



axogen[®] code
on interactions
with health care
professionals
("Health Care
Code")

**revolutionizing the
science of nerve repair[™]**

www.axogeninc.com

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Axogen Nation,

Axogen remains passionate about restoring nerve function and quality of life to patients with peripheral nerve injuries. We are also committed to conducting our business ethically and in compliance with applicable laws, rules and regulations, guidelines, policies, and industry practices that guide Health Care Professionals and their facilities and the medical device and biologics/pharma industry. Axogen’s Code on Interactions with Health Care Professionals, our “Health Care Code”, is our way of consolidating and adopting compliance best practices focused on integrity across our interactions with Health Care Professionals.

Compliance is every Axogen Corporate Representative’s responsibility. In this spirit, if you become aware of any actions that may violate this Health Care Code, I urge you to Speak Up. We need everyone to join in making sure that Axogen remains compliant. You can Speak Up by contacting us through our hotline (844)-989-2990 or axogen@ethicspoint.com.

For questions or concerns about any compliance issue you may also reach out to any compliance team member or email compliance@axogeninc.com. Thank you for always being a trusted resource and partner and always acting with integrity.

Kind regards,

A handwritten signature in black ink that reads "Karen Zadorej". The signature is written in a cursive, flowing style.

Karen Zadorej
Chairman, Chief Executive Officer, and President

1 quick guide for using axogen’s health care code

1.1 Format of Axogen’s code on interactions with health care professionals

Axogen’s code of conduct on interactions with Health Care Professionals (HCPs) (hereafter referred to as the Health Care Code) is formatted with links to supporting reference materials, defined terms in “Definitions” boxes, helpful Question & Answer boxes (?), Practical Tips (💡), or Do’s & Don’ts guidelines to further assist your understanding.

2 preamble

2.1 Axogen’s Mission Vision and Values

Axogen exists to restore nerve function and quality of life for individuals with peripheral nerve injuries. We are building the preeminent peripheral nerve company by:

1. Being the company where exceptional people want to work;
2. Increasing awareness of the impact of nerve damage on quality of life;
3. Providing innovative, clinically proven, and economically effective solutions to transform and improve patients’ lives;
4. Being the trusted resource and partner for patients, clinicians, providers and payors; and
5. Driving sustainable, long-term growth to achieve this mission and vision.

2.2 Why Axogen’s Health Care Code is Unique

Due to the nature and types of Axogen products, we must abide by a myriad of applicable laws, regulations, and industry standards, including the PhRMA and AdvaMed industry codes. Our Health Care Code is unique as it adopts requirements from these various laws, regulations, and industry standards and codes. While no code can address every situation, in our Health Care Code we aim to address interactions that are most often met across Axogen’s business and provide a set of principles and expectations that are contemporary, best fit, and practical for all to follow.

This Health Care Code is our way of consolidating compliance best practices and ethical conduct guidelines focused on integrity across interactions with HCPs, such as our customers and business partners. Interactions with HCPs outside of the U.S. and across the world must also comply with applicable laws, regulations, and industry codes of practice; accordingly, in the event of a conflict between this Health Care Code and any foreign requirements, the more restrictive provisions apply. This Health Care Code applies to all Axogen Company Representatives.

DEFINITIONS

Health Care Professionals

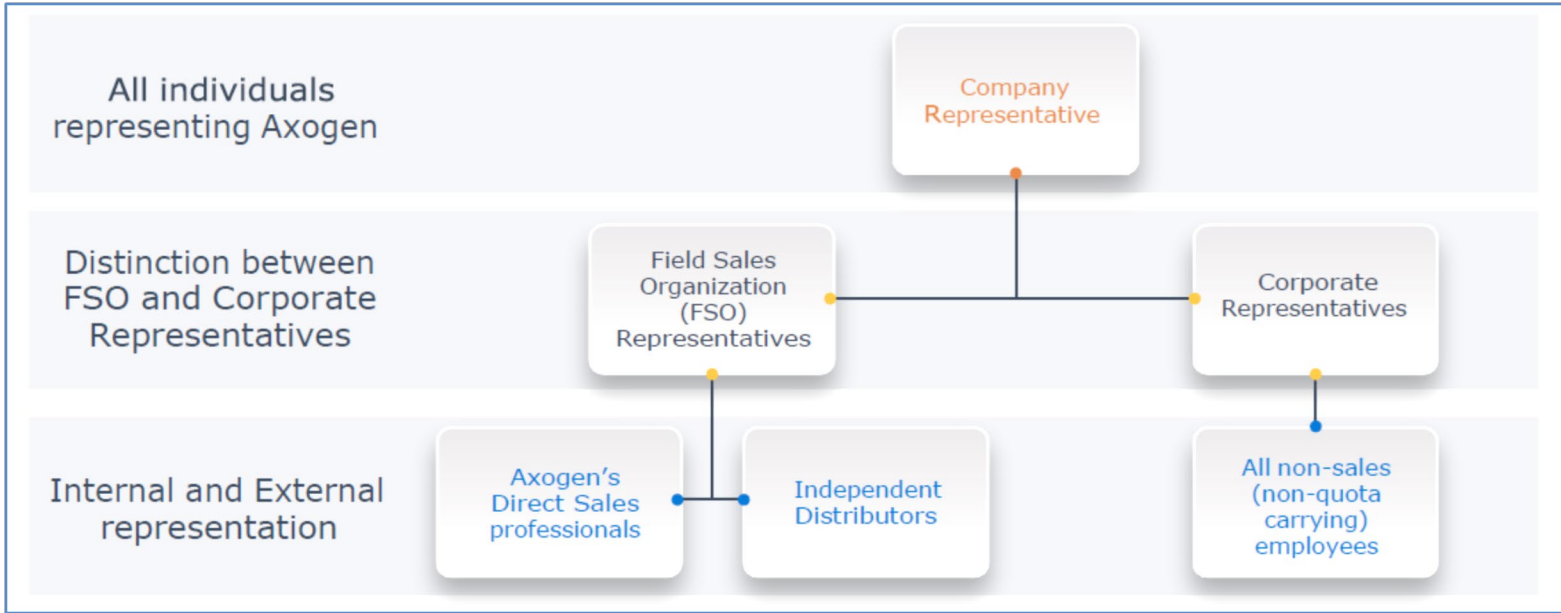
(HCPs): Means any person or entity that is: **(a)** authorized or licensed in the United States to provide health care services or items to patients or **(b)** who is involved in the decision to purchase, prescribe, order, or recommend a Product in the United States. This term includes individual clinicians (for example, physicians, nurses, and pharmacists, among others), provider entities (for example, hospitals and ambulatory surgical centers), and administrative personnel at provider entities (for example, hospital purchasing agents). This term does not include Health Care Professionals who are bona fide employees of Axogen.

