Kimberly-Clark Healthcare
Guidelines for Interactions with Healthcare Professionals

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Introduction to
Guidelines for Interactions with Healthcare Professionals

Kimberly-Clark Healthcare (“K-C”) is committed to compliance with the U.S. healthcare laws and regulations that govern our interactions with healthcare professionals. Compliance demonstrates our commitment to integrity in our operations and builds trust with patients, healthcare professionals, institutions and the government. These guidelines are an application of the K-C Corporate Code of Conduct. These provisions provide greater guidance with respect to certain laws that uniquely affect the K-C Healthcare business.

For purposes of our guidelines, the term “healthcare professional” includes those individuals and entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe K-C’s medical technology products in the United States. This includes both clinical and non-clinical people who make product-related decisions of the sort listed. It also includes decision-makers within group purchasing organizations. This definition is intended to encompass anyone with material influence over purchasing decisions. Healthcare professionals include both individuals that are our customers, as well as those who are not.

These guidelines apply to our interactions with healthcare professionals in the United States. Although our interactions with healthcare professionals in other areas of the world are technically not covered by these guidelines, we will abide by these guidelines in those situations because we must comply with the Foreign Corrupt Practices Act (FCPA) and its anti-bribery provisions. The FCPA prohibits the payment of any type of kickback to a foreign official or political party to secure or maintain a business advantage.

How to Use These Guidelines

These guidelines are meant to establish a uniform way of conducting the areas of our operations that involve interactions with healthcare professionals. These guidelines should serve as instructions for the categories of interactions which are covered. If you have any questions or are unsure how to interpret or apply these guidelines, do not hesitate to seek guidance from your team leader, or you may contact the Compliance Officer or the Legal Department.

Overview of the Anti-Kickback Law

The key federal law in the United States that governs our interactions and relationships with healthcare professionals as it relates to fraud and abuse issues is the anti-kickback law. The anti-kickback statute and its implementing regulations provide that anyone who knowingly and willingly offers, gives, solicits or receives anything of value to influence or reward the ordering, purchase or referral of federal or state healthcare program business can be charged with a felony.

This law prohibits K-C from providing payments, gifts, or other things of value to healthcare professionals that are intended to induce someone to purchase a product when that product is reimbursable by Medicare, Medicaid or another federal or state healthcare program. One of the
goals of the anti-kickback law is to ensure that a healthcare professional’s decisions are based on their independent medical judgment and are not tainted by motives of personal gain. The law seeks to protect healthcare professionals from improper influence that might result in increased costs to Medicare, Medicaid and other government programs, as well as negatively affect patient care. Thus, all K-C activities must benefit patients, enhance the practice of medicine, and not interfere with the independent professional judgment of healthcare professionals.

The law does have a number of “safe harbors” which protect legitimate arrangements. K-C’s guidelines are drafted to ensure our compliance with an applicable safe harbor whenever possible.

The following are examples of conduct that would be prohibited by the anti-kickback law:

- Providing a grant to a customer or a professional society that is contingent on the purchase or recommending of K-C products.
- Purchasing services from a healthcare professional at a fee which is above a reasonable fair market value for the service. For example, the law would prohibit paying a consultant a fee, which is higher than the value of his services as a means to reward the consultant for past purchases and to induce to buy more products.
- Providing a gift to a doctor to influence the doctor’s purchase of a K-C product.

As indicated above, the law is aimed at products and services which are reimbursable by federal and state healthcare programs. K-C markets products which are reimbursable by Medicare and Medicaid. Because it is not possible to know with certainty whether a healthcare professional participates in Medicare, Medicaid or another federal and state healthcare program, K-C treats all healthcare professionals as if they are subject to the anti-kickback law. In other words, our guidelines are applicable across the board to all of our interactions with healthcare professionals, whether the anti-kickback law is technically implicated or not.

**Implementation and Enforcement of These Guidelines**

Compliance with these guidelines is mandatory. A violation of these guidelines subjects you to discipline in accordance with our existing disciplinary policies. Depending on the number of infractions or the nature of the offense, penalties may include an official reprimand that will be included in the individual’s personnel file, job reassignment or demotion, or employment termination. The Vice President of Sales and Marketing or the Vice President of Regulatory Affairs, as appropriate, will consult with the Legal Department in evaluating the conduct and the disciplinary actions to be taken, if any. Additionally, a violation of these guidelines may subject you to sanctions under federal law. In appropriate circumstances, K-C may report such cases to law enforcement authorities.

If you learn of conduct by an individual employed by K-C, or working on K-C’s behalf, who does not comply with these guidelines, or if you believe you might have inadvertently failed to comply are unsure, you must report the conduct. These reports should go to your team leader,
the Compliance Officer, or the Legal Department. If you would like to make your report anonymously, you may make the report to K-C’s Ethics Hotline (consult the company intranet for instructions on accessing the Ethics Hotline). All reports should be made in good faith based on a reasonable belief that misconduct has occurred. No K-C employee should be concerned about any reprisal or reprimand for coming forward with a report; K-C encourages open and proactive communication and dialogue.

