

# Biom'up

## Policy on Interactions with Health Care Professionals

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## I. Preamble: Goal and Scope of Policy

There are many forms of interactions between Biom'up, our Representatives, and HCPs that advance medical science or improve patient care, including those that:

- *Promote the Advancement of Medical Technologies.* Developing cutting edge medical technology and improving existing products are collaborative processes between Biom'up and HCPs. Innovation and creativity are essential to the development and evolution of medical devices, often occurring outside the laboratories of medical device companies.
- *Enhance the Safe and Effective Use of Medical Technologies.* The safe and effective use of sophisticated implants, surgical instrumentation, new surgical techniques, and cutting-edge biologics and emerging medical technology often requires that HCPs are provided with appropriate instruction, education, training, service, and technical support. Regulators may also require this type of training as a condition of product approval.
- *Encourage Research and Education.* Industry support of *bona fide* medical research, education, and enhancement of professional skills improves patient safety and increases access to medical technologies

**Any interpretation of the provisions of this Policy, as well as Representatives' interactions with HCPs not specifically addressed in this Policy, should be made considering the following principle: Biom'up and its Representatives shall encourage ethical business practices and socially responsible industry conduct and shall not use any unlawful inducement in order to sell, lease, recommend, or arrange for the sale, lease, or prescription of, our products. In case of questions contact the Compliance Leadership.**

*This Policy applies to the activities of all Biom'up employees and Representatives in the United States. It is expected that they will adhere to this Policy. Biom'up is committed to making sure its interactions with HCPs comply with all applicable laws and regulations. This Policy cannot address every situation, but its principles provide essential guidance. However, you should seek guidance on the appropriate course of conduct when you have questions about the Policy. Please contact the Compliance Leadership, if questions do arise regarding ethical decisions or situations.*

## II. Definitions

The following terms in this Policy shall have the meanings detailed below unless otherwise indicated.

**"Arrangements"** means every arrangement or transaction entered into by Biom'up that (a) involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and (b) is between Biom'up and any actual or potential source of health care business or referrals of health care business to Biom'up or any actual or potential recipient of health care business or referrals from Biom'up. The term "source" shall include any physician, contractor, vendor, or agent; and the term "health care business or referrals" shall be read to include referring, recommending, or arranging for, ordering, leasing or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.

**"Charitable Donation"** means tax-exempt charitable contributions and/or financial donations that are philanthropic in nature and are provided to not-for-profit foundations or institutions.

## POLICY ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

“Code” means the Biom’up Code of Business Conduct.

“Compliance Leadership” The US Chief Compliance Officer and the Compliance Committee (including sub-committees). Responsible for reviewing and enforcing the policies and requirements set forth in this Policy.

“Consultant” means any surgeon, Ph.D., HCP, non-physician practitioner, medical fellow, resident/student, or any employee or agent of any educational or health care organization the Company retains for any personal or professional services or compensates or remunerates in any way, directly or indirectly, for, or in anticipation of, personal or professional services relating to its products or services. Consultant does not include accountants, auditors, attorneys, fair market value specialists, CME providers, reimbursement specialists, or any non-physician engineering or marketing consultants.

“Consulting Agreement” means all contracts with Consultants for services to be performed on behalf of the Company, including, but not limited to, compensation agreements, payments, remuneration, honoraria, speaking engagements, teaching, publications, clinical studies, fee-for-service consulting, product development and license agreements, research and professional services agreements.

“Consulting Services” or “Services” means any and all professional services provided by a Consultant to or on behalf of the Company.

“Contractual Arrangements” means every written Arrangement including all Arrangements related to the provision of goods or services, to or from Biom’up, including but not limited to, arrangements involving training, education, consulting, research, clinical studies, focus groups, physician advisory boards, intellectual property, and grants.

“Policy” means the Biom’up Policy on Interactions with Health Care Professionals.

“Education” means communicating information directly concerning, or associated with, the use of Biom’up’s medical technologies, e.g., information about disease states and the benefits of medical technologies to certain patient populations.

“Educational Grant” means grants that may be made to support the genuine medical education of HCPs, medical students, residents, and fellows participating in fellowship programs that are affiliated with charitable or academic organizations. Where consistent with the Code, grants may be made for the purpose of supporting education of patients or the public about important health care topics to other medical personnel.

“Fair Market Value” (“FMV”) means the value in “arms-length” transactions, consistent with the general market value; in the context of HCP Consulting Services, FMV means the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties who are not in a position to generate business for one another. FMV may vary by physician specialty and stature in addition to the type of service being performed.

“FDA” means the U.S. Food and Drug Administration.

“Federal Health Care Program” means any plan or program that provides health benefits, whether directly or indirectly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government, including, but not limited to, Medicare, Medicaid, VA, and TRICARE/CHAMPUS.

“Fellowship” means post-residency training programs that allow new physicians to continue their training and specialize in a specialty or sub-specialty. Sponsoring fellowships is philanthropic in nature but also serves to advance the education and training of new physicians.

## POLICY ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

“GPO” means a group purchasing organization.

“Health Care Professional” (“HCP” or “HCPs”) means individuals or entities who (1) are involved in the provision of health care services and/or items to patients; and (2) purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Biom’up’s medical technologies in the United States. The phrase Health Care Professional is to be interpreted broadly and includes both persons providing services (such as licensed surgeons or consultants) and persons who do not provide services directly, but who are involved in the decision to purchase, lease, or recommend a Medical Technology. HCPs include, for example, purchasing agents, physician’s practice managers and management within GPOs.

“HHS-OIG” means the U.S. Department of Health and Human Services, Office of Inspector General.

“Hourly Rate” means the Fair Market Value hourly rate.

“Medical Technologies” means medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage, and alleviate health conditions and disabilities in order to enable patients to live longer and healthier lives.

“Modest” means reasonable in terms of cost and venue.

“Needs Assessment Process” means the annual process whereby Biom’up will reflect our expected, commercially reasonable needs for all Consulting Services to fulfill our medical, clinical, training, educational, and research and development needs for the ensuing year. The Needs Assessment Process and any modifications shall be used as a basis for Consultant selection and all Consulting Agreements, Services, and Payments.