Company Representative: Any Axogen employee, independent contractor, or agent acting on Axogen’s behalf. Company Representatives include Corporate Representatives, Field Sales Organization (FSO) representatives, and distributors of Axogen products. **(See Figure 1)**

Corporate Representative: An Axogen Employee not reporting to the Commercial Sales Team or being compensated based on the sales of Axogen products. Examples include Members of the Clinical Operations, R&D, Medical Affairs, Marketing, Senior Leadership or Executive Team, Legal & Compliance Team. **(See Figure 1)**

Field Sales Organization (FSO) Representative: An Axogen Employee who reports into the commercial sales team and/or is compensated based on the sales of Axogen’s products or carrying a quota. FSO Representatives are incentivized by sales and commissions, special promotional initiatives, and bonus structures associated with product sales. Examples are Sales Representatives, Area Sales Managers, Regional Sales Directors, and Area Vice Presidents. **(See Figure 1)**

FIGURE 1: Axogen Organizational Representatives



DEFINITIONS

Anti-Kickback Statute (AKS): The Federal Anti-Kickback Statute (AKS) is a law which prohibits knowingly and willfully offering, paying, soliciting, or receiving anything of value to induce or reward referrals of or the purchase of items or services reimbursable by a federal health care program.

Foreign Corrupt Practices Act (FCPA): The FCPA and its anti-bribery provisions prohibit any offer, payment, promise to pay, or authorization of money or anything of value to any person, while knowing that all or a portion of such money or thing of value will be offered, given or promised, directly or indirectly, to a foreign official to influence the foreign official in their official capacity, induce the foreign official to act in violation of their lawful duty, or to secure any improper advantage to assist in obtaining or retaining business for or with, or directing business to, any person.

Unlawful Inducement: Means the prohibitions found in the AKS and FCPA statutes to unlawfully induce or reward the generation of business.


AdvaMed Code: Means the industry code that provides medical device companies with guidance on ethical interactions with HCPs. It can be found at: [2023-AdvaMed-Code-of-Ethics.pdf](https://www.adva-med.com/2023-AdvaMed-Code-of-Ethics.pdf)

PhRMA Code: Means the industry code on interactions with HCPs that is applicable to pharmaceutical and biotech companies. It can be found at: [Code on Interactions with Health Care Professionals | PhRMA](https://www.phrma.org/interactions-with-health-care-professionals-pharma)


23 Decision Making and Independence

Axogen expects your professional, ethical, and socially responsible interactions with HCPs are of the highest standards and do not include unlawful inducements or interference with HCP’s decision making and independence.

All Company Representatives must abide with the Anti-Kickback Statute (AKS) and Foreign Corrupt Practices Act (FCPA) requirements. No Company Representative should offer or provide anything of value in a manner, or on conditions that could interfere with the independence of a HCP’s independent judgment or prescribing practices. No Company Representative should offer or provide any grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items to a HCP in exchange for prescribing products or for a commitment to continue prescribing products.



“Safe Harbors” exist which protect business arrangements from implicating the AKS. It is always best to fit arrangements with HCPs within a Safe Harbor. For more information or assistance with interactions with HCPs contact the Legal & Compliance Team.



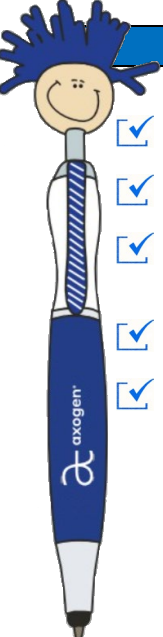
Q. Are HCPs only Physicians?
A. No. An HCP can be any individual in the position to purchase, prescribe, order, or recommend our Product(s).

3 general ethical conduct in health care professional interactions

3.1 Communicating the Safe & Effective Use of our Product

At Axogen, patient safety is our top priority; accordingly, ensuring our Products are safe and effective is essential. The U.S. Food and Drug Administration (FDA) and other governing bodies regularly publish guidelines and principles on medical, scientific, educational, and promotional communications. Axogen’s regulatory, compliance, marketing and medical affairs teams strive to ensure that all approved content aligns with these guidelines.

It is the responsibility of all Company Representatives to abide by these principles. Further, FSO Representatives bear additional responsibility as the frontline resource to HCPs at their site of care. Often, the communications between FSO Representatives and HCPs are the primary or sole point of contact between Axogen and the HCP. Such communications therefore are both critical to the exchange of information intended to enhance the practice of medicine and subject to scrutiny if that information does not follow these principles. FSO Representatives may only share information that is approved and lawful and consistent with the claims of the Products Axogen markets.

COMMUNICATION DO'S	COMMUNICATION DON'TS
 <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Be accurate and not misleading. <input checked="" type="checkbox"/> Make claims only if they are on-label <input checked="" type="checkbox"/> Make claims about a product only when appropriately substantiated. <input checked="" type="checkbox"/> Reflect balance between risks and benefits. <input checked="" type="checkbox"/> Be consistent with FDA requirements governing such communication. 	<ul style="list-style-type: none"> <input type="checkbox"/> Promote Products before getting approval to market them. <input type="checkbox"/> Suggest or encourage any unapproved or off-label uses of Products. <input type="checkbox"/> Exaggerate the benefits of our Products and technologies or hide any potential risks of use. <input type="checkbox"/> Make claims that are not supported by appropriate Product testing or clinical data. <input type="checkbox"/> Make false or disparaging claims about competitors or competitors’ product. <input type="checkbox"/> Make any changes to approved advertising or promotional material or create your own.

FSO Representatives may not initiate, nominate, or otherwise engage in discussions on consulting arrangements or off-label applications of Products, nor may they interfere with a HCP’s judgment or decision making.

3.2 Company Representatives Providing Technical Support in the Clinical Setting

Axogen’s Products require storage, handling, technical, and surgical care for their safe and effective use. Company Representatives may play an important role in the clinical setting by providing support on the safe and effective use of Axogen’s products. Some examples include:

- Company Representatives may need to explain Axogen’s Product ordering, shipping, storage, thawing, soaking, and technical handling requirements.
- Company Representatives may assist the clinical/operating room team to ensure that the appropriate range of necessary Product is available during a procedure.