The responsibility for implementing these guidelines will lie with the K-C Legal Department. K-C will provide regular training to employees including, but not limited to, sales and marketing personnel, to ensure compliance with applicable laws and company guidelines. In addition, K-C will conduct audits, at least once a year, to monitor compliance with the K-C guidelines and will investigate, when appropriate, potential instances of non-compliance.

The Legal Department will be charged with enforcing these guidelines, and any modifications to or deviations from the guidelines must be approved by the Legal Department.
Tab A

K-C-Sponsored Product Training and Education

Introduction

K-C is committed to ensuring that healthcare professionals are educated about the safe and effective use of our products and the related disease-states. Activities that train and educate healthcare professionals about our products and their proper use may include speaker programs, healthcare symposia, and “webinars.” These events may be held on a local, regional or national level. Although the types of events may differ, the guidelines below apply equally to all events.

The purpose of a product education and training program is to inform physicians about our products, so the program must focus on educational content and the setting for the program must be conducive to the educational activity.

K-C may sometimes engage a third party to facilitate training and education events or programs. It should always be remembered that K-C remains responsible for ensuring that the program complies with these guidelines, regardless of whether it is organized by our team or a third party, and with applicable law such as, but not limited to, the Food and Drug Administration’s labeling and promotional requirements.

Engagement of Speaker

A qualified speaker is often engaged to provide the product training or education. The engagement of a speaker must be in accordance with the process of approving consultants described in the guidelines entitled, “Healthcare Professional Consultants,” at Tab H. Speakers must execute a consultant agreement. Please refer to the guidelines entitled, “Healthcare Professional Consultants,” at Tab H for information on the execution of a consultant agreement and the level of compensation that is appropriate for speakers.

K-C will provide travel and hotel accommodations for the speaker as needed. If K-C is providing a speaker with a flight to the event, the company will provide a coach-class ticket for travel and a reasonable travel budget to cover the cost of out-of-pocket expenses (e.g., food, cab). All travel arrangements must be arranged through the K-C travel service.

Speakers must provide a full, clear and conspicuous disclosure that K-C is the sponsor of the program.

Venue for the Event

The location of the event should be appropriate for education and training on the use of our products. The event should be conducted in a clinical, educational, conference or other setting. A conference facility or a meeting facility within a hospital is an appropriate venue. A private
room at a restaurant may be appropriate if the restaurant is modest as judged against the standards of the local area and is conducive to learning.

**Selection of Invitees**

Current and prospective customers may be invited to educational and training programs. Note that spouses and other guests of healthcare professionals should not be invited to the event. K-C should only invite healthcare professionals and members of their staffs which have a legitimate interest and role in the discussion. For example, it may be appropriate for a physician to bring nurses, office managers or physician assistants.

**Travel Expenses of Invitees (Not Applicable to Speakers)**

It is generally not appropriate to pay for travel expenses for an invitee who is not a speaker, although the provision of complimentary parking is always appropriate. If the purpose of the program or event is to educate the healthcare professional on the proper use of the K-C product and it is not possible to teach at the healthcare professional’s place of business, K-C will reimburse to the extent the company reimburses its own employees for travel, such as mileage if the healthcare professional lives or works in the vicinity the program venue (i.e., within 30 minutes of the event).

If a healthcare professional does not live or work in the vicinity and needs to travel to attend the event for product use training purposes, it is appropriate to pay for reasonable travel expenses, to include only accommodations in a nearby hotel and, if a flight is necessary, coach airfare. Note, however, that travel expenses should only be covered if there is not expected to be a similar training or educational program available in the healthcare professional’s area within a reasonable amount of time. These travel arrangements should be approved in advance by the Legal Department.

Under no circumstances should a healthcare professional (other than the speaker, if applicable) be compensated for attending the event. No per diem payments or honoraria may be provided to compensate the healthcare professional for time in attending the event.

**Related Hospitality and Meals**

It is appropriate to offer refreshments during an educational program. If the program is held during a traditional meal time, it is appropriate to provide a modest meal in conjunction with the event. Please see the guidelines entitled “Meals with Healthcare Professionals” at Tab D for information about the provision of meals.

As a general rule, training and education programs should not involve entertainment provided outside of the scope of the event. The only exception to this general guideline is an educational or training event that takes place over a two-day period. In those instances, the provision of a meal and reasonable entertainment in the evening between days is appropriate. However, the entertainment must be subordinate in time and focus of the main program, and all attendees must be invited. For example, it would be appropriate to provide a modest meal and a cocktail
reception with a jazz band for all attendees; but it would not be appropriate to take a small number of selected attendees to a popular sporting event.

