ZimVie.
- **Distributors** - Must maintain their own Corporate Compliance Program and are encouraged to leverage the elements of an effective compliance program, the general principles and policy statements set forth in this Manual, and the ZimVie CoBCE.

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

An effective Healthcare Compliance Program includes policies and procedures designed to ensure compliance with applicable laws, practices, and regulations.

- **ZimVie Employees** - Must adhere to all corporate compliance policies and procedures, including but not limited to those outlined in this Manual.
- **Distributors** - 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. Distributors are responsible for developing and implementing additional policies and procedures, as necessary, to govern their organization and meet their obligations to ZimVie. Distributor policies or procedures, such as those pertaining to expense reimbursement, may not contradict or minimize the effectiveness of any portion of this Manual.



## Element 2: Designate a Compliance Officer and Compliance Committee

An effective Healthcare Compliance Program is led by a Compliance Officer. Compliance Committees and Compliance personnel additionally establish and implement the compliance operations of the organization.

- **ZimVie Employees** – Must operate within the compliance parameters set forth by ZimVie Healthcare Compliance.
- **Distributors** - Each Distributor must designate a **Compliance Liaison** and **Spend Gatekeeper**. The Compliance Liaison and Spend Gatekeeper are the surrogates to a compliance officer and compliance committee for a distributorship and their relationship with ZimVie. The name, title and contact information for the Compliance Liaison and Spend Gatekeeper should be provided to ZimVie Healthcare Compliance and any changes should be communicated immediately. The Compliance Liaison and Spend Gatekeeper may be the same person or multiple people.

### *Compliance Liaison*

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

### *Spend Gatekeeper*

A **Spend Gatekeeper** is an individual responsible for managing, tracking and disclosing to ZimVie all relevant transfers of value provided to HCPs and healthcare institutions in accordance with applicable federal and state transparency reporting laws. Spend Gatekeepers are responsible for documenting this information in the ZimVie MediSpend system.

## Element 3: Conduct Effective Training and Education

Sales Personnel are responsible for engaging in training and education that will empower them to learn, understand, and operationalize healthcare compliance policies and procedures.

- **ZimVie Employees** – Must complete all required training and education as required by ZimVie.
- **Distributors** - The Distributor and Compliance Liaison must ensure that all owners, employees, sales representatives, independent agents, and their subcontractors (*i.e.*, Distributor personnel) working on its behalf complete required ZimVie compliance training. This includes, but is not limited to, zLearn training, webcasts, in-person meetings, and any other medium or mechanism that may disseminate applicable compliance information.

### *New Distributor Personnel Training*

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 ZimVie CoBCE.

### *Training Records and Roster*

Distributors should maintain appropriate records of training completions, as well as training materials. Distributors must frequently review their roster of Distributor personnel and promptly communicate the names of new Distributor personnel to ZimVie for inclusion in applicable ZimVie rosters, trainings, communications, and learning management system records.

## Element 4: Develop Effective Lines of Communication

An effective healthcare compliance program will prevent, detect, and remediate compliance risk. Sales Personnel are responsible for raising potential concerns. Failure to report may constitute knowledge of or participation in a potential compliance issue. ZimVie Healthcare Compliance is responsible for ensuring mechanisms are in place to provide compliance guidance and receive reports of potential non-compliance. Your ZimVie Healthcare Compliance Team is always available for questions, comments, or reports related to compliance.

- **ZimVie Employees** – May access healthcare compliance information on the ZimVie intranet and by contacting ZimVie Healthcare Compliance.
- **Distributors** – Distributors may access ZimVie Healthcare Compliance information through designated repositories and by contacting ZimVie Healthcare Compliance. Distributors should make this information available to their employees and agents.

### *ZimVie Speak Up Hotline*

Potential or known compliance violations involving ZimVie employees and Distributors may be reported through the Compliance 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. ZimVie investigates all reports. Retaliation against any individual who makes a good faith report of a suspected compliance or legal issues is strictly prohibited.

- Phone: +1 (800)-461-9330 then select “ZimVie”
- Online: [zimvie.com/speakup](https://zimvie.com/speakup)
- Email: [compliance.hotline@zimvie.com](mailto:compliance.hotline@zimvie.com)
- Text (North America Only): 970-762-2067

### *Potential Non-Compliance by Competitors*

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

- Contact ZimVie Healthcare Compliance;
- Contact your Distributor Compliance Liaison;
- 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)

## Element 5: Enforce Standards through Well Publicized Disciplinary Guidelines

ZimVie works to ensure that compliance standards and expectations are applied consistently throughout the organization.

- **ZimVie Employees** – Failure to meet your responsibilities around compliance may result in disciplinary action, up to and including termination.
- **Distributors** – 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. Distributors are required to report instances of non-compliance to ZimVie Healthcare Compliance.

## Element 6: Conduct Internal Monitoring and Auditing

ZimVie auditing and monitoring activities help to detect and prevent potential healthcare compliance concerns. ZimVie may conduct these activities in response to identified risks.