“Occasional” means no more than eighteen (18) per year.

“Payment” means any and all compensation or remuneration, direct or indirect, in cash or in kind, paid to, or for the benefit of, Consultants, including, but not limited to, payments and reimbursements for personal or professional services, any type of securities, registered or unregistered, meals, entertainment, travel, gifts, grants, honoraria, charitable contributions, donations, sponsorships, research grants, fellowships, clinical studies, professional meetings, product training, medical education, research funding, product development services, in-kind services (e.g., use of aircraft), advertising, promotion, and marketing expenses or support, and royalties or other payments for transfer of documented intellectual property.

“Representative(s)” means any agent engaged by Biom’up to act on behalf of the Company, except for the independent contractors engaged as promotional agents for Biom’up products who, in lieu of this Policy, shall be required to adhere to the Advanced Code of Ethics on Interactions with Health Care Professionals (2009).

“Research Grant” means grants to support independent medical research with scientific merit.

“Resort Location” means luxury hotels or resorts located on or immediately adjacent to a beach, ski resort, golf course, destination spa, vineyard, or other similar recreational amenities.

“Training” means training on the safe and effective use of medical technologies.

### III. Product Training and Education

Biom’up has a responsibility to make education and training on our products and medical technologies available to HCPs. Biom’up may also provide education to HCPs. Training and education may be sponsored by Biom’up or a Biom’up distribution partner. “Training” means training on the safe and effective use of medical technologies. “Education” means communicating information directly concerning or associated with the use of Biom’up’s medical technologies, e.g.,

## POLICY ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

information about disease states and the benefits of medical technologies to certain patient populations. Training and Education programs include, but are not limited to, “hands on” training sessions, wet labs, lectures and presentations, and grand rounds. In fact, FDA mandates training and education to facilitate the safe and effective use of certain medical technology. Such programs often occur at centralized locations (necessitating out-of-town travel for some participants), and may extend more than one day. With regard to Biom’up programs focused on the education and training in the safe and effective use of Biom’up products and medical technologies:

- Product training and education program material(s) must be reviewed and approved, at a minimum, by regulatory, clinical and medical affairs.
- Programs and events must be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities conducive to the effective transmission of information. In some cases, it may be appropriate for a Biom’up Representative to provide training and education at the HCP’s location.
- Programs requiring “hands on” training on medical technologies and/or medical procedures must be held at training facilities, medical institutions, laboratories, or other appropriate facilities. The training staff must have the proper qualifications and expertise to conduct such training.
- HCP attendees may be provided with modest meals and refreshments in connection with these programs. Any such meals and refreshments must be modest in value and subordinate in time and focus to the educational or training purpose of the meeting.
- Biom’up may pay for reasonable travel and modest lodging costs incurred by attending HCPs where there are objective reasons to support the need for out-of-town travel to efficiently deliver training and education on products and/or medical technologies. It is not appropriate for Biom’up or its Representatives to pay for the meals, refreshments, travel, or other expenses for spouses and/or guests of HCPs, or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.
- Participants cannot be compensated for their time related to attending Biom’up-sponsored training and education programs. Faculty members can only be compensated for services provided and related expenses as provided in this Policy.
- Resort locations are not acceptable locations for training and/or education events, as they are generally not deemed conducive to training, education, or the effective transmission of knowledge and should be avoided as venues for programs and events. The location and lodging must be selected based upon program requirements such as proximity to a training facility, medical institution, laboratory, or other appropriate facilities, convenience of attendees, and cost savings to Biom’up.
- Training and/or education programs provided by Biom’up concerning a Company product must be consistent with the indications for use cleared or approved by the FDA and with the approved labeling of the product. Any Consultants that Biom’up retains to serve as faculty at a training or education program will be instructed to comply with this requirement.

Biom’up employees are required to have any materials that will be presented reviewed and approved by regulatory, clinical and medical affairs prior to participating in any training and/or educational programs.

#### IV. Supporting Third Party Educational Conferences

*Bona fide* independent, educational, scientific, or policymaking conferences to promote scientific knowledge, medical advancement and the delivery of effective health care. These typically include continuing medical education (“CME”) conferences or events hosted by providers accredited by the Accreditation Council for Continuing Medical Education (“ACCME”), independent, non-accredited scientific or educational programs, grand rounds, and other programs.

These conferences may be supported in various ways:

- *Conference Grants.* A grant must be provided directly to the conference sponsor to reduce conference costs. No funding may be provided through a conference sponsor or directly to subsidize the costs of non-faculty attendees, except that subsidies may be provided either to a training institution or the conference sponsor to allow attendance by medical students, residents, fellows, and others who are HCPs in training. Conference grants may be provided when: (1) the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; and (2) the training institution or the conference sponsor selects HCPs who are in training. Such grants should be paid only to organizations with a genuine educational purpose or function, and may be used to reimburse only the legitimate expenses for *bona fide* educational activities. Such grants also should be consistent with relevant standards established by the conference sponsor and/or body accrediting the educational activity. Conferences supported by Biom’up must also meet the following requirements: (1) The conference sponsor should independently control and be responsible for the selection of program content, educational methods, and materials; (2) Biom’up personnel may not suggest topics, engage in scripting, target points for emphasis, or otherwise attempt to influence program content; (3) Biom’up may have no role in selecting faculty or attendees; (4) Biom’up will require the program sponsor to provide meaningful disclosure to the audience of Biom’up’s funding of the program, any significant relationships between Biom’up and program faculty and moderators, and whether any unapproved uses of products will be discussed; (5) the program must be non-promotional and free from commercial bias; (6) at a live program, there must be opportunities for meaningful discussion or questioning, and no promotional activities may take place in the meeting room.
- *Conference Meals and Refreshments.* Funding may be provided to the conference sponsor to support the provision of meals and refreshments to conference attendees. Biom’up may itself provide modest meals and refreshments for HCP attendees if such meals and refreshments are provided to all HCP attendees and in a manner that is also consistent with applicable standards established by the conference sponsor and the body accrediting the educational activity. Any meals and refreshments should be modest in value, subordinate in time and focus to the purpose of the conference, and clearly separate from the continuing medical education portion of the conference.
- *Faculty Expenses.* Grants may be made to conference sponsors for reasonable honoraria, travel, lodging, and modest meals for HCPs who are *bona fide* conference faculty members.
- *Advertisements and Demonstration.* Company may purchase advertisements and lease booth space for Company displays at conferences.