Gifts

It may be appropriate to provide healthcare professionals with a gift in conjunction with their attendance at the event. Any gift must comply with the guidelines entitled “Gifts and Branded Items” at Tab E. The gift should not be advertised to attendees or used as a way to induce a healthcare professional to attend the event. Instead, it should be a token of K-C’s appreciation provided in a fashion that is subordinate in focus to the event. For example, it may be appropriate to have a branded coffee mug at each seat at the event, or to provide attendees with a branded tote bag to carry their program materials.
**Tab B**

**Third-Party Educational Events and Trade Shows**

**Introduction**

K-C supports bona fide, independent conferences focused on education, scientific discussion or policymaking as a way to promote medical advancement, the delivery of effective healthcare and scientific knowledge. These events may be regional, national or international, and include events hosted by medical associations, continuing medical education providers and healthcare institutions (some of which may be our customers).

We may purchase display space at medical meetings or may be asked to sponsor health-related meetings that allow for booths or displays. Such events may also include health fairs where consumers can be educated about us and our products. It is important to remember that K-C’s interactions with healthcare professionals who visit our display booth and with the organizers of the event are covered by our guidelines.

**Financial Support**

The most common way that K-C supports third-party educational events is through financial grants. This grant is provided directly to the event sponsor to reduce the overall costs of the event. The sponsor of the event decides how to best use K-C’s funds, although K-C may indicate a general use for the funds (for example, K-C may offer a grant designated for use in covering speaker travel costs). The grant should be in accordance with the guidelines entitled “Grants” at Tab I.

It is not appropriate for K-C to provide financial support to a particular healthcare professional, so that the healthcare professional may attend a third-party’s educational event unless the healthcare professional is attending on behalf of K-C (e.g., as a speaker or a consultant). If a healthcare professional decides to attend such an event and is not acting on K-C’s behalf, it should be at his or her own expense. Providing financial support for a healthcare professional to attend an event sponsored by K-C is addressed in the guidelines entitled “K-C-Sponsored Product Training and Education” at Tab A.

**Compensation for Booth Space**

Frequently, K-C will be charged a fee for having a booth or display at an event. Before agreeing to participate, the Vice President of Marketing must review the requested fee to determine if it is reasonable and consistent with fees charged for booths at other, similar events. K-C may not participate in an event if the fee charged is unreasonable, not fair market value, or not consistent with fees charged by other events.
Games and Gifts at K-C’s Booth

To make a visit to K-C’s booth or display space enjoyable, it is appropriate to provide a simple game for visitors to play. It is appropriate to provide prizes for individuals who win a game or to provide a gift to all visitors to the booth, regardless of whether they participate in the game. Prizes provided to the winners of a game may be either: (i) an item that supports patient care and is valued under $100 (such as an educational poster for an exam room); or (ii) a medical textbook or anatomical model, valued under $100. Gifts provided to all visitors to the booth should be nominally priced items which are related to a healthcare professional’s practice (for example, pens or notepads).

Assistance in Selecting Speakers and Materials

Occasionally, the sponsor of a third-party educational event will ask K-C for help in selecting speakers and faculty for an event or for creating educational materials for use in a conference. If requested in writing, K-C may make recommendations of individuals to serve as speakers or faculty and may provide educational materials that may be of interest. However, the third-party event organizer remains responsible for, and control over, the event’s content. In addition, K-C must disclose to the third party any business relationship that exists between K-C and the recommended speaker. K-C should also suggest non-K-C-affiliated speakers. K-C must not condition any financial support for a third-party program on the ability to choose speakers or to prepare materials; the third party is solely responsible for speaker selection and material preparation and dissemination.

Related Hospitality and Meals

K-C may provide funding to the third-party event sponsor to support the event’s meals and hospitality. Additionally, K-C may itself provide meals and receptions for attendees of the event if the third-party sponsor of the event deems such hospitality to be appropriate. K-C’s hospitality should be provided pursuant to the following guidelines:

- If possible, all healthcare professionals attending the conference should be invited to K-C’s hospitality event. If the conference is particularly large, making it impossible to invite all attendees, then K-C should invite a variety of individuals, including, for example, some customers, non-customers, thought leaders, and event faculty. K-C must not invite only its “best”, highest volume or value customers.

- K-C’s event should be subordinate to the conference in time and focus. K-C’s hospitality should not be offered at a time when a conference event is scheduled. K-C’s event should not be so lavish or advertised heavily so as to take attention away from the conference.

- K-C should set a reasonable budget for its hospitality. For this purpose, K-C should set a guideline of $100 per invitee in the United States, inclusive of all related costs (e.g., transportation to the venue, food, alcohol). Outside of the United States, expenses should be limited to mid-priced and reasonable restaurants and hospitality, as considered acceptable by local business standards.
and practices (but should not exceed the equivalent of what $100 would cover in the United States). Any modifications to this guideline must receive the prior approval of the Legal Department.

- The location of K-C’s hospitality may be an entertainment venue, such as a museum, restaurant or local attraction. The venue should be conducive to discussions and interactions among attendees.

- If possible, an educational discussion or program regarding K-C and its products should be provided at the hospitality event. For example, it would be appropriate to have a representative of K-C provide a 15 minute lecture on company products before a meal is served or before a tour begins.