- **ZimVie Employees** – Are subject to auditing and monitoring in accordance with corporate policies and procedures.
- **Distributors** – Distributors should regularly review their business practices related to the promotion and sale of ZimVie products. Findings should be reported to ZimVie Healthcare Compliance in a timely manner. Distributors are also subject to auditing and monitoring by ZimVie. The following areas should be considered for assessment by Compliance Liaisons:
  - 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
  - Employee and Agent Screening

## Element 7: Respond Promptly to Detected Offenses through Corrective Action

ZimVie takes all known or suspected instances of non-compliance seriously. 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.

ZimVie prohibits retaliation against anyone who makes a good faith report of a known or suspected concern. “Good Faith” does not mean that the individual must 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 ZimVie should report the situation to Healthcare Compliance or through the Speak Up Hotline.

Sales Personnel must cooperate with internal investigations.

- **ZimVie Employees** – Must cooperate with internal investigations. Failure to do so may result in disciplinary action, up to and including termination.
- **Distributors** – The Distributor Principal, 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 to ZimVie*

Distributors must notify ZimVie of any known or suspected violations of any law pertaining to the operations of the Distributor's business. Distributors must also notify ZimVie of any known or suspected violations of any healthcare or medical device regulation, industry code, government health care program requirement, ZimVie's CoBCE, or the requirements in the Manual, either through ZimVie Healthcare Compliance or the Speak Up Hotline.

#### *Cooperation with Internal Investigations*

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

## PART 2: ZimVie Healthcare Compliance Requirements

### A. Employee and Sales Representative Screening

Sales Personnel must not be excluded from participation in Federal Healthcare Programs to conduct business on behalf of ZimVie.

<p><b>ZimVie Employees</b></p>	<p>Excluded Parties Screening for W2 employees is conducted by ZimVie Corporate HR as part of the employee background check process.</p> <p>ZimVie 1099 Sales Representatives are screened as part of the Accounts Payable Process (TIN Check Payee Verification).</p> <p>Such screening includes checking to ensure the name of the individual does not appear on:</p> <ul style="list-style-type: none"> <li>• HHS – OIG’s List of Excluded Individuals and Entities at <a href="https://exclusions.oig.hhs.gov/">https://exclusions.oig.hhs.gov/</a></li> <li>• FDA Debarment Screening: <a href="https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/fda-debarment-list-drug-product-applications">https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/fda-debarment-list-drug-product-applications</a></li> </ul> <p>If it is determined 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 individual or entity is subject to immediate termination.</p>
<p><b>Distributors</b></p>	<p>Excluded Parties Screening for all Distributor personnel and their Sales Representatives should be conducted by the Distributor prior to contracting with distributor personnel.</p> <p>Such screening includes checking to ensure the name of the individual does not appear on:</p> <ul style="list-style-type: none"> <li>• HHS/OIG’s List of Excluded Individuals and Entities: <a href="https://exclusions.oig.hhs.gov/">https://exclusions.oig.hhs.gov/</a></li> <li>• FDA Debarment Screening: <a href="https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/fda-debarment-list-drug-product-applications">https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/fda-debarment-list-drug-product-applications</a></li> </ul> <p>If it is determined 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, at a minimum, the Distributor shall immediately notify ZimVie Healthcare Compliance, remove such individuals or entities from all responsibilities relating to any of ZimVie’s business operations and terminate the affiliation of any such individual or entity with ZimVie.</p>

## B. Conflicts of Interest

### Avoiding Conflicts of Interest

A conflict of interest may arise when Sales Personnel interests have the potential to influence, interfere with, or appear to interfere with their ability to carry out obligations under the Manual and/or an agreement with ZimVie. Conflicts of interest are often able to be resolved, but only after proper disclosure and discussion with Healthcare Compliance.

<b>ZimVie Employees</b>	ZimVie Employees have an obligation to avoid conflicts of interest and to proactively report any potential or actual conflicts.
<b>Distributors</b>	<p>In order to avoid potential conflicts of interest when engaging Distributor personnel or other vendors, Distributors must (at a minimum) abide by the following guidelines:</p> <ul style="list-style-type: none"> <li>• Any business relationship with any Distributor personnel or other vendor must be memorialized in advance by written agreement, specifying the 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.</li> <li>• If Distributor or any Distributor personnel promote or sell items other than ZimVie's products, the individual will not condition any discount on any such other item on the purchase of ZimVie's products.</li> <li>• Distributor may not have HCP ownership. (<i>See Part 3: Interactions with HCPs and Public Officials</i>)</li> <li>• 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.</li> </ul>

### Disclosing Conflicts of Interest

During the term of the business relationship between Sales Personnel and ZimVie any direct or indirect activity in which an actual or potential conflict of interest might arise must be disclosed. If there is any question as to whether a relationship or arrangement constitutes a conflict of interest, ZimVie Healthcare Compliance should be consulted for further guidance.