#### V. Sales, Promotional, and Other Business Meetings

Biom’up may conduct sales, promotional and other business meetings with HCPs to discuss product features, or negotiate contracts or sales terms. Often, these meetings occur close to an HCP’s place of business. It is appropriate for Representatives to pay for reasonable travel costs of attendees when necessary (e.g., for plant tours or demonstrations of non-portable equipment) and/or to provide occasional modest meals and refreshments in connection with such meetings. It is not appropriate to pay for meals, refreshments, travel, or lodging of guests and/or spouses of HCPs, or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting. Guests and/or spouses

## POLICY ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

of HCPs may not be invited, nor may they attend or participate in any sales, promotional or other business meetings. Unapproved uses of Biom'up products may not be discussed at such meetings.

### VI. Consulting Arrangements with Health Care Professionals

Biom'up may engage HCPs to provide a wide-range of valuable, *bona fide* consulting services through various types of arrangements, such as contracts for research, product development, development and/or transfer of intellectual property, marketing, participation on advisory boards, presentations at Biom'up-sponsored training and other services. FMV compensation may be paid to consultants provided the arrangement fulfills a legitimate business need, does not constitute unlawful inducement. A signed and executed agreement must be in place before any services are authorized or provided by the Consultant. Proper documentation of work performed as specified in the agreement must be provided before payment for such services will be made. In no event shall a consulting agreement, or any term of an agreement, be based on the volume or value of business that a Consultant generates or influences. The following factors support the existence of a *bona fide* consulting arrangement between Biom'up and HCPs:

- Biom'up consulting arrangements must be written, signed by all parties, and specify all services to be provided and the compensation to be paid. The signed and fully executed contract must pre-date the activities performed. If Biom'up contracts with a consultant to conduct clinical research services, a written research protocol is also required.
- Consulting agreements should be entered into only where a legitimate need and purpose for the services is identified in advance and documented, for example during Biom'up's Needs Assessment Process.
- Compensation paid to consultants should be consistent with fair market value in an arm's length transaction for services provided and should not be based on the volume or value of the consultant's past, present, or anticipated business.
- Selection of consultants should be on the basis of the consultant's qualifications and expertise to meet the defined need, and should not be on the basis of volume or value of business generated by the consultant. Business development and engineering personnel may provide input about the suitability of a proposed consultant, but do not control or have the ability to unduly influence the decision to engage a particular HCP as a consultant.
- Any discussion by Biom'up personnel of unapproved products or uses should be non-promotional and scientific. It should be made clear to participants that the product or use under discussion is investigational.
- The venue and circumstances for Biom'up meetings with consultants should be appropriate to the subject matter of the consultation and conducive to the effective exchange of information. Resort locations are not acceptable locations for training and/or education events, as they are generally not deemed conducive to training, education, or the effective transmission of knowledge and should be avoided as venues for programs and events.
- Biom'up-sponsored meals and refreshments provided in conjunction with a consultant meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting. Biom'up strictly prohibits recreation or entertainment in conjunction with these meetings.
- Biom'up may pay for documented, reasonable and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, modest meals, and lodging costs incurred by consultants attending meetings with, or on behalf of Representatives.
- *Provisions on Payment of Royalties.* At this time Biom'up does not enter into arrangements involving the payment of royalties to HCP's. No employee, agent, independent sales representative, or distributor, is authorized to commit to an arrangement involving royalty payments without approval from executive management.

**VII. Prohibition on Entertainment and Recreation**

Biom'up interactions with HCPs must be professional in nature and should facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, Biom'up or its Representatives must not provide or pay for any entertainment or recreational event or activity for any non-employee HCP. Such activities and items include, for example, theater, sporting events, golf, skiing, hunting, sports equipment, and leisure or vacation trips. Such entertainment or recreational events, activities, or items should not be provided, regardless of: (1) their value; (2) whether Biom'up engages the HCP as a speaker or consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.

**VIII. Modest Meals Associated with Health Care Professional Business Interactions**

Biom'up's interactions with HCPs may involve the presentation of scientific, educational, or business information and include, but are not limited to, the different types of interactions described throughout this policy. Such exchanges may be productive and efficient when conducted in conjunction with meals. Accordingly, modest meals may be provided as an occasional business courtesy consistent with Biom'up's limitations regarding the volume and costs for such meals, as defined in this Policy. The following requirements have been established:

*Purpose.* A modest and occasional meal should be incidental to the *bona fide* presentation of scientific, educational, or business information and provided in a manner that is conducive to the presentation of such information. The meal must not be part of an entertainment or recreational event.

*Setting and Location.* A modest and occasional meal should be in a setting that is conducive to *bona fide* scientific, educational, or business discussions. Such meals may occur at the HCP's place of business. However, in some cases the place of business may be a patient care setting that is not available for, or conducive to, such scientific, educational, or business discussions. In other cases, it may be impractical or inappropriate to provide a meal at the HCP's place of business, for example, (1) where the Medical Technology cannot easily be transported to the HCP's location, (2) when it is necessary to discuss confidential product development or improvement information, or (3) where a private space cannot be obtained on-site.

*Participants.* Biom'up or its Representative may provide a meal only to HCPs who attend the meeting. Biom'up may not provide a meal for an entire office staff where everyone does not attend the meeting. Biom'up also prohibits "dine and dash" meals, where a company representative is not present. Biom'up may not pay for meals for spouses or guests of HCPs or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

As outlined in this Policy, meals with HCPs must be modest and occasional. "Modest" is defined as reasonable in terms of cost and venue. Biom'up has established the following per person per meal limits, including taxes, tip and fees: \$200 for dinner, \$50 for breakfast, \$75 for lunch, and \$35 for in-office refreshments other than meals.

Our policy for calculating the per person cost of a meal provided in a group setting is to divide the total value of the food and beverages by the number of people who actually partook in the meal including HCP's, support staff and Biom'up employees and Representatives. All receipts for expenses, along with a detail of the persons in attendance, must accompany the employee's expense report.