- Spouses and other guests of healthcare professionals should not be invited to the hospitality event.

- If the third-party sponsor of the conference has additional or conflicting rules regarding hospitality provided during the conference, those rules must be observed.
Access to Patient Care Areas in the Field

Introduction

Field personnel will be interacting with many individuals when visiting healthcare professionals in physician offices, clinics and hospitals. These interactions may take place in locations such as the hospital, physician offices, and medical clinics where medical personnel will be engaged in direct patient care. As patient welfare is an extremely important priority for K-C, we have developed guidelines for the appropriate interactions with patients during visits with healthcare professionals.

Guidelines for Patient Interactions and Access to Patient Care Areas

If field personnel encounter patients during a visit with a healthcare professional or enter into areas where patients are cared for, the following guidelines must be observed:

- K-C representatives must have physician and/or appropriate procedure room staff approval prior to entering a procedure room. K-C representatives must comply with all reasonable and appropriate policies of the healthcare facility of which they are made aware regarding their presence in the procedure room, including any policy regarding patient approval or consent to observation.
- K-C representatives should wear their K-C name badge visibly on attire when in the procedure room, unless the healthcare professional’s policy requires a hospital visitor/vendor badge.
- K-C representatives should introduce themselves to the appropriate personnel (for example, the charge nurse) when entering a procedure room and should ask where they should stand. Always be cognizant of your presence in the room and quickly get out of the way if it becomes evident that your location is inconvenient.
- No K-C representative may touch or make physical contact with a patient or any of the clinical instrumentation or other materials used during a procedure except if specifically asked to do so by the medical staff present and, even then, such contact must be as minimal as possible and only to assist the medical staff with or educate them about K-C’s products.
- During a procedure, the K-C representative should not speak to the healthcare professional unless specifically addressed. In that event, the K-C representative should respond to the inquiries with precise factual information. The K-C representative shall offer no medical opinions, judgments, or evaluations of the patient’s condition.
- Remember that you are always acting as a representative of K-C. It is important that professional courtesies be extended and that field personnel behave appropriately.
**Tab D**

**Meals with Healthcare Professionals**

**Introduction**

K-C employees are permitted to occasionally take a healthcare professional out for a modest meal as long as the meal complies with these guidelines. Modest meals with healthcare professionals are allowed occasionally in conjunction with a product or disease-state discussion and in a venue that is conducive to scientific or educational communication. For example, the occasional meeting with a physician in a quiet, mid-priced restaurant is appropriate.

It is not appropriate to take a physician out to a purely social dinner at the expense of K-C. If you develop an independent friendship with a healthcare professional and chose to socialize with that individual, you must do so on your own time and at your own expense.

**Guidelines for Meals**

If you would like to take a healthcare professional out for a meal, the following guidelines must be observed:

- Meals can be arranged but only on an occasional basis, i.e., once per quarter per physician. Diligently track how often you take a particular healthcare professional out for a meal and be prepared to provide this documentation to a team leader.
- The meal must be “modest” in relation to local standards. Modest restaurants are mid-priced.
- The spending limit per person, inclusive of alcohol, taxes and gratuity, is $50 for lunch and $100 for dinner in the United States. If you foresee a problem staying within this budget, you may ask the Vice President of Sales & Marketing. This request and the Vice President’s approval must take place before the event is scheduled. Outside of the United States, expenses should be limited to mid-priced and reasonable restaurants and hospitality, as considered acceptable by local business standards and practices (but should not exceed the equivalent of what $100 would cover in the United States).
- Be cognizant of the budget when you make your personal selections off of the menu. Consider breakfast or lunch meetings as a way to control costs.
- One way to help stay within budget is to control the ordering of wine. This would avoid the problem of a healthcare professional ordering an expensive bottle of wine. Avoid inviting the healthcare professional to choose the wine.
- The restaurant chosen must be conducive to discussions. Loud, flashy restaurants with bands or entertainment would not be appropriate.
- If alcohol is consumed, it should be consumed in moderation. K-C employees must remember that they are representing the company at all times and should not overindulge.
• Spouses and other guests of healthcare professionals should not be invited to the meal. K-C should only invite healthcare professionals and members of their staffs that have a legitimate interest and role in the discussion. For example, it may be appropriate for a physician to bring the office manager to a meal to discuss a K-C product. If a healthcare professional insists on bringing a spouse or other guest, politely inform the healthcare professional that K-C is unable to pay for the spouse or guest meal.

• Field personnel may take meals or snacks with them when visiting a healthcare professional at that professional’s office, as long as discussions about K-C’s products or an educational topic take place when the food is consumed. Merely dropping off food without conducting a product-related presentation (sometimes called “dine and dash”) is not allowed.