TECHNICAL SUPPORT IN THE CLINICAL SETTING DO’S

Allowable activities:

- ✓ Company Representatives should enter and be present in the clinical setting only at the request of and under the supervision of a HCP.
- ✓ Company Representatives should be transparent that they are acting on behalf of Axogen in a technical support capacity.
- ✓ Company Representatives should not interfere with a HCP’s independent clinical decision-making nor directly interact with patient.
- ✓ Company Representatives should comply with applicable hospital or facility policies and requirements, including patient privacy and credentialing requirements.
- ✓ Axogen’s support should not eliminate any overhead or other expense that the HCP should otherwise incur while providing patient care. For example, technical support should not eliminate the need of personnel such as a surgical tech or provide materials such as sutures or instruments that are otherwise provided for patient care by the facility.

3.3 Demonstration, Evaluation, and Consigned Products

Axogen has established policies and mechanisms to provide products to HCPs that may help educate on, provide experience with, or improve access to those products.

Providing products to HCPs at no charge for evaluation or demonstration purposes can improve patient care, educate HCPs regarding the safe and effective use of Axogen Product(s) and enhance patient awareness. Under certain circumstances, Axogen may provide limited quantities of Product to HCPs at no charge to allow them to assess the appropriate use and functionality of the Product.

Demonstration Product. Company demonstration products are typically unsterilized single use products or mock-ups that are used for HCP and patient awareness and education. For example, a HCP may use a demonstration product to show a patient the type of device that will be implanted in the patient.



Transparency. Axogen must consider whether Federal or State law (for example, the U.S. Physician Payments Sunshine Act) requires reporting the value of evaluation products provided to HCPs.

DEFINITIONS

Product(s): Medical device(s), tissue and biologic product(s) offered by Axogen.

Demonstration or “Demo” Product: Product that is not intended for patient use (typically identified as not intended for patient use through designations like “Sample” or “Not for Human Use”), but may be used in cadaver or handling labs, patient demonstration, awareness, and education about the Product.

Evaluation Product: Product provided to Axogen customers as a “sample” for evaluating prior to a purchasing or ordering decision. Evaluation Product should only be provided on a limited basis and in a quantity that is reasonable for the evaluation purpose.

Consigned Product: Consigned products are Products that **(a)** Company provides to a HCP for use in and storage at the HCP’s patient care setting and **(b)** to which the Company retains title until the product is used.

Evaluation Product. Axogen conducts and supports educational and training programs designed to educate HCPs on the safe and effective use of our Products and general nerve repair techniques and solutions. Products that may be provided to HCPs for evaluation include for example, a single Avance nerve graft, or limited Axoguard product.

Axogen Products provided for evaluation are typically expected to be used in patient care. The number of Products provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances.

Axogen must provide HCPs with appropriate documentation to allow them to address any reimbursement reporting obligations, including providing information on the no-charge status of these products.

For additional information on appropriate documentation, safeguards, or necessary reporting obligations, you may reach out to Axogen’s Compliance Team. Compliance@axogeninc.com



Evaluation products should not be provided in lieu of professional education initiatives, but rather on rare occasions where a HCP was not able to attend or receive other formal training on the safe and effective use of Axogen’s Products through educational support or company conducted hands-on training.



Q. What are examples of appropriate reasons for providing evaluation products to an HCP?

A. Examples may include the HCP may have not recently purchased or used the products (i.e., the HCP is not familiar with the product); or the product may be marketed for a new indication or new surgical technique; among other reasons.

Consigned Products. Consigned products are Products that: (a) Axogen provides for use in and storage at the HCP’s patient care setting, and (b) to which Axogen retains title until the Product is used. Axogen’s consignment arrangements are subject to a Consignment Agreement that addresses the terms of consignment, for example, the quantity and number of products, any storage requirements, purchase and payment terms and other terms and conditions that govern those products and the parties’ relationship.

Axogen has implemented controls to monitor and manage consigned Products. These include (among other measures) taking periodic inventory of consigned Product for purposes such as billing and restocking; reconciling discrepancies between Axogen’s records and the number of Products used or verified during inventory; and return or removal of expired Product. Our controls ensure proper dealings with HCPs. Controls will vary for biologic Product.

34 Educational & Patient Benefit Items; Prohibition on Gifts

Gifts to HCPs are prohibited. To ensure Company Representatives’ interactions with HCPs are ethical and professional, our Health Care Code prohibits providing any items or gifts that are not educational to HCPs, regardless of the item’s value.

Any item given to a HCP’s staff should be treated as though it is given to the HCP and is subject to the applicable requirements herein. Any item of value provided to a physician-HCP or teaching hospital must be reported to the CMS Open Payments database in accordance with the Sunshine Law. See Section 7, for more information.

The following is a representative list of allowable and prohibited items under our Health Care Code.

EDUCATIONAL ITEM DO'S

- Anatomic models, graphics, or other patient education items;
- Instructional brochures, patient care, or treatment option materials;
- Textbooks (if they exceed \$100, pre-authorization is required); and/or
- Unbranded training instruments and products such as technique guides and disposable micro-instruments

Permitted educational and patient benefit items must be modest in value, at most occasional, and approved by Axogen prior to distribution.

Items must be requested through the grants, sponsorship, and donation portal (Compliance Portal) and approved prior to distribution. See QR code for link:



EDUCATIONAL ITEM DON'TS

- Practice related items of any value: Pens, note pads, mugs, organizers or other non-educational Axogen branded items;
- Personal use items such as scrubs, shirts, electronics, mobile devices, wearables, etc.;
- Flowers, edible arrangements, gift baskets, holiday gifts calendars or other office space furnishings;
- Music, movies, records, tickets, passes, or other vouchers;
- Cash, gift certificates or other payments for goods and services (except as reimbursement for bona fide services); and/or
- Gifts that recognize life events such as birthdays, anniversary, weddings, holidays, etc.

3.5 Prohibition on Entertainment & Recreation

Company Representatives shall not provide entertainment or recreation to HCPs in any form, for any reason, at any time. Company Representative’s interactions with HCPs are professional in nature and are intended to facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on education and informational exchange and to avoid the appearance of impropriety, Axogen’s Company Representatives may not provide or pay for any entertainment or recreational items or events. Personal out-of-pocket payment is prohibited.