"Occasional" is defined as infrequent. Biom'up's guideline on the number of meals that a Biom'up employee or Representative may have with any particular HCP, or group of HCPs, in general, is no more than eighteen (18) meals per year. Meals that are part of a pre-approved and legitimate training and/or educational event are excluded from this limitation.



**IX. Educational Items; Prohibition on Gifts**

Biom'up may occasionally provide items to HCPs that benefit patients or serve a genuine educational function for HCPs. Other than medical textbooks or anatomical models used for educational purposes, any such item should have a FMV of less than \$100.

Biom'up may not provide items that are capable of use by the HCP (or his or her family members, office staff or friends) for non-educational or non-patient-related purposes, for example a DVD player, MP3 player or iPod.

Biom'up may not give HCPs any type of non-educational branded promotional items, even if the item is of minimal value and related to the HCP's work or for the benefit of patients. Examples of non-educational branded promotional items include pens, notepads, mugs, and other items that have our Company's name, logo, or the name or logo of one of its medical technologies. Biom'up may also not provide HCPs with gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents.

This section is not intended to address the legitimate practice of providing appropriate sample products and opportunities for product evaluation as outlined in Section XI.

**X. Provision of Coverage, Reimbursement and Health Economics Information**

As medical technologies have become increasingly complex, so have payor coverage and reimbursement policies. Patient access to necessary Medical Technology may be dependent on HCPs and/or patients having timely and complete coverage, reimbursement, and health economic information. Consequently, Biom'up may provide such information regarding its medical technologies if it is accurate, objective, consistent with FDA approvals, and does not reference or discuss off-label uses. Biom'up may also collaborate with HCPs, patients and organizations representing our interests, to achieve government and commercial payor coverage decisions, guidelines, policies, and adequate reimbursement levels that allow patients to access its medical technologies.

Permissible activities involving the provision of coverage, reimbursement and health economic information may include, but are not limited to:

- Identifying the clinical value of Biom'up's medical technologies and the services and procedures in which they are used when providing coverage, reimbursement and health economics information and materials to HCPs, professional organizations, patient organizations, and payors.
- Collaborating with HCPs, their professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement and health economics issues; supporting HCPs and their professional organizations in developing materials and otherwise providing direct or indirect input into payor coverage and reimbursement policies.
- Promoting accurate Medicare and other payor claims by providing accurate and objective information and materials to HCPs regarding Biom'up's medical technologies, including identifying coverage, codes and billing options that may apply to those medical technologies or the services and procedures in which they are used.
- Providing accurate and objective information about the economically efficient use of Biom'up's medical technologies, including where and how they can be used within the continuum of care.
- Providing information related to Biom'up's medical technologies regarding available reimbursement revenues and associated costs.

## POLICY ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

- Providing information relating to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes in order to facilitate an HCP's decision to buy or use Biom'up's medical technologies.
- Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of Biom'up's medical technologies.
- Facilitating patient access to Biom'up's medical technologies by providing HCPs with assistance in obtaining patient coverage decision from payors. This assistance may include providing information and/or training on payor policies and procedures for obtaining prior authorization, and providing sample letters and information on medical necessity and appeals of denied claims. In addition, at the request of an HCP to facilitate patient access to Biom'up's Medical Technology, and subject to appropriate privacy safeguards, the Company may assist the patient by facilitating the preparation and submission of requests for coverage determinations, prior authorizations, pre-certifications and appeals of denied claims, relating to Biom'up's own Medical Technology; however, such assistance should not be provided as an unlawful inducement.

Biom'up may not interfere with an HCP's independent clinical decision making or provide coverage, reimbursement and health economics support as an unlawful inducement. For example, Biom'up shall not provide free services that eliminate an overhead or other expense that an HCP would otherwise incur as part of its business operations if doing so would amount to an unlawful inducement. Biom'up may not suggest mechanisms for billing for services that are not medically necessary, or for engaging in fraudulent practices to achieve inappropriate payment.

### XI. Research and Educational Grants and Charitable Donations

Biom'up may provide research and educational grants. Grants may not be provided as an unlawful inducement. All requests for grants must be reviewed by Compliance Leadership.

The Compliance Leadership are responsible for ensuring that grants (1) do not take into account the volume or value of purchases made by, or anticipated from, the recipient; (2) are not used as an unlawful inducement; and (3) are appropriately documented. Company associates from other departments may provide input about the suitability of a proposed grant but have no ability to control or unduly influence the decision of whether a particular HCP or institution will receive a grant or the amount of such grant.

The various types of Grant requests may include:

*Research Grants.* Research provides valuable scientific and clinical information, improves clinical care, leads to promising new treatments, promotes improved delivery of health care and otherwise benefits patients. In furtherance of these objectives, Biom'up may provide research grants to support independent medical research with scientific merit. Such activities should have well-defined objectives and milestones and may not be linked directly or indirectly to the purchase of medical technologies.

*Educational Grants.* Educational grants may be provided for legitimate purposes including:

- *Advancement of Medical Education.* Grants may be made to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs, which are affiliated with charitable or academic organizations. (For additional considerations regarding educational grants, see Section III, Supporting Third Party Educational Conferences.)

## POLICY ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

- *Public Education.* Grants may be made for the purpose of supporting education of patients or the public about important health care topics.

Biom'up may make educational grants to conference sponsors or training institutions. Educational grants may not be made to individual HCPs.

*Charitable Donations.* Biom'up may make monetary or Medical Technology donations for charitable purposes, such as supporting indigent care, patient education, public education, or the sponsorship of events where the proceeds are intended for charitable purposes. Donations should be motivated by *bona fide* charitable purposes and should be made only to *bona fide* charitable organizations or, in rare instances, to individuals engaged in genuine charitable activities for the support of a *bona fide* charitable mission. Diligence should be exercised to ensure the *bona fide* nature of the charitable organization or charitable mission.

### XII. Evaluation and Demonstration Products

Providing products to HCPs at no charge for evaluation or demonstration purposes can benefit patients in many ways. These benefits include improving patient care, facilitating the safe and effective use of products, improving patient awareness, and educating HCPs regarding the use of products. Under certain circumstances, Biom'up may provide reasonable quantities of products to HCPs at no charge for evaluation and demonstration purposes.