**Reimbursement Guidelines**

Reimbursement is available for occasional, modest meals provided to healthcare professionals in accordance with these guidelines. When submitting a reimbursement request, be sure to include a copy of the itemized receipt and indicate the names and titles of the guest, as well as the specific topics of discussion.
**Introduction**

K-C employees are permitted to occasionally give a gift to a healthcare professional as long as the gift complies with these guidelines. Any gift to a healthcare professional should be made without an expectation of receiving the recipient’s business or any other “quid pro quo” in return for the gift. Offering a gift with the intent to secure or reward business or to influence medical judgment implicates the anti-kickback statute.

**Guidelines for Gifts**

There are three categories of appropriate gifts.

Category 1 – nominally-priced, branded items which are useful in a healthcare professional’s practice. This would include, for example, pens, mouse pads, notepads, calendars and coffee mugs branded with K-C’s logo.

Category 2 – gifts valued under $100 which are useful for patient care. This would include, for example, educational posters and graphs for a patient examination room.

Category 3 – medical textbooks and anatomical models, not to exceed $100. This would include, for example, a medical textbook that aids healthcare professionals in their use of the types of products K-C markets.

No matter what category of gift you are giving, the following guidelines must be observed:

- Cash and cash-equivalent (e.g., gift card) gifts are never appropriate.
- Items intended for the personal benefit of a healthcare professional are never appropriate. This would include, for example, golf balls branded with the K-C logo, flowers and gourmet candy.
- All gifts must be related to the recipient’s practice or benefit the recipient’s patients.
- Gifts to government employees are never appropriate.
- Category 1 gifts of nominally priced, branded items such as pens and notepads with the K-C logo may be distributed more often (it is appropriate to leave behind branded “reminders” such as pens and magnets after every sales visit, unless the K-C product has a black-box warning label). A healthcare professional should only receive one Category 2 or Category 3 gift every six months, as these are more expensive gifts.
- Gifts may not be offered as a way to facilitate scheduling face-to-face time with a healthcare professional or to obtain some other benefit.
Approval Process for Gifts

Category 1 gifts of nominally-priced, branded items such as pens and notepads with the K-C logo may be distributed after the category or type of gift has been reviewed by the K-C Legal and/or Regulatory Department; however, field personnel should exercise discretion when giving these items. For example, a salesperson should not provide a physician’s office with an entire case of notepads, as the overall value of that gift would be more than nominal. Field personnel must obtain the approval of their team leader, the Compliance Officer, or the Legal Department before giving a Category 2 or Category 3 gift to a healthcare professional.
Tab F

Reimbursement Assistance

Introduction

K-C supports the accurate and responsible billing for our products by providing reimbursement information to healthcare professionals. This reimbursement information includes appropriate coverage rules, coding, and billing policies of various payors. However, there is a limit to the types of reimbursement assistance we can provide under the Anti-Kickback Law and K-C employees must not provide inaccurate information that could implicate the False Claims Act. The following establishes general parameters concerning the type of assistance a K-C employee may provide.

Providing Reimbursement Advice in the Field

From time to time, field personnel may be approached by a healthcare professional and asked for reimbursement assistance. For example, during a sales visit, a sales representative may be approached by a physician’s billing manager for advice on how to code a procedure; in another example, a physician may ask a representative how much revenue to expect from a particular payor for performing certain procedures. As a general rule, a sales representative should only provide factual information (e.g., HCPCS Code) and K-C approved marketing collateral. However, if the healthcare professional presses for information beyond such material, a sales representative may provide truthful, objective and balanced information learned and obtained through K-C formal and approved training and/or in consultation with the K-C Market Manager responsible for reimbursement-related information, or may refer them to the Centers for Medicare & Medicaid Services website, www.cms.gov. Remind the customer to confirm any information with the payor, as payor policies are subject to change.
Introduction

K-C may retain and compensate healthcare professionals as consultants for actual bona fide services and pay them fair market value fees for those services. K-C may retain healthcare professionals to act as consultants for a wide variety of purposes. For example, we retain healthcare professionals to act as an advocate in dealing with payors, to present training and educational programs, and to advise K-C on scientific and clinical matters. Scientific knowledge and/or hands-on experience with our products makes certain healthcare professionals especially knowledgeable, credible and effective speakers and and/or consultants.

Ongoing governmental investigations in our industry typically focus on improper payments to healthcare professionals and the intent behind such payments. The intent of these guidelines is to prevent impropriety, or the perception thereof, when entering into consulting arrangements with healthcare professionals. Consulting roles must be created and filled for legitimate, bona fide purposes. It is improper to pay a consultant when he or she has not performed any services or to offer a healthcare professional a lucrative consultant role as a way to influence him or her to use K-C’s products.

The Selection of Consultants

Before a consultant is selected, K-C must confirm that there is a true need for the consultant’s services. Once that need is identified, K-C may select a consultant to fill that need. K-C may have a need for multiple consultants in a particular area; if so, we should identify the number of consultants that we legitimately need and should select and engage only that number. Engaging “extra” consultants who are not needed is a violation of these guidelines.

A consultant should be selected and engaged on the basis of professional qualifications, expertise and skill set. A consultant position should never be offered as a “favor” or as a way to compensate a good customer.