ENTERTAINMENT & RECREATION DON'TS

Examples of **prohibited activities** include:

- Tickets to the theater, clubs, or sporting events, sporting equipment, golf, skiing, hunting, fishing, boating, cruises, or leisure or vacation trips, to any HCP.
- Such entertainment or recreational benefits should not be offered, regardless of **(1)** the value of the items; **(2)** whether the company engages the HCP as a speaker or consultant, or **(3)** whether the entertainment or recreation is secondary to an educational purpose.



Venues should not be renowned or extravagant. Luxury resorts, high-end restaurants and other recreational venues or events are not appropriate.



Q. Under what circumstances can Company Representative provide entertainment to HCPs?

A. None. Entertainment is strictly prohibited.



Q. Can Axogen sponsor a meal with entertainment (for example, live music)?

A. No. It is prohibited to provide or pay for any entertainment or recreational events. Further, all meals should be subordinate in time and focus to a bona fide discussion of scientific, educational, or business information and should not be part entertainment, even if were held in connection with a third-party program.

3.6 Provision of Health Economics & Reimbursement Information

The Health Economics and Reimbursement (HER) team assists with coding, coverage, and reimbursement support via a variety of tools and resources. Because the tools and resources the HER team provides may have an impact on a providers’ revenue, it is important to use these tools for educational purposes only and are not to be construed as authoritative.

The provider or entity billing a third-party payor is solely responsible for the accuracy of the codes assigned to the services or items in the medical record. It is important to remember that while a code may exist describing certain procedures and/or technologies, it does not guarantee payment by the payors.

Company Representatives may only provide HER information that has been reviewed and approved for distribution by the Axogen HER team. Below are practices that should be followed when sharing HER information.

HEALTH ECONOMICS & REIMBURSEMENT DON'TS

- Do not promote the spread between Product’s purchase price and a reimbursement amount as a reason to use/purchase the product.
- Do not compare the reimbursement/spread for use of the product with that of a competitor product.
- Do not make promises, assurances, or guarantees of coverage or reimbursement.
- Do not promote how much money a provider might make by using or switching to company Product.
- Do not provide billing or coding advice or direct the use of certain codes unless coding information is provided in an objective manner.
- Always convey to customers that they are responsible for determining appropriate coding and for submission claims.

3.7 Providing Modest Meals and Refreshments to Health Care Professionals

Meals and refreshments provided to HCPs must be provided in a manner and place that are conducive to the presentation and/or exchange of scientific, educational or business information, and any meals should be subordinate in time and focus to the presentation and/or exchange of scientific, educational or business information. [Axogen’s Travel and Expense Policy \(Axogen T&E Policy\)](#) should be consulted for additional information not covered in this Health Care Code and it may be found through Axogen’s LMS or Quality System. In no event should a Company Representative pay for any HCP meals or refreshments out-of-pocket.

No “Take-out”, “Dine & Dash”, or “Grab & Go” meals shall be provided by any Corporate Representative to in-office/in-hospital setting since attendance, participation and bona fide needs are required for HCPs and office staff. When meals are allowed, sandwiches and/or pizza are generally considered as “modest”. Additionally, since meals must be subordinate to the exchange of scientific information such meetings must be limited to “no more than occasional basis”.

DEFINITIONS


National Provider Identifier (NPI) is a unique 10-digit identification number for covered health care providers.

NPI Registry is a free directory of all active NPI records. [NPPES NPI Registry](#)

Business Needs are the opportunities that are of strategic importance to an organization.

MODEST MEALS & REFRESHMENT DO’S	
<p>For the HCPs and members of their staff with bona fide needs to participate or attend the meetings, meal or refreshments provided must be:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Modest, as judged by local standards (not to exceed limits outlined in Axogen T&E Policy); <input checked="" type="checkbox"/> Not part of an entertainment or recreational event; and <input checked="" type="checkbox"/> Provided in a manner conducive to professional communication. 	<p>To ensure compliance with the Health Care Code, business meetings must include the following documentation as part of expense reporting:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Date, time, and location of meeting; <input checked="" type="checkbox"/> Business need (be specific); <input checked="" type="checkbox"/> Attendee list (with NPI numbers confirmed through NPI Registry); <input checked="" type="checkbox"/> Itemized receipts of any food, beverage, or other costs associated with the meeting; and <input checked="" type="checkbox"/> Completed expense report submitted per the company policy.


FSO Representatives should address common HCP needs around Axogen Products during the HCPs’ working hours and within their facilities; however, when required, FSO Representatives may provide modest meals for business meetings that satisfy the criteria and documentation specified above.



A general discussion to build good business relationships is not an appropriate purpose for providing a meal to a HCP.


A meal should only be provided to a HCP as part of a bona fide business discussion. This includes, for example, discussions on Product development and improvement, pricing, or contract negotiations, among other legitimate topics. The discussion should account for most of the time spent during the meal.

A casual get-together or the development of general goodwill should not be the primary purpose of a meal with a HCP.



Q. Can a Company provide lunch to an HCP or medical office on a recurring basis?

A. Incidental meals may only be provided to HCPs and members of their staff so long as the presentation provides new scientific or educational value or different attendees are present.



Q. Is the provision of meals monitored by the Company?

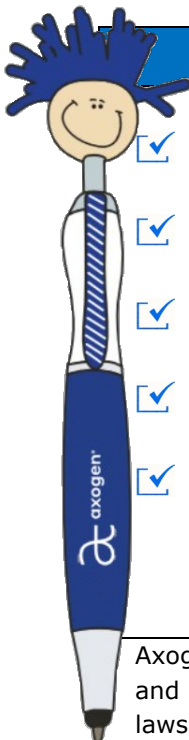
A. Yes. The Company, as part of an effective compliance program, has an obligation to take reasonable steps to confirm that a substantive interaction has occurred during the provision of meals.

3.8 Travel, Lodging, and Venue for Company Events

When appropriate and approved by an Axogen Corporate Representative (non-FSO Representative), Axogen may provide modest travel and lodging accommodations to HCPs. Depending on event, requests must be made through the [Compliance Portal](#) or approved travel agency, and must not be initiated, influenced, or otherwise managed by FSO Representatives.

Travel and lodging accommodations and costs must be modest and reasonable under the circumstances and comply with Axogen’s T&E Policy. All expenses must be accompanied by itemized receipts and submitted using compliance and finance system policies.