Biom'up products that may be provided to HCPs for evaluation include single use (e.g., consumable or disposable products) and multiple use products (sometimes referred to as "capital equipment").

These products may be provided at no charge to allow HCPs to assess the appropriate use and functionality of the product and determine whether and when to use, order, purchase, or recommend the product in the future. Biom'up products provided for evaluation are typically expected to be used in patient care.

*Single Use/Consumables/Disposables.* The number of single use products provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances.

*Multiple Use/Capital.* Multiple use products provided without transfer of title for evaluation purposes should be furnished only for a period of time that is reasonable under the circumstances to allow an adequate evaluation. The terms of an evaluation of such multiple use products should be set in advance and set forth in writing. Biom'up shall retain title to such multiple use products during the evaluation period and will promptly remove such multiple use products from the HCP's location at the conclusion of the evaluation period unless the HCP purchases or leases the products.

*Demonstration.* Company demonstration products are typically unsterilized single use products or mock-ups of such products that are used for HCP and patient awareness, education, and training. For example, an HCP may use a demonstration product to show a patient the type of device that will be implanted in the patient. Demonstration products are not intended to be used in patient care. Demonstration products are also typically identified as not intended for patient use by use of such designations as "sample-not intended for human use", or other suitable designation on the product, the product packaging, and/or documentation that accompanies the product.

Biom'up shall provide HCPs with documentation and disclosure regarding the no-charge status of evaluation and demonstration products.

**FREQUENTLY ASKED QUESTIONS  
REGARDING BIOM'UP 'S POLICY ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS**

SECTIONS I and II: PREAMBLE & GENERAL QUESTIONS

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**Q1. Why did AdvaMed develop a code distinct from the PhRMA Code on Interactions with Health Care Professionals?**

The AdvaMed Code of Ethics is intended to address the unique interactions that occur between medical device companies and HCPs, just as the PhRMA Code reflects the nature of interactions between pharmaceutical companies and HCPs. Distinguishing features in AdvaMed's Code arise primarily from the fact that Companies interact with HCPs because of the complexity and "hands on" nature of medical technologies and the importance of having HCPs understand how to use the technologies safely and effectively.

**Q2. Who are "Health Care Professionals?" Does the term include non-clinical people who make product purchasing decisions? Does it include decision-makers within GPOs?**

The phrase "Health Care Professionals" is intended to be broad in definition. It includes individuals or entities: (1) who are involved in the provision of health care services and/or items to patients; and (2) who purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe the Company's medical technologies. The phrase "Health Care Professional" includes both persons providing services (such as licensed physicians) and persons who do not provide services directly but who are involved in the decision to purchase, lease, or recommend a Medical Technology. These individuals include for example, purchasing agents, physician's practice managers and management within group purchasing organizations ("GPOs").

**Q3. Does the Policy apply to gifts, meals, refreshments, and other benefits provided by Companies to government employees?**

Yes, the Policy applies to gifts, meals, refreshments, and other benefits provided by Companies to government employees if the employees are HCPs. Companies also should be aware that there may be specific legal restrictions on providing gifts and other benefits to government employees, and that these restrictions may, in some cases, be more restrictive than the Policy.

**Q4. Does the Policy cover interactions with Health Care Professionals whose primary place of work is outside the U.S.? Does it cover interactions outside the U.S. with Health Care Professionals who work in the U.S.?**

The Policy applies to interactions with HCPs to the extent that they provide services or products in the United States. This would include interactions with HCPs who work in the United States, even if the interaction occurs outside the country (such as at a conference or other event). Of course, there are other laws and ethical requirements that may pertain to interactions with HCPs located both inside and outside the United States. Compliance with those laws and requirements must be maintained.

**Q5. Are combination products covered by the Policy?**

Yes, interactions related to combination products (e.g., those that are both biologics and devices or drugs and devices) are covered by the Policy.

**Q6. Does the Policy address arrangements between Biom'up and a Health Care Professional relating to licensing a new medical technology to Biom'up?**

Any arrangements that involve providing services to Biom'up are considered consulting arrangements. Interactions relating to product development and intellectual property are subject to the general principle that Biom'up shall encourage ethical business practices and socially responsible industry conduct and shall not use any unlawful inducement in order to sell, lease, recommend, or arrange for the sale, lease, or prescription of, their products.

**Q7. What do the terms “modest” and “occasional,” mean?**

The Policy seeks to balance an interest in civility with the desire to avoid even the appearance that meals and refreshments may be used as an inducement to purchase or refer for product. Accordingly, the Policy differentiates, depending on the type of meeting, the type of meals and refreshments that may be extended to HCPs by Representatives. The Policy contemplates that any meals and refreshments should be subordinate in time and focus to the purpose of the meeting.

“Modest” means moderate or low value and “occasional” has been defined as no more that eighteen (18) per year. Meals and hospitality should be ancillary to a legitimate documented purpose. Biom'up has imposed limits on the frequency and amount of such expenditures.

As outlined in this Policy, Biom'up has established modest and occasional limits on meals with HCPs. Biom'up has established a cap on meal expenses not to exceed \$200 per person for dinner, \$50 for breakfast, \$75 for lunch, and \$35 for in-office refreshments other than meals. This include taxes, tips, and fees.

**Q8. May a Biom'up employee or agent pay for meals or refreshments for a Health Care Professional that the Biom'up could not provide under the policy, if Biom'up neither pays for the meals or refreshments nor reimburses the employee or agent?**

No. The Policy should be viewed as applying to Biom'up's employees and agents even if they pay for benefits themselves. Depending on the circumstances, it may be appropriate for an employee or agent of Biom'up to engage in certain activities with an HCP if each pays his or her own way.

**Q9. May Biom'up or its Representatives offer to provide laptop computers with independent value to any purchasing manager whose hospital purchases at least 1,000 medical devices that Biom'up has just introduced?**

No. It is not appropriate for Biom'up or its Representatives to provide any item of value to an HCP that is intended to induce the referral of business, or the recommendation or arranging for the referral of business to Biom'up. Further, it is not appropriate to provide anything of value to an HCP that, directly or indirectly, takes into consideration the value or volume of the business that is or may be generated by the HCP, unless permitted by law (e.g., appropriate discounts).