<b>ZimVie Employees</b>	<p>ZimVie Employees must report all possible conflicts of interest that involve HCP or HCI relationships to Healthcare Compliance.</p> <p>Conflict of interest disclosures should occur prior to hiring; re-screening/updated disclosures are conducted annually. Conflict of interest disclosures should be documented, and ZimVie may periodically audit the results of these screenings and disclosures.</p> <p>Conflicts related to close personal relationships that do not involve HCPs (e.g., workplace relationships, outside employment, etc.) should be reported to Human Resources.</p>
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<b>Distributors</b>	<p>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 ZimVie may periodically audit the results of these screenings and disclosures.</p> <p>Materials are available from ZimVie Healthcare Compliance to assist with screening. Please contact Healthcare Compliance for further assistance.</p> <p>Any report that constitutes a potential conflict of interest must be reported to ZimVie Healthcare Compliance for further assessment.</p>
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**Conflicts of Interest with an HCP**

ZimVie generally does not hire HCPs for sales activities to avoid potential or actual conflicts of interest. Any exceptions or special circumstances must be reviewed by Healthcare Compliance prior to hire.

<b>ZimVie Employees</b>	<p>ZimVie prohibits the hiring of team members who are licensed (even if inactive) healthcare providers. If there are special circumstances that require compliance review, please contact Healthcare Compliance for further guidance.</p>
<b>Distributors</b>	<p>ZimVie strongly discourages the hiring of team members who are licensed (even if inactive) healthcare providers. If there are special circumstances that require compliance review, please contact Healthcare Compliance for further guidance.</p> <p>ZimVie 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 ZimVie. Family or other close relationships may never be used to unduly influence purchasing decisions by HCPs and Public Officials.</p> <p>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 ZimVie 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 ZimVie products, or (ii) receive any compensation in connection with such sales.</p> <p>The Distributor must not permit the Distributor personnel related to an HCP or an HCP's Close Family Member to promote or sell ZimVie products to any members of the related HCP's practice group unless approved by ZimVie Compliance in writing.</p>

### C. Document Retention

Sales Personnel must maintain all records that relate to the sale and promotion of ZimVie products.

<b>ZimVie Employees</b>	ZimVie Employees are required to follow ZimVie document retention policies.
<b>Distributors</b>	<p>Distributors must maintain books and records that accurately and fairly reflect in reasonable detail all transactions relating to ZimVie business and provide ZimVie, or a third party designated by ZimVie, access during ordinary business hours and as may be reasonably necessary to perform auditing and monitoring.</p> <p>Books and records related to ZimVie business include, but are not limited to, documents and information relating to:</p> <ul style="list-style-type: none"> <li>• Marketing, promotion, and/or sale of ZimVie products;</li> <li>• Any type of payment to and relationship with any HCP and/or third party relating to or benefitting the ZimVie business; and</li> <li>• Anything of value provided to any HCP, customer, and/or third party in relation to ZimVie business.</li> </ul> <p>Distributors must maintain the following documents:</p> <ul style="list-style-type: none"> <li>• Expense Reimbursement forms, receipts, and other supporting documentation;</li> <li>• Sales Healthcare Compliance Manual and Certification;</li> <li>• Training Records;</li> <li>• 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);</li> <li>• All payment records of any kind relating to financial arrangements (e.g., credit card statements, ledger entries, invoices, receipts);</li> <li>• Monthly HCP Spend documentation (agendas, presentations, sign-in sheets, receipts with line-item detail, etc.);</li> <li>• Complete documentation related to exclusion screening of Distributor personnel;</li> <li>• Complete documentation related to conflict of interest disclosures and screenings;</li> <li>• Documentation from any review activities; and</li> <li>• Documentation related to investigation of potentially non-compliant activities and corrective actions.</li> </ul>



## PART 3: Interactions with HCPs and Public Officials

Sales Personnel are obligated to engage HCPs in an ethical and compliant manner. Such engagements must be conducted in accordance with ZimVie's Healthcare Compliance policies, procedures, standards of conduct, the requirements and expectations outlined in this Manual, and the Distributor's agreement with ZimVie.

### A. Prohibited Arrangements

ZimVie Sales Personnel 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.

ZimVie'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, Sales Personnel are prohibited from engaging in the following financial arrangements:

- Payments of any kind directly or indirectly to a HCP or third party with the purpose of influencing or attempting to influence a 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 in their or their partner's 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).*)
- Distributors 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<sup>1</sup>, 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).

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<sup>1</sup> Educational grants provided by ZimVie typically support general meeting expenses such as audio/visual, venue costs, development, accreditation, cadaveric expenses, and occasionally HCP Honoraria and travel. ZimVie grant funding does not cover expenses such as gifts, entertainment, rewards, recognition plaques, building construction, etc. Grants must be approved through ZimVie corporate procedures.

## Gifts and Entertainment

Providing gifts and entertainment to HCPs, Public Officials, and/or their Close Family Members, partners, friends, or staff is strictly prohibited. Gifts and entertainment are prohibited regardless of whether reimbursement is sought from ZimVie or not. This prohibition has no exception and applies to all circumstances and life events (*i.e.*, career milestone, wedding, funeral, etc.).

Prohibited gifts include, but are not limited to: ZimVie 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. Managers should review and approve the expense prior to purchase.