Axogen will apply the following principles when evaluating whether it is appropriate to pay for HCPs’ travel and lodging costs:

TRAVEL & LODGING DO’S	TRAVEL AND LODGING DON'TS
 <ul style="list-style-type: none"> ✓ Establish an objective, legitimate business need to support out-of-town travel for HCPs; ✓ Ensure travel and lodging is modest, reasonable, and accompanied by itemized receipts; ✓ Establish controls around timing and location of HCP travel arrangements; ✓ Ensure the setting is conducive to the exchange of information; and ✓ Ensure the setting is centrally located and easily accessible in relation to the place of origin of the invited participants. 	<ul style="list-style-type: none"> ✗ Pay for, or subsidize the travel or lodging of spouses, guests of HCPs, or any other person who does not have a bona fide professional need to attend a meeting; ✗ Pay for a HCPs personal travel and lodging; ✗ Book or schedule company conducted events because of entertainment or recreational facilities; or ✗ Book or schedule company-conducted events at luxury hotels or resort facilities without appropriate justification.
<p>Axogen is aware that other laws or regulations may apply to the reporting of payments for HCPs’ meals, travel and lodging, including potentially more restrictive state laws. Axogen shall comply with the more restrictive state laws, when applicable.</p>	

4 company-led HCP interactions

4.1 Axogen Business Meetings with HCPs

Axogen may identify a legitimate need and conduct business meetings with HCPs. These HCPs may be Axogen Consultants or non-consultant customers. Based on the complexity, unique patient presentations, and technical questions or concerns, or in the case of consultants, work, or service product support needs, Axogen will apply the following principles when organizing and conducting business meetings with HCPs:

BUSINESS MEETINGS WITH HCPs DO’S
<ul style="list-style-type: none"> ✓ Legitimate Need. Axogen must have a legitimate need to conduct the meeting. For example, we may identify a need to show HCPs product prototype, clinical research protocols, technique development, or nerve repair surgical content development. ✓ Setting. Axogen may hold meetings at, or close to a HCP’s place of business or facility, another centralized location, or at Axogen’s own facility that may be a more appropriate setting for the meeting. The setting for an Axogen-conducted meeting must be conducive to the discussion of relevant information. ✓ Attendees. Each HCP in attendance must have an objective, legitimate need to attend an Axogen business meeting. Depending on the defined purpose of the meeting, FSO Representatives may aid in the planning, logistics, or attend the meeting if appropriate. ✓ Travel & Lodging. HCPs attending an Axogen meeting may be provided travel and lodging per Axogen’s T&E Policy. ✓ Meals & Refreshments. HCPs attending an Axogen meeting may be provided modest meals and refreshments which must be subordinate to the exchange of information and in compliance with Axogen’s T&E Policy.
<p>Depending on the defined purpose of the meeting, FSO Representative may aid in the planning, logistics, or attend the meeting if appropriate.</p>



A **legitimate need** arises when a Company requires the services of a Health Care Professional to achieve a specific objective, such as the need to train Health Care Professionals on the technical components of safely and effectively using a product; the need for clinical expertise in conducting product research and development; or the need for a physician’s expert judgment on clinical issues associated with a product.

Designing or creating an arrangement to generate business or to reward referrals from the contracted Health Care Professional (or anyone affiliated with the Health Care Professional) are NOT legitimate needs for a consulting arrangement.



Q. What are some examples of legitimate needs for Axogen Business meetings with HCPs?

A. Discussion of Product features, sales terms, company service offerings, Product line offerings, health economics information, purchase contract arrangements, plant or facility tours, equipment demonstration, new product development, clinical testing needs, prototype handling, clinical research protocols, technique development, or the development of nerve repair surgical content.

4.2 Jointly Conducted Education and Marketing Programs

Axogen may partner with HCPs to conduct joint education and marketing programs to highlight both Axogen Product and HCPs’ ability to treat a condition. Axogen and HCPs should serve as bona fide partners and equitably share costs, resources, and time for the program. FSO Representatives should not initiate, manage, or influence any aspect of any education and marketing program with a HCP, but may provide limited feedback and support if requested by Corporate Representatives.

Axogen applies the following principles when determining whether to engage in a joint education and marketing program:

JOINTLY CONDUCTED EDUCATION & MARKETING PROGRAMS WITH HCPs DO’S

- ✓ **Legitimate Need.** There must be a bona fide, legitimate need for Axogen to engage in the activity for its own educational or marketing benefit.
- ✓ **Appropriate Controls.** Axogen has establish controls to help ensure that decisions to engage in these arrangements are not made as an unlawful inducement. Axogen will also require HCPs participating in these arrangements to comply with its guidelines on providing information related to its Product’s labeling and guidelines for furnishing appropriate health economics information, among other controls.
- ✓ **Marketing Materials.** Jointly conducted education and marketing programs must be balanced and promote both Axogen and its Products, and the HCP and the range of services offered for the diagnosis and treatment of related medical conditions.
- ✓ **Bona fide Partners.** Axogen and the HCP should serve as bona fide partners in the program and should make equitable contributions towards the activity and costs (for example, developing content, invitations, space rental, AV needs, and other production costs).
- ✓ **Written Agreement.** The arrangement must be documented in a written agreement that describes the purpose of the arrangement and the roles, responsibilities, and contributions of each party, including payment of costs.

Depending on the defined purpose of the meeting, FSO Representative may aid in the planning, logistics, or attend the meeting if appropriate.

4.3 Speaker Programs and Company-Conducted Training & Education

The U.S. Department of Health and Human Services, Office of Inspector General (OIG), has issued a Special Fraud Alert on in-person Speaker Programs. The Special Fraud Alert highlights what the OIG deems as “inherent fraud and abuse risks” associated with these types of programs. Due to OIG’s concern that one purpose of a Speaker Program may be to induce HCPs, Speaker Programs are highly scrutinized and therefore must be held strictly in accordance with this Health Care Code. Speaker Programs must be submitted to the Compliance Portal for review and approval.

During the Speaker Program, Speakers and their materials should clearly identify Axogen as the presentation’s sponsor and indicate that the Speaker is presenting information that is consistent with FDA guidelines on Axogen’s behalf. Axogen provides all Speakers with appropriate training, as discussed further below, and periodically monitors and audits its Speaker Programs for compliance.

DEFINITIONS

Speaker Program is a company-sponsored program where HCPs provide an educational presentation to other HCPs about Axogen products, or a disease state and the HCP-Speaker is compensated by Axogen. For more information on the Special Fraud Alert visit: [SFA speaker programs 11.13 v2 \(hhs.gov\)](#)

Satellite Symposium is a Company-organized and funded program that is appended to a Third-Party Program agenda but that the Third-Party Organizer does not control. These programs often take place during meal breaks at the Third-Party Program and may address education and training topics that coincide with the Third-Party Program’s focus.