If you have a need for a consultant, contact your team leader. If you have a particular individual in mind to serve as the consultant, let your team leader know that as well. Your team leader will forward the request and information to the appropriate persons for approval.

The Approval Process

Before a consultant may be engaged, he or she must be approved by the Director of Global Clinical Affairs, or Healthcare’s Medical Director, or one of their direct reports if the consultancy will relate to disease state, potential clinical trials or research, or other medical or technical-related functions. If the consulting service to be performed is exclusively related to an approved or cleared K-C product for on-label, marketing purposes, the Vice President of
Sales and Marketing or a direct report must approve. The Legal Department, including the Compliance Officer, may also approve any retention of a consultant.

Until a consultant has been approved, he or she may not provide services to K-C. K-C personnel must never make a formal offer to a healthcare professional to serve as a consultant, and should never make a promise that an individual will be selected as a consultant, until the required approval has been obtained.

**Once approval has been properly obtained, a consultant agreement is to be executed in accordance with K-C’s existing corporate signature authority policy.**

**Compensation to Consultants**

Consultants should be paid for the bona fide services that they render. Payment should be consistent with fair market value for the services provided. K-C must exercise diligence to confirm that a payment rate is reasonable and consistent with the relevant marketplace.

K-C will provide travel and hotel accommodations as needed for the provision of the consultant’s services. Please refer to Tab A, “K-C-Sponsored Product Training and Education,” for information on travel arrangements.

K-C Sales and Marketing personnel should never make an offer or promise of compensation to a potential consultant. If a potential consultant asks about payment, refer the individual to the appropriate Vice President. Do not make any commitments of compensation or provide examples of past compensation amounts. Compensation for consultants engaged for purposes other than professional education events will be negotiated and set by the appropriate Vice President or Director, in consultation with the Legal Department, as appropriate.

**Execution of a Consultant Agreement**

All consultants must sign a written agreement before they provide services. The agreement must be signed in accordance with K-C’s corporate signature authority policy. K-C has a template consultant services agreement for this purpose, which must be reviewed and approved by the Legal Department. The consultant agreement specifies the services that the consultant will provide, the basis for and rate of payment to be paid to the consultant and the invoice detail needed to prove the rendering of services, if applicable (for example, if the consultant is hired to perform research, the consultant may need to provide an invoice of milestones reached in order to receive payment).

The K-C Legal Department will maintain a file of all consultant agreements signed. This file will be used to confirm that all consultant agreements comply with applicable law and K-C policies and to avoid duplicate service and duplicate payment arrangements.
Consultant Meetings

On occasion, it may be necessary to gather certain consultants together in one location for a meeting. For example, if a group of consultants was engaged to conduct research, it may be necessary to meet as a group to discuss the research study’s progress or results. As another example, K-C may hire a group of consultants to sit on an advisory board for a certain topic and may need to call a meeting of the advisory board. Also, from time to time, K-C holds a speaker’s bureau training session, where consultants who have been engaged as speakers travel to a centralized location to be trained.

In such instances, K-C must consider and have appropriate answers for the following questions:

- **Purpose**: What is the purpose for the meeting and what are its anticipated benefits? There must be a legitimate purpose for the meeting and the meeting must result in some benefit to K-C (for example, the meeting results in well-trained speakers or provides valuable information from opinion leaders on an advisory board).
- **Output**: What needed services will consultants provide in the context of the meeting? The consultants attending the meeting must have an active role and a purpose for attending.
- **Frequency**: If multiple meetings are proposed, can the number be supported objectively? Are multiple meetings needed to cover different areas of the country, or would it be more efficient to travel to a centralized location? Are the same consultants attending multiple versions of the same meeting? If so, consider cutting back on the number of meetings or the individuals who are participating. In addition, K-C should not merely retain certain consultants, merely due to the volume of business generated by the healthcare professional. In addition, K-C should not engage more consultants than is necessary to accomplish the main objective’s goals.
- **Repetition**: Have previous meetings addressing the same subject or issue been held before? If so, is there a legitimate need for another meeting on the same subject at this time? How does this meeting build on the prior meetings? Holding a consultant meeting for no real purpose is improper.

There must be a legitimate purpose and need to hold a consultants meeting. The purpose of a meeting must not be:

- Merely to provide healthcare professionals with an opportunity to meet and mingle with their peers.
- To have healthcare professionals listen passively to promotional messages about our products.
- To have an opportunity to “wine and dine” healthcare professionals.

Healthcare professionals who attend meetings in a passive capacity are not consultants performing services and cannot be paid.
As with educational events hosted by K-C, the venue for a consultant meeting must be conducive to the business purpose of the meeting. The event should be conducted in a clinical, educational, conference or other setting. A conference facility or a meeting facility within a hotel is an appropriate venue. A private room in a restaurant may be appropriate if the restaurant is modest as judged against the standards of the local area and is conducive to learning.

The geographical location of a consultant meeting should be selected for ease of travel and convenience for all participants (for example, the availability of an efficient airport). Resort locations and lavish destination spots may not be appropriate.