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

### HCP Meals

In providing any meal to an HCP or Public Official, Sales Personnel must ensure that meals are:

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

If a state, healthcare institution, or other governing mechanism has stricter policies around transfers of value to HCP's than ZimVie's, the stricter policy should be followed.

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

\*Meal limits are inclusive of all beverages, taxes, and gratuities but they do not include room rental fees, catering fees, or other similar fees.

## HCP Transportation

Sales 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 a ZimVie business activity. ZimVie Medical Education Team Members support HCP travel for approved ZimVie medical education and training courses and activities (e.g., Local/Regional meetings, bio-skill courses, and corporate sales training).

## Transparency Reporting

Meal and transportation transfers of value to HCPs must be reported in the applicable ZimVie tracking database for transparency reporting.

- **ZimVie Employees** - Report via Concur. Itemized receipts and other supporting documentation must be provided consistent with ZimVie's compliance and finance policies.
- **Distributors** – Spend Gatekeepers report via MediSpend. Itemized receipts and other supporting documentation (*i.e.*, sign-in sheets, receipts, and meeting agendas) must be tracked and maintained by the Distributor and is subject to review during audits.

To help ensure accurate reporting and alignment with the above meal limits and travel, receipts must not be split. The only exception to the prohibition on splitting checks is when an HCP wants to split a check to pay for himself/herself. Supporting documentation must still be maintained and reported in accordance with applicable policies in these instances.

## C. Promotional, Educational, and Product Support Materials

Promotional, Educational, and 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 ZimVie products, services, techniques, or instruments. These items may be provided to HCPs and patients when servicing a genuine educational or informational purpose related to ZimVie products if they:

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

Sales Personnel may never create or distribute materials that have not been approved by ZimVie. Similarly, Sales Personnel must not alter, edit, or re-purpose any ZimVie approved materials, communications, or applicable documentation in any way (e.g., emails, bulletins, papers, etc.). Finally, Sales Personnel may only use materials in the way they are approved for use (i.e., "internal use only" materials should not be used externally, materials approved for HCPs should not be used with other audiences such as patients, etc.).

Some product support materials and educational items provided to HCPs must be reported for transparency reporting. Itemized receipts and other support documentation must be tracked and maintained. See Part 10: Transparency Reporting for further information.

### Acceptable and Prohibited Materials

ACCEPTABLE	PROHIBITED
<ul style="list-style-type: none"> <li>• ZimVie surgical technique guides</li> <li>• ZimVie Consumer Materials</li> <li>• ZimVie Marketing Collateral</li> <li>• ZimVie approved white paper or industry journal reprints</li> <li>• Anatomical models</li> <li>• Etched samples/demonstration product</li> <li>• Textbooks</li> <li>• ZimVie Template Documents</li> <li>• ZimVie Patient ID cards</li> <li>• ZimVie product information on locked memory sticks</li> </ul>	<ul style="list-style-type: none"> <li>• Extra Instrument Sets</li> <li>• X-ray bag</li> <li>• Generic X-ray markers</li> <li>• Subscriptions to Medical Journals</li> <li>• Blank or unlocked media devices (jump drives/memory sticks)</li> <li>• Office supplies</li> <li>• Clothing/Scrubs</li> <li>• Clip Boards</li> <li>• Goniometer</li> <li>• Pens</li> <li>• Unused Generic Sawbones</li> <li>• HCP Referral cards or similar collateral</li> <li>• Product information loaded onto iPads, electronic notebooks, etc.</li> </ul>

#### Journal Reprints

All journal reprints provided by Sales Personnel must be on-label and approved for use by ZimVie prior to distribution. Journal reprints also may have a reportable value for transparency purposes and must be tracked and reported accordingly.

If an HCP has a request to review literature outside of a product’s FDA approved/cleared indications, refer the HCP to your ZimVie Clinical team for further assistance. Sales Personnel may not be involved in requests for off-label information.

#### Anatomical Models

Sales Personnel may provide HCPs a reasonable quantity of anatomical bone models for use in patient education and awareness at no charge. Models must be relevant to the HCP’s practice, specific to ZimVie systems, and purchased through approved marketing websites. Anatomical models provided for patient education are not reportable for transparency purposes.

#### Etched Samples / Demonstration Products

Demonstration product must comply with business unit specific policies, procedures, and/or guidance. Demonstration Products must be identified as such and never supplied for human use.

## Textbooks

Sales Personnel 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 Sales Personnel must primarily contain content affiliated with the therapeutic areas supported by ZimVie
- Must have the resident/fellow sign the ZimVie Letter of Agreement prior to receiving a textbook;
- Must provide the textbook directly to the resident/fellow recipient; and
- Must track and report the value of the textbook to the HCP
  - **ZimVie Employees** - Must purchase via corporate credit cards and expense via Concur. Manager approval is required prior to purchase.
  - **Distributors** - Must track and report the value in MediSpend. All documentation, including the Letter of Agreement, should be kept for auditing purposes.