Axogen applies the following principles when conducting training and education programs:

SPEAKER PROGRAMS & COMPANY-CONDUCTED TRAINING WITH HCPs DO’S

- ✓ **Setting.** Axogen conducts training and education programs (including hands-on technical training) in settings that are conducive to the effective transmission of information. These may include clinical, educational, conference, or other settings, such as hotels or other commercially available meeting facilities. It could also include the HCP’s location. Luxury resorts, high-end restaurants, and entertainment, sporting, or other recreational venues or events are not appropriate.
- ✓ **Attendees.** HCPs must have a bona fide educational need to attend an Axogen-sponsored training or education program (for example, the need to obtain technical instruction on how to use a new Product).
- ✓ **Guests.** Friends, significant others, family members, and other guests of a speaker or an invited attendee are not appropriate Speaker Program attendees unless such individuals have an independent, bona fide educational need to receive the information presented.
- ✓ **Repeat attendance or Topic.** Repeat attendance at a Speaker Program on the same or substantially the same topic is generally not appropriate unless the attendee has a bona fide educational need to receive the information presented. Attendance by speakers as participants at programs after speaking on the same or substantially the same topic is generally not appropriate.
- ✓ **Travel and Lodging.** Travel and lodging accommodations and costs must be modest and reasonable under the circumstances.
- ✓ **Meals and Refreshments.** The meal or refreshments should be modest as judged by local standards and subordinate in time and in focus to the bona fide discussion and presentation of scientific, educational, or business information. Axogen provides meals and refreshments in a manner conducive to the presentation or discussion of such information. The meal or refreshments should not be part of an entertainment or recreational event.

The following **additional principles** apply to Axogen’s retention of HCPs as speakers at Axogen-sponsored speaker programs.

First, Axogen pays the HCPs it engages as speakers fair market value compensation for their time and reimburses certain reasonable travel, lodging, and meal expenses the HCPs incur in connection with the Speaker Programs as described in the Travel and Lodging section above.

Second, Axogen selects HCPs as speakers based on defined criteria such as general medical expertise and reputation, knowledge and experience regarding a particular therapeutic area, and communication skills. Axogen does not select HCPs to serve as speakers based on HCPs’ volume or value of referrals or potential future revenue that the speakers could generate by prescribing or ordering Axogen’s products.

Third, HCPs engaged by Axogen as speakers also participate in Axogen’s speaker training programs. Speaker training is an essential activity because the FDA holds companies accountable for the presentations of their speakers. Axogen provides HCPs who participate in Axogen-sponsored presentations reasonable compensation for their time and reimburses them for reasonable, modest travel, lodging, and meal expenses. Such compensation and reimbursement should only be offered when (1) the participants receive extensive training on Axogen Products or other specific topic to be presented and in compliance with FDA requirements for communications; (2) this training will result in participants providing bona fide service to the company; and (3) the participants meet the general criteria for bona fide consulting arrangements.

4.4 Satellite Symposium

A Satellite Symposium may be conducted in connection with commercial sponsorships in support of Third-Party Programs. Axogen is responsible for the content of the Satellite Symposium. While Satellite Symposia are generally included on the Third-Party Program’s agenda and promotional materials, these are considered Company-conducted events. Companies should be transparent in promoting these as such.



Q. A Company considers inviting 50 physicians/consultant to a 2-day and 1-night speaker-training program at a regional golf resort. They would be educated by a faculty on the full range of data surrounding the disease state and the company’s drug product, on presentation skills, and on FDA regulatory requirements. Training session take both days, and the company provides a few hours of golf and expensive meals, such as lobster and filet mignon. Does this program conform to the Code?

A. No. This arrangement would no conform. Speaker training meetings should be held at appropriate venues that conducive to informational communication and training at a golf resort is not an appropriate venue.



Q. Can a Company offer meals and refreshments at a Satellite Symposium?

A. Yes, a Company may offer meals and refreshments at a Satellite Symposium, provided that Company complies with (a) the Third-Party Program Organizer’s or the relevant accrediting body’s standards; and (b) the meals and refreshment provided are modest.



Did you know Company-organized meeting, training, or educational session (such as an advisory board, consultant meeting, or product education session) held in close proximity (physically or temporally) to a Third-Party Program is **NOT** considered a Satellite Symposium if it is not appended to or included in the Third-Party Program.

4.5 Informational Presentations by Field Sales Organization (FSO) Representatives & Accompanying Meals

Due to fraud and abuse risks potentially associated with the FSO Representative relationship with HCPs, extra care must be exercised in these interactions to avoid the perception that Axogen’s FSO Representative may be rewarding, inducing, or otherwise influencing a HCP’s independent decision-making in the use, prescribing or recommending of our Products.

The highly technical applications of Axogen’s platform of nerve repair solutions warrant the need for exchanges of information on the science, medical, technical, and surgical applications for their safe and effective use. FSO Representatives may only present approved materials to HCPs and their staff who have a bona fide need to attend and provide modest meals in accordance with this Health Care Code’s section “Providing Modest Meals and Refreshments to Health Care Providers”. These interactions should occur during business hours and at the HCP’s work sites. Examples of these interactions may include, but are not limited to:

- Product handling lab
- In-service prior to initial cases, when cases are performed in a new facility, or when new support staff are hired
- When new HCPs or their institutional organization leaders are interested in learning about the technology used in their facilities

5 consulting agreements with health care professionals

5.1 Consulting Arrangements with Health Care Professionals

Based on a legitimate need, Axogen may engage HCPs through written consulting agreement(s). FSO Representatives must not initiate, influence nor control the HCP consulting process. FSO Representatives may provide limited feedback on a HCP’s qualifications, experience or other information only if requested by Corporate Representative.

Axogen uses a strategic plan to identify areas of focus and business needs. Department leaders follow an annual needs assessment and budgeting process to identify, and plan needs for each annual cycle. Consulting services are one part of these identified needs. These needs are broken into service categories for which consultants may be utilized to improve or develop safe and effective treatments for patient.

DEFINITIONS

Fair Market Value (FMV): An objective means of quantifying essential expertise, credentials, and accomplishments. Axogen’s FMV is calculated via the Compliance Portal FMV Module to ensure compliance with laws.

Compliance Portal: Compliance platform that houses pertinent information associated with HCPs and is used for tracking and documenting surgeon credentials, screenings, and engagement as well as monitoring and auditing HCP interactions. This includes the management of Grants, Donations and Sponsorships.