**Q10. May Biom'up or its Representatives provide support for a Health Care Professional-sponsored social event, such as an office party?**

No. Such support would be inappropriate.

SECTION III: BIOM'UP -SPONSORED TRAINING AND EDUCATION

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**Q11. Why may it be appropriate under the Policy for Representatives to pay for travel to training and education sessions?**

In order to efficiently deliver training at appropriate facilities, the Policy contemplates that Representatives may bring HCPs together at a central location, which may make out-of-town travel necessary. Note that this section addresses only meetings focused on training and education on Biom'up products, and only for persons who could legitimately benefit from training. (Meetings focused on sales, promotional, and other business meetings are discussed under Section V.) Outside of this context, such payments would not be appropriate.

**Q12. May Biom'up pay for travel to a Biom'up-sponsored general educational program (not specific to Biom'up's products)?**

It may be appropriate for Biom'up to conduct general educational sessions, but these are not the types of programs for which Biom'up-supported travel would be appropriate under the Policy. In contrast, paying for HCP travel may be appropriate when Biom'up is conducting training and education on the safe and effective use of its products.

SECTION IV: SUPPORTING THIRD PARTY EDUCATIONAL CONFERENCES

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**Q13. May Biom'up designate attendees or faculty who will speak at third-party educational conferences?**

No. The Policy contemplates that an independent third party will select faculty and attendees. The ultimate selection should be made by the conference sponsor and the payment may not be tied to the selection of a particular faculty member.

**Q14. Can Biom'up provide an educational grant to support the attendance of a Health Care Professional at a third-party educational conference?**

The Policy contemplates that grants could be made to the conference sponsor or training institution, which will select the attendees and faculty. Furthermore, the Policy contemplates that the benefited attendees would be medical students, residents, fellows, or other HCPs in training. Biom'up can provide grants to conference sponsors for reasonable honoraria, travel, lodging, and meals for HCPs who are *bona fide* conference faculty members. The conference sponsor must be responsible for and control the selection of faculty.

The determination of whether an educational grant to support the attendance of an HCP at a third-party educational conference is made by the Compliance Leadership and discussed under Section IV.

**Q15. If Biom'up provides a grant for a medical student to attend an educational conference, may the funds be used to cover both travel expenses and registration fees?**

Yes, provided that the grant is given directly to a training institution or a third party educational conference sponsor.

**Q16. May Biom'up sponsor an off-site sales, promotional, or other business meeting that is ancillary to a third-party educational conference?**

Yes, provided that the sales and promotional meeting or other activity has a legitimate business purpose and meets all applicable requirements of the Policy. Biom'up must also comply with applicable conference sponsor guidelines. Sales and promotional meetings should be evaluated under Section IV. However, Biom'up-sponsored product-related

## POLICY ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

educational programs should be evaluated under Section III. In either case, it should be determined whether the conference sponsor has guidelines that cover that type of off-agenda activity, and if so, the sponsor's guidelines should also be honored. If this Policy has rules that are more restrictive, this Policy controls any decisions.

### SECTION V: SALES, PROMOTIONAL, AND OTHER BUSINESS MEETINGS

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**Q17. Why does the Policy not allow business courtesies to be extended to guests/spouses in connection with sales, promotional or other business meetings?**

Biom'up's Policy is mindful of the desire to avoid even the appearance that business courtesies are being given as improper inducements to promote Biom'up's products. It is not appropriate to pay for meals, refreshments, travel, or lodging of spouses or guests of HCPs or any other person who does not have a *bona fide* interest in the information being shared at the meeting.

**Q18. May the Company conduct a sales, promotional, or other business meeting at a resort location and pay for a Health Care Professional's travel to the meeting?**

Generally, this would not be appropriate. Biom'up should be deliberate in selecting the location and venue for such meetings. Biom'up should select a location and venue that is appropriate for, and conducive to, accomplishing the purpose of the meeting in a manner similar to the location and venue selection for training and educational meetings. Selection of a resort location would not likely meet these standards and may give rise to an appearance of impropriety. In addition, the location should be evaluated for consistency with the provisions in Sections III and IV, which provide that it may be appropriate at sales, promotional, or other business meetings to provide occasional modest meals or refreshments and, with respect to providing travel, that the travel be "necessary". Furthermore, the policy provides for limited special circumstances of "plant tours and demonstrations of non-portable equipment" as specific examples of when travel might be necessary.

**Q19. May Biom'up indirectly provide meals or refreshments when the provision of meals or refreshments does not conform to the Policy, for example, by reimbursing a distributor who provides these meals while marketing the Company's products or medical technologies?**

No. Biom'up shall always promote adherence to the Policy by intermediaries when they are engaged in marketing Biom'up's products or medical technologies. Biom'up shall not knowingly encourage or condone an intermediary's engaging in conduct that would be prohibited by the Policy. Biom'up and its Representatives may not do indirectly what they may not do directly.

**Q20. May a Representative provide pizza for the staff of a medical office?**

Providing pizza for the staff of a medical office would be permissible under the Policy if the Representative provides an informational presentation to the medical staff in conjunction with the meal of modest value, so long as the location of the presentation is conducive to a scientific or educational communication. Merely dropping off food for the office staff, however, would not be consistent with the Policy.

**Q21. May a Representative invite Health Care Professionals to a meeting at a café bookstore to learn about a new Biom'up product where coffee and refreshments are served and each attendee is given a gift certificate for books in the amount of \$30?**

No. While the presentation may present scientific or educational information and the coffee and refreshments may be appropriately provided, an open-ended gift certificate is a cash equivalent. A medical textbook, a book on patient

care, or a gift certificate redeemable solely for a medical textbook or book on patient care could be provided if it is not of substantial value.

SECTION VI: CONSULTING ARRANGEMENTS WITH HEALTH CARE PROFESSIONALS

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**Q22. Is a clinical investigator considered a “consultant” under Section VI?**

Yes. If the clinical investigator is providing services to Biom’up in return for compensation, he or she is considered a consultant.