## D. HCP Consultant Identification and Selection

Appropriate ZimVie corporate personnel identify and select HCPs for various consulting services (e.g., Training and Education, Product Development, Clinical Research, etc.) in accordance with corporate Compliance policies. Sales Personnel involvement is very limited, and sales personnel may only provide information about potential HCP consultants in response to specific requests from ZimVie corporate personnel.

Sales Personnel may not solicit, influence, or attempt to influence, the engagement of an HCP as a ZimVie consultant. Attempts to do so by Sales Personnel may cause ZimVie to cancel an actual or potential HCP engagement to avoid any perceptions of inappropriate business activity.

## E. ZimVie Medical Education

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

Sales Personnel may not organize or lead Medical Education events. Sales Personnel may provide information to the Medical Education teams to assist in the identification of product training needs for HCPs. Sales Personnel are prohibited from soliciting or agreeing to allow HCPs to teach, proctor, or provide training and education consulting services for ZimVie or for local Distributor product training or education events, whether paid or pro-bono.

## F. Sales and Product Support Activities

Sales Personnel product support activities are distinct and separate from ZimVie Medical Education activities. Product support activities allow Sales Personnel to inform HCPs about the features and benefits of ZimVie'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 ZimVie products.

### HCP Consulting at Product Support Activities

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

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

### Product Support Location and Timing

Product support activities may occur at a location and time that is conducive to the exchange of relevant product information. For product support activities occurring at third party conferences, check with the ZimVie conference organizer for details and options relevant to that event.

### 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 and all meal policies apply. 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 ZimVie Employees and Distributors to help support third-party driven training or education activities that include ZimVie products.

Sales Personnel who are solicited to support third-party directed product training using ZimVie products must direct these requests to the appropriate ZimVie resource:

- For medical education requests, contact the Medical Education Team.
- For requests for product or monetary support only, refer the requestor to the ZimVie grants portal at <https://www.zimvie.com/en/about-us/grant-resource-center.html>
- See also “Part 4: Charitable Donations and Educational and Research Grants”

## G. Evaluation Products

Evaluation products provide HCPS/HCOs with an opportunity to evaluate safe and effective use of ZimVie products during live patient care. Sales Personnel may provide a limited quantity of approved no charge evaluation products to eligible HCPs and/or Healthcare Institutions/Organizations (“HCO”) in accordance with the guidelines below. Availability of Evaluation Product is dependent on the product line and may vary.

*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 “trial” requirement as part of their product procurement process.

*Requirements:*

- Product Evaluations require pre-approval by ZimVie. Contact your sales operations team for further information.
- Sales Personnel must have eligible product evaluators (HCPs/HCOs) complete a product evaluation agreement by or before the surgery/patient procedure and/or within the time period outlined in the agreement (e.g., Capital Equipment);
- Reimbursement must not be sought by the healthcare professional and/or medical institution from any public or private insurance carriers for the evaluation product(s);
- Sales Personnel must be trained on ZimVie’s product evaluation procedures in order to be eligible for inventory reconciliation; and
- Capital or other multi-use evaluation equipment not returned after 90 days will be charged to the facility and subject to transparency reporting.

Sales Personnel who fail to comply with the product evaluation requirements may be prohibited from product evaluation requests and/or other discipline prescribed by ZimVie. Distributors may additionally be subject to out-of-pocket inventory costs.

## PART 4: Charitable Donations and Educational and Research Grants

### Charitable Donations

A Charitable Donation is defined as monetary funding or in-kind product or equipment for charitable purposes such as indigent care, patient, or public education. Donations may only be made to legitimate philanthropic entities and for bona fide charitable purposes.

Charitable donations must not be contingent upon, or related to, the past, present, or potential future recommendation, use, prescription, purchase, lease, or procurement of ZimVie products or services.

<p><b>ZimVie Employees</b></p>	<p>Must refer all HCP or medical institution related Charitable Donation requests to the applicable corporate designee or department for appropriate review. ZimVie Sales Employees should not be involved in decisions related to corporate funding of HCP-related Charitable Donation requests.</p>
<p><b>Distributors</b></p>	<p>Charitable donations by Distributors are permitted if all the following apply:</p> <ul style="list-style-type: none"> <li>• 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;</li> <li>• 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);</li> <li>• Request does not exceed \$7500 USD (requests exceeding \$7,500 USD require approval from ZimVie Healthcare Compliance);</li> <li>• Request is unrestricted;</li> <li>• Charitable donations and/or charitable fundraising support to a particular organization occurs only occasionally;</li> <li>• Payment is not made to individual HCP, HCP practice, or hospital department (e.g., orthopedic or neurosurgery departments);</li> <li>• A written agreement or invoice must be executed or received prior to paying for a charitable donation.</li> </ul> <p>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.</p> <p><b>Examples of Permitted Charitable Donations</b></p> <ul style="list-style-type: none"> <li>• Requests from a hospital, hospital foundation or other third party requestor for financial support for indigent patients, patient education and/or outreach offerings;</li> <li>• Galas and golf events to raise funds for patient education and indigent care (e.g., 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;</li> <li>• Donations to local non-HCP charities such as youth athletic leagues, Red Cross, local races, etc.</li> </ul>



## Charitable Product Donations - US

ZimVie may partner with legitimate philanthropic organizations to facilitate donating ZimVie products to U.S. licensed physicians performing surgeries in the U.S. at no cost to patients who qualify for charitable assistance.