Screening: Exclusion and sanction screening including, but not limited to a review of the List of Excluded Individuals/Entities (LEIE) and the System for Award Management (SAM).



Q. Why does the Health Care Code restrict the involvement of FSO Representatives in the selection of consultants?

A. The Code requires this separation to avoid the perception that Axogen has entered a contract with a HCP to secure or reward the HCP for purchasing, using, or recommending Axogen’s Products or other sales considerations.

The conditions for bona fide consulting agreements are:

CONSULTING ARRANGEMENTS WITH HCPs DO’S

- Legitimate Need.** Consulting services must be clearly identified in advance of requesting the services and entering arrangements with the prospective consultants; The number of HCPs retained for each service category should not be greater than reasonably needed to achieve strategic objectives.
- Selection Criteria.** Directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular HCPs meet those criteria. Consultant selection is solely based on HCPs qualification to meet the businesses’ legitimate need and will not be based on any prior, current, or future Product purchases or use .
- Fair Market Value.** Assessed using objective measures and applied universally to all consultants. Axogen will not compensate above Fair Market Value.
- Screening.** Consultants are automatically subjected to any applicable screenings prior to any engagement.
- Written contract.** Details the nature of the consulting services to be provided and the basis for payment and specifies that the agreement shall not be based on past, present or future business.
- Records Retained.** Related to the requested service consultants provide, along with any transfer of value for reimbursement of agreed upon work product and associated expenses.
- Reporting.** Any payment or any transfer of value will be reported annually to CMS Open Payments as required.

HCP engagement is managed, monitored and audited in the [Compliance Portal](#). This includes all internal processes such as nominations, engagement, and renewals.

5.2 Clinical Studies & Research Arrangements

Axogen complies with industry standards and principles on the proper conduct of clinical trials.

Clinical Studies and research arrangements require a written Clinical Trial Agreement (CTA) with all parties involved in the research. CTAs should only be entered into to fulfill a legitimate research purpose. Payments to clinical investigators or their Institutions should be reasonable and based on work performed by the investigator or investigator’s staff, not on any other considerations. Axogen determines compensation based on fair market value of the services provided. In no instance will Axogen provide compensation or financial support as an inducement for HCPs, to use, prescribe, purchase or recommend Axogen Product or to influence the outcome of a clinical trial.

Certain laws and regulations require registration and reporting of clinical trial results. Axogen registers clinical studies on clinicaltrials.gov.

CLINICAL RESEARCH DO’S

Research arrangements **must**:

- Have scientific merit and/or medical value;
- Involve investigators or institutions selected on the basis of criteria relevant to the research;
- Involve “fair market” compensation for services provided; and
- Be conducted in compliance with scientific and ethical standards, and applicable laws and regulations.

CLINICAL RESEARCH DON'TS

Support must **never** be provided to:

- Establish a relationship with a HCP or Institution,
- Gain or improve access to a HCP, or
- Reward past, present, or future use of Axogen Products.



53 Royalties

Company Representatives should only enter into royalty arrangements with a HCP if the HCP makes novel, significant, or innovative contribution(s) to the development of its product, technology, process or method. FSO Representatives may not initiate, manage, nor influence any aspect of consulting arrangements with HCPs but may provide limited feedback if requested by Corporate Representatives. Any questions on Royalty Agreements should be directed to either the Compliance or Legal Department.



Company should not condition royalties paid in exchange for Intellectual Property on the requirements that a HCP purchase, order, or recommend any Product, products to be developed or require HCP to market a product or technology upon commercialization.

6 grants, donations, and sponsorship support

Axogen is committed to supporting global independent scientific and professional education activities, as well as humanitarian efforts that align with our mission to revolutionize nerve repair, benefit the medical community, and improve patients’ quality of life.

Request for support must be initiated by the requesting individual or entity through our [Compliance Portal](#). All requests must align with Axogen’s pre-planned grants, donation and sponsorship support program, and are reviewed by specialized committees that have the authority to approve or decline applications based on merit, consistency with our mission, and availability of resources.

Requests for support are considered on a case-by-case basis and must be consistent with Axogen’s internal policies, this Health Care Code and other laws, regulations and industry standards.

Awards are directly provided solely to entities (e.g., professional societies, charitable organizations, training institutions, universities, medical centers, etc.) and not to individual HCPs.

Axogen does not offer or provide any grants, donations, or support to HCPs to induce nor obligate any person or entity to purchase, prescribe, order or otherwise make use of (or arrange for/recommend the use of) Axogen’s Products.

Company Representatives should neither commit grant funding nor list Axogen as a sponsor/supporter of any activity until formal approval from the Grant Committee has been communicated and/or a formal Letter of Agreement indicating approved support has been executed.

FSO Representatives may not control or influence the process for evaluating grant or sponsorship requests or make requests on behalf of HCPs.



It is not appropriate to tie any commercial activities or discussions with any grant(s), sponsorships, or charitable donations.

Sales activities should always be kept separate from Grant Committee consideration.



Q. During a sales negotiation, a large Health Care Organization requested Sponsorship of their upcoming charitable event. Is it appropriate to provide the sponsorship funding to secure this sale?

A. No. The provision of grants, sponsorships, and donations should never be comingled with any commercial activity.

6.1 Educational Grants: Supporting Educational Initiatives, Medical Education, Third-Party Educational Programs & Professional Meetings

Axogen supports accredited and non-accredited, high-quality educational events that maintain, develop, or increase HCPs’ knowledge, skills, and professional abilities. Axogen considers requests from independent educational providers, such as hospitals, academic centers, and societies/associations or medical education companies, for support that are free from commercial influence or bias.

EDUCATIONAL GRANT DO’S

To qualify for consideration from Axogen’s Grant’s Committee, requests **must**:

- ✓ Be initiated by the requesting party through [Axogen’s Compliance Portal](#);
- ✓ Include all required documentation such as clearly defined educational goals, agenda, topics, event location, date, and budget for requested support;
- ✓ Be held at a venue that is conducive to the exchange of educational information;
- ✓ If meals are included, demonstrate that they do not detract from the primary purpose of the event and are considered modest and in-line with Axogen’s T&E Policy; and
- ✓ NOT be controlled or unduly influenced by a FSO Representative.