**Q23. Is there a limit to the number of consultants Biom’up may retain under Section VI?**

Only as many consultants as are as necessary to fulfill Biom’up’s requirement for *bona fide* services. Moreover, the requirements of Section VI must be satisfied for each consultant.

**Q24. May a consultant be placed under retainer with services provided as requested?**

Yes, provided the requirements of Section VI are met.

**Q25. What happens if a consultant is engaged but the project is cancelled or modified without using the consultant’s services?**

The Policy contemplates that if the requirements of Section VI were met when the consultant was engaged and then unanticipated circumstances prevent performance, the question of whether or how much payment is made to a consultant would be a matter determined by the underlying consulting agreement. However, any such payment should be reasonable under the circumstances.

**Q26. What factors should Biom’up consider when evaluating the venues and circumstances for meetings with consultants?**

Biom’up should assess (1) whether there is a *bona fide* business justification for holding the meeting; (2) whether the location and venue are suitable for and conducive to the exchange of information between Biom’up and consultant; (3) whether the value of any Biom’up sponsored lodging is reasonable; (4) whether any ancillary meals and hospitality are modest in value (or alternatively, the FMV of such meals and hospitality are taken into consideration when determining the FMV of the compensation to be provided to the consulting HCP) and are subordinate in time and focus to the business part of the meeting; and (5) whether the overall meeting has a genuine business purpose and tenor and does not represent improper inducement of the HCP.

**Q27. When is a Health Care Professional considered a “consultant”? What types of arrangements with consultants are covered under Section VI.?**

Any relationship between an HCP and Biom’up where services provided to Biom’up by the HCP are exchanged for remuneration constitutes a consulting arrangement and should comply with Section V. Examples of consulting arrangements include agreements to provide education and training, speaking engagements, proctoring and preceptorships, reference center or center of excellence arrangements, participation on advisory boards or focus groups, medical technology development and research services arrangements (such as post-market research agreements, research and development agreements and clinical studies), and arrangements for the development and/or transfer of intellectual property. Research and educational grants are not considered consulting agreements and are addressed in Section XI.



**Q28. Can the selection of a consultant include his or her experience, usage or familiarity with specific Biom'up products?**

A consultant should be selected on the basis of his or her qualifications and expertise to meet a defined need. It is possible that these qualifications could include experience with, usage of, or familiarity with a specific Medical Technology. However, neither selection of, nor compensation paid to consultants may be intended to reward past, or future, usage or constitute an unlawful inducement. Consultant qualification and legitimate and *bona fide* service needs are defined, for example during Biom'up's Needs Assessment Process, and evaluated by Biom'up's Compliance Leadership.

**Q29. How are Clinical Study Agreements treated under the Policy?**

Arrangements that involve the provision of clinical research services by an HCP in return for compensation are a type of consulting arrangement and are subject to the same principles as other consulting agreements under the Policy. They should be governed by a written service agreement, and compensation should be based on FMV for the services provided. The clinical program for which the services are being provided should fulfill a legitimate research purpose.

A Clinical Study Agreement typically is entered into between Biom'up and an HCP that is a facility, institution, or practice group, and compensation for the clinical research services is paid to that entity. An individual HCP may act as a study investigator but also provide related services in his or her capacity that is outside the scope of the services covered in the Clinical Study Agreement (e.g., protocol development). In that case, a separate consulting arrangement with that HCP will be required.

**Q30. How can Biom'up establish "Fair Market Value"?**

There are different valuation methods that may be used to establish fair market value. In all instances objective, verifiable criteria should be used and documented. Most often fair market value should be assessed by an independent third-party.

**Q31. What is considered a "legitimate need" to engage a Health Care Professional as a consultant?**

A legitimate need arises when Biom'up requires the services of an HCP in order to achieve a proper business objective. There are many proper business objectives. However, engaging an HCP for the purpose of generating business directly from such HCP (or a health care provider that is affiliated with the HCP) is not a proper business objective. Thus, there is a legitimate need to engage an HCP only if the arrangement would have been entered into absent an opportunity to generate business directly from the HCP. Further, the level of consulting services to be obtained from an HCP should not exceed the amount that is reasonably necessary to achieve a Company's proper business objective.

SECTION VII: PROHIBITION ON ENTERTAINMENT AND RECREATION

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**Q32. May Biom'up or its Representatives invite a group of Health Care Professionals to a suite at a professional sports game for a 45-minute scientific and educational presentation followed by a buffet and the three-hour game?**

No. The provision of entertainment and/or recreational activities, including entertainment at sporting events in connection with an educational or scientific presentation or discussion, is inconsistent with the Policy.

**Q33. Under what circumstances would the Policy permit Biom'up or its Representatives to provide entertainment or recreational activities directly to Health Care Professionals?**

## POLICY ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

Entertainment and recreational activities should not be provided to HCPs. HCPs should not be invited to sporting events, concerts, or shows, or be provided with recreational activities such as hunting, fishing, boating, ski trips, or golf outings, even if those entertainment events or recreational activities are used to facilitate informational interchanges between Representatives and HCPs. Similarly, it would be inappropriate to provide these types of entertainment and recreational events in conjunction with promotional scientific presentations by medical experts.

- Q34. Could a sales representative invite a Health Care Professional out for a round of golf and lunch where the combined cost of the golf and lunch is \$65 and the Health Care Professional is very busy and difficult to see in her office?**

No. It is not consistent with the Policy to provide entertainment or recreational activities such as golf. HCPs should not be invited to sporting events, concerts, or shows, or be provided with recreational activities such as hunting, fishing, boating, ski trips, or golf outings, even if those entertainment events or recreational activities are used to facilitate informational interchanges between Representatives and HCPs.

### SECTION VIII: MODEST MEALS ASSOCIATED WITH HEALTH CARE PROFESSIONAL BUSINESS INTERACTIONS

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- Q35. Is a general discussion to build good relationships a “business presentation” such that it is appropriate to provide a business meal?**

No. A business presentation may include substantial discussions related to a medical technology, development and improvement of a medical technology, pricing, or contract negotiations. The business discussion should account for most of the time spent during the meal. Development of general good will and business relationships should not be the primary purpose of a business meal and should not be used for entertainment or recreational purposes.