- **ZimVie Employees** - Must direct all charitable product donation requests to the appropriate corporate personnel.
- **Distributors** - Are prohibited from donating or authorizing the donation of any ZimVie products without express authorization from ZimVie.

For more information, please contact Healthcare Compliance.

## Charitable Product Donations – OUS (Medical Missions)

ZimVie 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 and required documents at least ninety (90) days prior to the date product is needed in order to be considered for this type of charitable product donation.

Sales Personnel must direct organizations to the appropriate corporate designee or department for further information.

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 are separate and distinct from non-charitable purposes such as research, educational or in-kind educational product grants (see Educational Grants and Research Grants).

## Educational Grants and Research Grants

A grant is defined as monetary funding or ZimVie 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. Grant support must not be contingent upon, or related to, the past, present, or potential future recommendation, use, prescription, purchase, lease, or procurement of ZimVie products or services. Educational and Research Grants requests must be referred to the appropriate corporate designee or department. Sales Personnel may not be involved in decisions related to corporate funding of grant requests.

## PART 5: Advertising and Promotion

All advertising and promotional content associated with ZimVie products must be reviewed and approved by appropriate ZimVie corporate functions.

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.

### Commercial Sponsorship and Exhibit Booth Space Purchases

A Commercial Sponsorship is defined as a payment or in-kind support provided to a third party in exchange for advertising or promotional opportunities for ZimVie. An Exhibit Booth is one type of benefit that may be received by ZimVie in exchange for a Commercial Sponsorship.

To purchase a Commercial Sponsorship, the following steps should be followed:

- 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 U.S. and Canada Commercial Sponsorship and Exhibit Assessment Form. The form will indicate whether compliance approval is required. If required, send to your Healthcare Compliance Team for review.
- A written Letter of Agreement (“LOA”) must be executed prior to paying for a 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.

<b>ZimVie Employees</b>	All sponsorships, including exhibits/booths, must be coordinated by the approved corporate designee or department.
<b>Distributors</b>	Distributors are permitted to purchase booth/tabletop exhibit space at third-party educational events (CME or non-CME), provided the above guidelines are followed. You should follow the process outlined by your business unit for approvals.

Examples of permissible and prohibited benefits:

<b>Permissible</b>	<b>Prohibited</b>
Exhibit/Display Table or Booth	Not using the exhibit or display opportunity as purchased
Badges for Team Members	Badges for HCPs
Advertisements and/or branding in event materials (e.g., programs, banners, apps, keycards, lanyards)	Tickets for HCPS for recreational or fundraising events
Advertisements and/or branding on physical conference spaces (e.g., elevators, benches, water fountains, charging stations)	Branded, non-educational promotional items (e.g., reusable tote bags, pens, notepads, mugs, thumb drives, or other items with company or product logos)
Ability to hand out routed and approved sales and/or educational materials	Awards for HCPs

<b>Permissible (continued)</b>	<b>Prohibited (continued)</b>
Branded, non-reusable promotional items (e.g., coffee sleeve, napkins, paper cups, plastic bags)	Other non-educational and/or reusable items offered by the third party organizer (e.g., water bottles, tote bags, t-shirts)
Ability to talk about ZimVie products/services	Raffles for items or gifts
Exclusive or group sponsorship of a reception, meal, or coffee break (but may require transparency tracking and reporting)	
Attendee Lists	

### Badge and Registration Fees

Badge and Registration Fees should be processed through appropriate mechanisms.

<b>ZimVie Employees</b>	ZimVie Employees should contact the appropriate corporate designee for badge and registration support questions.
<b>Distributors</b>	<p>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:</p> <ul style="list-style-type: none"> <li>• Payment is not made to individual HCP, HCP practice or hospital department (e.g., orthopedic or neurosurgery departments);</li> <li>• 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);</li> <li>• Payment receipt is provided; and</li> <li>• If the event is a large association meeting, such as NASS, check with ZimVie corporate on badge availability.</li> </ul> <p>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.</p>

### Journal Clubs and Grand Rounds

Sales Personnel are permitted to support Journal Clubs and Grand Rounds, including meals, if all the following conditions apply:

- In addition to the display or exhibit of ZimVie product, time is given on the event agenda to conduct a product discussion or educational presentation (minimum 25 minutes);
- Payment for the meal is not made to an 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 ZimVie meal policies and dollar limits, including reporting per the applicable transparency requirements.

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

## Co-Marketing

Sales Personnel who are interested in Co-Marketing Programs conducted by or on behalf of ZimVie in conjunction with a Healthcare Professional should contact their Healthcare Compliance and Marketing Business Partners to seek guidance on the requirements to conduct such an activity.