6.2 Sponsorships: Supporting Third-Party Educational Programs and Professional Meetings

Axogen considers requests for funding opportunities from external organizations that provide promotional opportunities that align with our commitment to improve the standard of care for patients. Promotional opportunities may include, but are not limited to, the promotion of Products via branded materials or exhibit space, promotional placement of logos at educational, society, or foundation events aimed at HCPs or patients, or providing speakers for the event.

SPONSORSHIP DO’S

To qualify for consideration from Axogen’s Grant’s Committee, requests **must**:

- ✓ Be initiated by the requesting party through [Axogen’s Compliance Portal](#);
- ✓ For an event that serves an educational or charitable purpose;
- ✓ For patients, HCPs, or HCPs-In-Training;
- ✓ Have program content, faculty, agenda, materials, or methods that are NOT controlled by Axogen;
- ✓ Have no significant gaps in the educational agenda that are filled with entertainment or recreational activities;
- ✓ NOT be controlled or unduly influenced by a FSO Representative; and
- ✓ Have submitted all appropriate documentation including the information about the requesting Organization, event date, location, attendees, promotional brochures, agenda, event materials, and detailed budget.



6.3 Charitable Donations: Supporting Charitable Programs

We consider requests to provide charitable donations for professional or patient organizations whose objectives align with our mission and therapeutic areas. We may also provide Product donations for charitable purposes, such as supporting indigent care or in sponsorship of events where the proceeds are intended for other domestic or international humanitarian needs, and free from commercial influence or bias.

Donations shall be determined by the charitable objective and shall be made only to bona fide charitable organizations (registered 501[c][3] or not-for-profit institutions).

CHARITABLE DONATION DO'S

To qualify for consideration from Axogen's Grant's Committee, requests **must**:

- ✓ Be initiated by the requesting party through [Axogen's Compliance Portal](#);
- ✓ For a charitable purpose;
- ✓ For patients with peripheral nerve injuries;
- ✓ NOT be controlled or unduly influenced by a member of FSO Representative;
- ✓ Have submitted all appropriate documentation including the information about the requesting Organization, event date, location, attendees, participating surgeons, planned procedures, facility information, shipping information.



Products shipped in support of indigent patient care and/or humanitarian needs in a country outside of the United States may require approval and assistance from members of Axogen's Regulatory Affairs team in identifying a viable shipping pathway. If we are unable to ship the products directly to the mission location, we may ship to the HCP so that they may ship or hand-carry the products as they deem appropriate.

6.4 Investigator Initiated Studies: Supporting Independent Third-Party Research Grants

Axogen is committed to pre-clinical, clinical, and other investigator initiated, independent studies that may improve current or lead to new treatments, improve access to care, or benefit quality of life. We support research with scientific merit that is initiated, sponsored, and conducted by independent investigators. Support may be either monetary and/or in-kind contributions.

INVESTIGATOR-INITIATED STUDY DO'S

To qualify for consideration from Axogen's Grant's Committee, requests **must**:

- ✓ Be initiated by the requesting party through [Axogen's Compliance Portal](#);
- ✓ For independent scientific research designed and initiated by an Investigator external to Axogen;
- ✓ Have clearly defined milestones and objectives;
- ✓ NOT be controlled or unduly influenced by a member of the FSO Representative; and
- ✓ Have submitted all appropriate documentation including the information about the requesting Principal Investigator and Institution, study protocol, objectives, milestones, publication/dissemination plan, and detailed budget.



7 Transparency Laws & Disclosure Requirements

7.1 U.S. Physician Payment Sunshine Act (Open Payments)

The U.S. Physician Payment Sunshine Act (“Sunshine Act” or “Open Payments”) is a Federal law that mandates reporting to the U.S. government’s Centers for Medicare and Medicaid (CMS), certain Payments and Transfers of Value, or Indirect Payments or Transfers of Value made to Physicians and/or Teaching Hospitals. Reporting must be both timely and accurate; otherwise, Axogen may be subject to penalties. Company Representatives must complete their HCP-reimbursement entries in Concur promptly and accurately for proper submission of timely Open Payments filings.

7.2 State Sunshine Laws & Marketing Disclosures

Many states have also enacted sunshine-like laws which, for transparency purposes, require the reporting of payments or transfers of value to HCPs and/or physicians in that state, additional marketing and/or disclosure rules, as well as restrictions on industry interactions with HCPs. Axogen will comply with these state laws, even if more restrictive than this Health Care Code, when applicable.

DEFINITIONS

Physicians include: Doctor of Medicine (MDs), Doctors of Osteopathy (Dos), Optometrists (OD), Podiatrists (DPMs), Dentists (DDS), Chiropractors (DC) and teaching hospitals as well as Physician Assistants (PAs), (Nurse Practitioners (NPs), Clinical Nurse Specialists (CNSs), Certified Registered Nurse Anesthetists (CRNAs), Anesthesiologist Assistants and Certified Nurse Midwives (CNMs).

Teaching Hospital(s): Those hospitals listed annually on the Centers for Medicare and Medicaid Open Payment Website. The Open Payments website can be found at: Home | [Open Payments \(cms.gov\)](https://www.cms.gov/openpayments)

Payments or Transfer of Value: Any monetary compensation, honoraria, consulting fees, research grants, or other financial benefits. Any payment or transfer of value including non-monetary items such as meals, travel expenses, educational materials, or in-kind support

Indirect Payments or Transfers of Value: Refers to Payments or other Transfers of Value made through a third party, where Company has required, instructed or otherwise directed the payment or transfer



Q. Does reporting payment and transfers of values to Physicians mean we are also compliant with or have met the safe harbors of the Anti-Kickback Statute?

A. No. These are separate laws enforced by different government agencies each containing different penalties. Company must always abide with both.

8 Reporting Concerns, Disciplinary Action, and Waivers

8.1 Reporting Concerns

Axogen encourages all Company Representatives to Speak Up if you suspect a violation of this Health Care Code. Company Representative should feel comfortable asking questions, raising concerns, or seeking guidance without fear of retaliation. Any Company Representative who engages in retaliation will be subject to disciplinary action, up to and including termination of employment.

8.2 Disciplinary Action

Axogen will take appropriate action for any misconduct. Violations may result in disciplinary action, up to and including termination of employment. Serious violations could also result in legal liabilities for Axogen and/or the individuals involved.

8.3 Waivers

Waivers of any provision of this Health Care Code are rare and may only be granted by Axogen’s Chief Compliance Officer. Waivers for executive officers may only be granted by the Board of Directors and must be promptly disclosed to shareholders.



Ethics & Compliance Hotline
axogen.ethicspoint.com
(844)989-2990