Consultants attending the meeting may be reimbursed for reasonable travel (coach fare) and lodging expenses at nearby hotels. K-C cannot pay for extended stays at a hotel prior to or after the meeting, nor can it pay for travel or additional lodging costs for spouses or other guests.

It may be appropriate to provide a meal or hospitality in conjunction with a consultant meeting. All meals provided should be modest and should follow the guidelines entitled “Meals with Healthcare Professionals” at Tab D. Any hospitality or meals should be subordinate in time and focus to the consultant meeting. Appropriate hospitality would include a cocktail reception for professional networking, with light entertainment such as a jazz band or a tour of a local attraction. It would not be appropriate to take a small number of selected attendees to a popular sporting event. K-C should set a reasonable budget for its hospitality. Please refer to Tab A for guidelines on hospitality. Any modifications to this guideline must receive the prior approval of the Legal Department.

Spouses and other guests of healthcare professionals who may have traveled to the consultant meeting should not be included in any meals or hospitality.

It may be appropriate to provide healthcare professionals with a small gift in conjunction with their attendance at the meeting. Any gift must be distributed in accordance with the guidelines entitled “Gifts and Branded Items” at Tab E. The gift should not be advertised or used as a way to induce a consultant to attend the event; instead, it should be a token of K-C’s appreciation provided in a fashion that is subordinate in focus to the meeting. For example, it may be appropriate to have a branded coffee mug at each seat at the meeting, or to provide attendees with a branded tote bag to carry their meeting materials. Such gifts and branded items should be evaluated first by the Legal Department and/or Regulatory Department.
**Introduction**

K-C may make donations and grants to third-parties for a variety of legitimate purposes, including the support of bona-fide educational initiatives, research with merit, and charity/public interest. It is not appropriate for K-C to make a grant with the intent of inducing the use of our products or as a “favor” to a recipient to thank or encourage them for using our products. All grants must be issued in accordance with these guidelines.

I. **Description of Grant Types and Requirements for Consideration.**

   A. **Educational Grants.** K-C provides educational grants to healthcare providers for a variety of educational activities. Examples of these areas are Continuing Medical Education (“CME”) programs presented by accredited providers, patient or community education programs, the provision of patient or provider educational materials, and the sponsorship of qualified fellowships. These grants will support legitimate areas of educational need and will benefit healthcare professionals and/or their patients. Educational grants to medical or other healthcare professional associations, societies or trade groups, to disease-based research, education or patient advocacy groups or to comparable entities are generally permitted.

   The fact that K-C may be provided with a booth or display space at an educational event in return for providing a grant does not change the character of the grant – it is still a grant. If K-C decides on its own to purchase booth space at a third-party event or trade show, this is not a grant and the guidelines entitled “Third-Party Educational Events and Trade Shows” at Tab B should be followed.

   The following requirements apply to any educational grant that K-C may consider funding:

   - Involves an area of legitimate interest to K-C (i.e., of current scientific or medical interest and relevance).
   - Meets acceptable educational criteria, including materials that appear to be rigorous and of high quality, with faculty or authors who are knowledgeable and experienced in the field.
   - If the grant will support a scholarship or fellowship, the recipient’s criteria for identifying the individuals that will benefit from the grant are rigorous and based on scientific or medical accomplishments, skills and abilities. While K-C may suggest speakers, if asked, with appropriate disclosure of any K-C relationship to the speaker, K-C is not involved in directly selecting the individual who receives the award; the decision remains with the grant recipient.
   - Any invitations, programs or materials developed for an event sponsored through a grant by K-C must include a statement making clear that K-C has
provided grant funding (for example: “This program is made possible [in part] through an educational grant from K-C”).

B. **Research Grants, Including Investigator-Initiated Studies.** Research grants, whether in monetary form or in the form of free product to be used in research, are made in order to support ongoing investigation related to our products or in disease state areas where K-C wants to support important research. These grants are generally made to healthcare professionals or institutions for research that they have initiated (often called “investigator-initiated” studies or research). The research is sponsored and conducted by independent investigators, as opposed to research that is sponsored by K-C. The grant’s purpose is to support research that has compelling scientific or clinical merit.

All protocols for the research must be written by the sponsor or investigator, not by K-C. However, in response to an unsolicited request, K-C may provide general comments and advice. K-C must never actually write protocols for independent research.

C. **Charitable Grants.** K-C may make contributions of funds or goods to a charitable organization for a bona-fide charitable purpose. Charitable contributions can also be made to certain governmental entities, such as a public university, as well as medical societies and civic organizations. Examples of charitable grants include corporate sponsorship of a benefit fundraiser (such as a walk-a-thon), contributions to a hospital to assist in the support of indigent patients or the development of a new technology to aid patients, support for a community service project, and donations to patient support groups. Charitable grants to medical or other healthcare professional associations, societies or trade groups, disease-based research, education or patient advocacy groups or comparable entities are generally permitted.