It is important to note that Co-Marketing Programs are different than the trainings ZimVie conducts to train and educate HCPs on the safe and effective use of its products and services. All Co-Marketing Programs require a written agreement in accordance with healthcare compliance and marketing guidelines, the use of routed and approved materials, and appropriate cost sharing between the HCP or HCO and ZimVie. Depending on the type of Co-Marketing Program, additional healthcare compliance parameters may apply.

## PART 6: 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 ZimVie. Sales Personnel must not engage in negotiations or any other meetings with government or payers, unless specifically authorized by ZimVie.

Sales 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 ZimVie. Additionally, only 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), Sales Personnel may not contact or negotiate with entities involved in the specialty distribution channels. Management of communication and relationships with specialty distribution channels are the responsibility of ZimVie.

All customer inquiries regarding reimbursement or coding information should be directed to the relevant product manager for further guidance.

## PART 7: 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/PHI” 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).

ZimVie requires that Sales Personnel comply with 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.

Anytime Sales Personnel are working with protected health information, personal information or confidential information, the “minimum necessary” standard should apply, which means to only access, disclose or use the minimum amount of such information that is 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.

For protected health information or personal information in the course of work, Sales Personnel 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 Sales Personnel become 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 ZimVie Global Privacy Officer, or ZimVie Legal or Healthcare Compliance Department immediately.

<b>ZimVie Employees</b>	ZimVie Employees must comply with all applicable corporate policies and procedures related to privacy and security. Different business units may have different privacy and/or security obligations.
<b>Distributors</b>	<p>Distributors should have guidelines and procedures in place for retaining and destroying personal 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.</p> <p>Distributors who are engaged as Business Associates should additionally ensure they understand and comply with the terms of their Business Associate Agreement (BAA). The terms of the BAA are subject to auditing and monitoring.</p>

Sales Personnel 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 ZimVie products. If you have a specific protected health information or personal information scenario to discuss, or questions about privacy obligations and responsibilities, please contact the ZimVie Global Privacy Officer.

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

**Canadian Privacy Law**

For the purposes of Canadian privacy law, a Distributor is a third party processor on behalf of ZimVie of any personal information received while distributing ZimVie 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 to 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 always safeguarded.

**PART 8: Social Media Guidelines**

Social Media policies are governed by the ZimVie Corporate Communications Team. The Corporate Communications Team works collaboratively with cross functional team members, including Healthcare Compliance, to ensure our social media presence operates with ethics and integrity, and within appropriate parameters given the laws and regulations which we must operate within. All questions related to Social Media use, including personal use of social media related to ZimVie and/or our products and services, should be directed to the Corporate Communications Team.

## PART 9: Transparency Reporting

In order for ZimVie to comply with federal and state transparency laws, all Sales Personnel must completely and accurately report payments and other transfers of value provided directly or indirectly to HCPs and teaching institutions, or at the request of HCPs and teaching institutions, as directed by ZimVie Healthcare Compliance.

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

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

<p><b>ZimVie Employees</b></p>	<p>HCP meals and ground transportation should be expensed via corporate credit cards and processed via Concur. All corporate policies governing expense processing apply.</p> <p>All other transfers of value have different reporting mechanisms depending on how they are processed via ZimVie corporate departments. Any time you provide something that has a transfer of value, it is your responsibility to ensure it is processed and/or tracked through the appropriate corporate mechanism. If you are unsure if something is reportable, contact Healthcare Compliance.</p>
<p><b>Distributors</b></p>	<p>The recording of transactions in the applicable tracking database (MediSpend) must be performed by the tenth (10<sup>th</sup>) calendar day of the month following the date of the transaction, unless specifically instructed otherwise by ZimVie Healthcare Compliance.</p> <p>Distributors must retain copies of all itemized receipts and supporting documentation, including any HCP spend from Distributor personnel. This documentation must be maintained pursuant to the requirements set forth in this Manual.</p> <p>When an individual leaves a Distributor's organization, Distributor must use best efforts to obtain any HCP spend the departing individual incurred.</p> <p>HCP-related payments that are charged back to a Distributor will be tracked and recorded by ZimVie. Please do not report items that are charged back to Distributor as it will risk double reporting of those expenses.</p> <p>Distributors are required to annually certify that all HCP spend has been accurately and completely reported to ZimVie in the MediSpend system.</p>

## 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 Sales 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 an HCP participates in a business meal in New York, and is licensed in both New York and Massachusetts, the restrictions imposed by Massachusetts apply.

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

In addition to Massachusetts and Vermont, other states may enact laws that govern our interactions at any time. It is your responsibility to understand the laws that apply to the sales in your geography. If you become aware of a potential new law focused on medical device manufacturers, or have questions about an existing law, please contact ZimVie Healthcare Compliance for support.

### **Massachusetts:**

- Meals: Meals provided to Massachusetts HCPs must be both modest and educational in nature, and the location of the meal must be conducive to a bona fide educational purpose.
- Massachusetts HCPs may attend facility tours using the approved ZimVie Travel Agency.

### **Vermont:**

- Meals: Sales 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: ZimVie and its Sales Personnel 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.
- ZimVie and its Sales Personnel may not provide any meals directly to a Vermont HCP at any third-party educational conference. This means that ZimVie and its Sales Personnel 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 may attend facility tours using the approved ZimVie 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, ZimVie and its Sales Personnel 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: Healthcare Compliance Monitoring and Auditing

Sales Personnel are subject to auditing and monitoring in accordance with ZimVie policies and procedures.