### SECTION IX: EDUCATIONAL ITEMS; PROHIBITION ON GIFTS

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- Q36. May branded promotional items of minimal value that are “related to a Health Care Professional’s work or for the benefit of patients” be provided to a Health Care Professional?**

No non-educational, branded promotional items may be provided, even if the item is of minimal value and related to the HCP’s work or for the benefit of patients (e.g., pens, notepads, mugs, and other items with Biom’up’s name, logo, or logo of a Biom’up product).

- Q37. May Biom’up or its Representatives provide a small (i.e., valued at less than \$100) gift such as flowers or a fruit basket to a Health Care Professional or to a Health Care Professional’s family upon significant life events such as a birth, death, or serious illness?**

No. Biom’up is prohibited from giving flowers, fruit baskets, etc. to recognize HCP life events (wedding, birth, anniversary, death, etc.)

- Q38. May Biom’up or its Representatives provide a gift valued at less than \$25 (e.g., a box of cookies or bottle of wine) to a Health Care Professional during the holiday season?**

No gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents may be provided to a Health Care Professional regardless if the value of such gift is minimal.

- Q39. May a Health Care Professional or a Health Care Professional’s office or staff be provided a gift such as flowers, gift baskets, meals, snacks, wine, or other refreshments?**

## POLICY ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

No. These types of gifts and refreshments are not considered related to the HCP's work or for the benefit of patients. However, if food is provided in connection with either sales or promotional meetings, conferences, or training and education, see Sections III, IV, and V to evaluate when meals and receptions may be appropriate.

**Q40. Is the \$100 limit determined on a per-gift or per-year basis?**

Representatives occasionally may provide modest gifts to HCPs, but only if the gifts benefit patients or serve a genuine educational function. Other than the gift of medical textbooks or anatomical models used for educational purposes, any gift from Biom'up should have a FMV of less than \$100. The \$100 limit is intended to be a per-gift amount; however, consideration should be given to the frequency of providing gifts to any one individual (note the requirement that the gifts only be occasional). Repeated gifts to the same person, each with a value below the \$100 threshold, could violate the spirit of the Policy, the purposes of which are set forth in the Preamble. Similarly, gifts to multiple representatives of a physician practice group or to multiple representatives of a hospital materials management or faculty department could also violate the spirit of the Policy.

**Q41. May gifts be given to the staff of a Health Care Professional who is not themselves Health Care Professionals?**

No. Gifts given to the staff of an HCP should be treated as though they are given to the HCP and are subject to the provisions of Section VII.

**Q42. May Biom'up or its Representatives raffle an item during a trade show, such as two round-trip airline tickets, that it could not otherwise give as a gift?**

No. A Company may not raffle or give away at a trade show an item that it could not otherwise give an HCP under Section IX.

**Q43. What types of items are considered to be for the benefit of patients?**

Items intended for the benefit of patients could include educational brochures. However, scrubs and office supplies would not be considered an item for the benefit of patients.

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## SECTION X: PROVISION OF COVERAGE, REIMBURSEMENT, AND HEALTH ECONOMICS INFORMATION

**Q44. Is it appropriate to demonstrate that a product can be used in an economically efficient manner?**

It may be appropriate to provide accurate information relating to the costs, savings and revenues associated with the use of a particular product. Without this information, it may be difficult for an HCP to properly evaluate whether it is economically feasible or desirable to purchase any particular product.

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## SECTION XI: RESEARCH AND EDUCATIONAL GRANTS AND CHARITABLE DONATIONS

**Q45. May grants be given to a for-profit organization, such as a legitimately sponsored research grant to a for-profit hospital? What about a research grant to an individual Health Care Professional?**

This section of the Policy addresses charitable giving. Funding a research project at a for-profit institution, or paying an individual researcher, would not qualify as a charitable gift. However, that does not, by itself, mean that the

## POLICY ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

funding would violate the Policy. For example, if the funding constituted payment for a legitimate service, it could be appropriate under Section VI: "Consulting Arrangements with HCPs" (which should be consulted in evaluating proposed arrangements to make payments for the performance of services).

**Q46. May Biom'up or its Representatives pay for or provide tickets to a Health Care Professional or their spouse or guest to attend charitable events, such as galas and golf outings?**

No. Biom'up or its Representatives may not pay for or provide tickets to HCPs or their spouses or guests to attend charitable events, such as galas and golf outings.

**Q47. May Biom'up give a Health Care Professional a research grant that is unrestricted and can be used for any purpose?**

No. Biom'up may only give research grants if they are in support of research that has defined goals, objectives, and milestones.

## SECTION XII: EVALUATION AND DEMONSTRATION PRODUCTS

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**Q48. May Biom'up provide a recently approved product without charge to a Health Care Professional for evaluation?**

Yes, but Biom'up must provide the HCP with documentation about the product to allow the HCP to appropriately address any obligation to report for reimbursement purposes.

**Q49. A Health Care Professional has requested that Biom'up provide it with a multiple use product to evaluate. How long can Biom'up provide the product at no charge to the HCP?**

The specific length of time reasonably necessary for an HCP to assess a multiple use product will depend on the frequency of anticipated use, the duration of required training, the number of HCPs who will need to evaluate the product, the length of time necessary to evaluate different product features, and similar considerations. Biom'up must provide the HCP with documentation and disclosure regarding the no-charge status of evaluation products.

**Q51. Is a demonstration or evaluation product that is provided at no charge to a Health Care Professional considered a gift?**

No. Demonstration and evaluation products are not considered gifts under Section XI.

## ADDITIONAL QUESTIONS

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**Q52. Does the Policy offer legal advice?**

No. The Policy is intended to facilitate ethical behavior, and is not intended to be, nor should it be, construed as legal advice. You have an independent obligation to ascertain that your interactions with HCPs comply with all current laws and regulations.

**Q53. Will Biom'up provide advice on how specific provisions of the Policy would apply to specific practices that are being contemplated?**

This FAQ is designed to provide information regarding the Policy. Specific questions should be addressed to the Biom'up Compliance Leadership.

**Q54. Does the Policy govern the actions of Biom'up's agents and distributors?**

Biom'up expects that its employees and representatives will adhere to the Policy.