The following requirements apply to any charitable grant that K-C may consider funding:

- The dominant purpose of an event or recipient organization must be to raise money for a charity or charitable purpose.
- Any benefit to K-C (for example, a booth at an event) must be minimal and incidental to the main purpose of the donation.
- Any fundraising activity should be broadly publicized and the recipient organization should solicit donations from a wide variety of organizations.

D. **Company-Initiated Grants.** On occasion, K-C may initiate a grant. Company-initiated grants should be given only to foundations and charitable entities or bona-fide, third-party educational events in areas of interest to K-C. It is not appropriate to initiate a grant to a healthcare professional or customer of K-C.

II. **Grant Approval Process.**

A. **Fraud and Abuse Requirements.**

A grant must never be tied in any way to the past, present or future purchase, prescription or recommendation of any K-C product. K-C should never imply, nor permit any grant recipients to infer, that the purpose of a grant is to motivate increased use of our products or as an appreciation for product use.
1. In determining whether to make any grant, K-C will not consider:
   - whether or how much the recipient or any related party purchases or recommends K-C products;
   - whether the grant may reward the recipient, any event attendees, or any other person for the purchase or recommending of our products;
   - whether the grant may induce the recipient, any event attendees, or any other person to purchase or recommend our products; or
   - whether the grant will assist in sales and/or marketing efforts for our products.

2. K-C must not approve grants to:
   - A state or federal elected official or employee, contractor or agency.
   - A health insurance company.
   - To pay a customer’s business or internal operating expenses that are personal in nature and have no benefit to patient care (for example, grants to renovate a patient waiting room or for a physician’s office staff holiday party).

Although sales and marketing personnel may provide customers and contacts with K-C-approved brochures and/or written application instructions for submission of grant requests, sales and marketing personnel may not sponsor or support a grant request before the Grants Committee, make a presentation in support of the grant, or otherwise be involved in the application or decision process. Evidence of influence or commitment of funding by field personnel will generally result in denial of the grant.

**B. The Approval Process.**

All grants must be approved by all or part of the Grants Committee. The Grants Committee is comprised of representatives from the following departments: Global Clinical Affairs, Legal, Regulatory, and a business representative. The Grants Committee will meet as necessary to discuss and vote on all grant requests received and any additional grant-related issues. It is imperative that all grant requests be made as early as possible to enable the Grants Committee time to fully consider them.

1. The grant approval process begins with the receipt of a request for a grant from a third-party, or, for company-initiated grants, from within the company. A request for a grant must be made in writing and be made by, or on behalf of, the potential recipient (if K-C receives an oral request, ask the requester to also submit a written request). The request letter must clearly explain the request for funds, the amount requested, and/or the activity that the organization wants K-C to support. The request should also clarify if the potential grant recipient is a tax-exempt entity. When a request is received by any K-C employee, the request should be immediately referred to the Grants Committee. If additional information is needed about the potential recipient, the Grants Committee will request it.

2. The application process requires that the requesting party certify that it does not take grants into account when making decisions about which products it will purchase, recommend, or put on its formulary, as applicable.
3. Once the Grants Committee has all of the information it requires in order to make a decision about the grant, the approval review process begins. During the approval review process, the Grants Committee should seek input and recommendations from other functional areas as appropriate. When reviewing a request for a research grant, the Grants Committee must consult with the clinical team to review the scientific merits of the research.

4. The review process consists of the “Partial Committee Review” and the “Full Committee Review” processes.

   (a) **The Partial Committee Review Process.** If the request is valued at $5,000.00 or less, any two members of the Grants Committee must review the grant request. If both members agree that the grant should be funded, then the grant may be funded without further review. If only one member believes the grant should be funded, the Full Committee Review process is triggered. If neither of the members believes the grant should be funded, the request is declined and the review process is concluded.

   (b) **The Full Committee Review Process.** If the request is for a value over $5,000.00, the entire Grants Committee must review the grant request. If three of the four members agree that the grant should be funded, then the grant may be funded without further review. If less than three members believe the grant should be funded, then the request is declined and the review process is concluded.

5. If the grant is approved, the recipient must provide K-C with a detailed letter of commitment (if the grant recipient has a form grant agreement, it will be reviewed by the Grants Committee) outlining the amount K-C is donating, the purpose of the grant (with a commitment by the recipient to use the funds for that purpose), and any obligations of the recipient to provide K-C with updates or information about the progress of the sponsored event or activity. Once the letter is provided and any follow-up questions are addressed, a grant check should be processed in a manner as indicated by the instructions on the request letter or accompanying information.

6. If the grant is declined, the Grants Committee must send the requesting party a denial letter.

7. The Grants Committee must designate the budget against which the grant should be logged. If the grant originated within a certain department, then that department’s budget will cover the grant. If the grant request did not originate within a particular department, the Grants Committee should make a reasonable determination as to the appropriate budget.

8. Decisions about grants are to be kept confidential. K-C employees should not disclose whether and to whom grants have been awarded.

9. For more information about K-C’s guidelines for grants, please see the attached document.