<b>ZimVie Employees</b>	All relevant employee activities are subject to auditing and monitoring.
<b>Distributors</b>	<p>As a regular part of its global healthcare compliance program and pursuant to its contractual audit rights, ZimVie will periodically conduct auditing and monitoring activities of its Distributors, which may involve the following:</p> <ul style="list-style-type: none"> <li>• Site visits;</li> <li>• Books and Records assessments;</li> <li>• HCP expense assessments;</li> <li>• Ride-alongs;</li> <li>• Local Distributor events;</li> <li>• Industry events (e.g., Society Meetings, third-party educational conferences, trade shows, etc.); and</li> <li>• Other</li> </ul> <p>The purpose of these visits is to ensure compliance with the ZimVie's healthcare compliance guidelines and expectations outlined in this manual.</p> <p>Distributors and Compliance Liaisons must cooperate with ZimVie personnel to successfully coordinate and support these visits.</p>

## Part 12: Non-Compliance

Sales Personnel must proactively engage ZimVie Healthcare Compliance with any business scenarios that may impact compliance with ZimVie policies and procedures.

<b>ZimVie Employees</b>	Failure to comply with this Manual, agreements with ZimVie, or Healthcare Compliance policies and procedures may result in disciplinary action, up to and including termination.
<b>Distributors</b>	Failure to comply with this Manual, agreements with ZimVie, or Healthcare Compliance policies and procedures may subject the Distributor and/or Distributor Personnel to disciplinary action, disqualification from representing ZimVie products and services, and/or contract termination.

# Annual Screening Checklist

**Instructions for Use:** The following template is available for Distributors to use with their team to meet the annual screening requirements of this Manual. Distributors are not required to use this form and are encouraged to consult with their independent counsel on execution of these requirements as appropriate for their business.

**Sales Rep Name:**

**Territory:**

**Date:**

1.	<p><b>Are you a Healthcare Professional (HCP)?</b></p> <p><b>If yes, please provide the following:</b></p> <ul style="list-style-type: none"> <li>• Active or Inactive</li> <li>• License / NPI number</li> <li>• Healthcare Institution Affiliations</li> <li>• HCP Type</li> <li>• State(s) of Licensure</li> </ul>	<p><b>Yes</b>      <b>No</b></p>
2.	<p><b>Have you been excluded from a government program? Click "Launch" buttons to perform the following searches:</b></p> <ul style="list-style-type: none"> <li>• OIG/HHS List of Excluded Individual</li> <li>• FDA Disbarment</li> </ul> <p><b>If yes, please describe the circumstances around your exclusion.</b></p>	<p><b>Yes</b>      <b>No</b></p>
3.	<p><b>Are any of your close family members an HCP?</b></p> <p>• "Close Family Member" includes birth or adoptive parents, spouses or partners, children, siblings, stepparent, stepchild, stepbrother, stepsister, father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, grandparent or grandchild, and spouse of a grandparent or grandchild. ZimVie broadly construes this to include other familial-type relationships, including individuals who reside in the same household.</p> <p><b>If yes, please describe:</b></p> <ul style="list-style-type: none"> <li>• Name of HCP(s)</li> <li>• HCP Type(s)</li> <li>• Name of affiliated healthcare institution(s) where the HCP(s) have rights to practice</li> <li>• Details about whether you interact with those HCP(s) in connection with your product promotion or service responsibilities</li> <li>• Details about if/when this relationship has been disclosed and/or reviewed previously</li> <li>• Details about if/when this relationship was approved or denied previously</li> </ul>	<p><b>Yes</b>      <b>No</b></p>
4.	<p><b>Do you have material ownership in any medical device, biologic or pharmaceutical companies and/or do you share any other business relationship(s) with a HCP(s)?</b></p> <p><b>If yes, please describe the following:</b></p> <ul style="list-style-type: none"> <li>• Is the company in competition with ZimVie products and services?      <b>Yes</b>      <b>No</b></li> <li>• Is the company partly owned by an HCP or HCPs?      <b>Yes</b>      <b>No</b></li> <li>• Describe the nature of the company and/or relationship</li> </ul>	<p><b>Yes</b>      <b>No</b></p>
<p><b>Was this form reviewed and approved by appropriate distributorship leadership?</b>      <b>Yes</b>      <b>No</b></p> <p><b>Name of Reviewer:</b> _____ <b>Date:</b> _____</p> <p><b>Were there any disclosures that required a report to ZimVie?</b>      <b>Yes</b>      <b>No</b></p> <ul style="list-style-type: none"> <li>• If yes, when was the disclosure reported?</li> <li>• If yes, who was the disclosure reported to?</li> <li>• If yes, what was the final resolution of the disclosure?</li> </ul> <p style="text-align: center;"><b>**If any disclosures require reporting to ZimVie, please contact Healthcare Compliance.**</b></p>		