

**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.

Further, these guidelines have been updated to remain consistent with the AdvaMed Code of Ethics. Our revised guidelines, just like the revised AdvaMed Code, contain a greater focus on the concepts of transparency and concern for the appearance of impropriety. This has led to stricter rules about gifts to such professionals, which have been severely limited, and the elimination of entertainment for healthcare professionals.

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 globally, unless specifically instructed otherwise by the Legal Department because we must also 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 trained on the safe and effective use of our products and educated about patient benefits and related disease-states. Activities that train and educate healthcare professionals about our products and their proper use may include speaker programs, healthcare symposia, and “web-inars.” 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 training and education program is to train and educate physicians about our products, patient benefits and related disease-states. 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 training and education. 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 training and educational 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 of 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.

### **Meals and Entertainment**

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. To ensure the appropriate focus on an educational and/or informational exchange of ideas and to avoid the appearance of impropriety, K-C may not provide or pay for the entertainment of any healthcare professional. Entertainment includes such activities as attending sporting events or the theater, playing golf or hunting. This prohibition on entertainment applies regardless of the cost or value of the activity.

## 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. Prizes provided to the winners of a game must comply with the guidelines' rules relating to gifts at Tab E, but essentially the prizes 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. Non-educational, branded promotional items (for example, coffee mugs, pens t-shirts or notepads) are not permitted even if they are of minimal value.

## **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 Meals and Refreshments**

K-C may provide funding to the third-party event sponsor to support the event's meals and refreshments. 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. If K-C invites fewer than all attendees, any meals provided must comply with the rules relating to meals at Tab D.
- K-C's event should be subordinate to the conference in time and focus and clearly separate from the continuing medical education portion of the program. 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 meals and refreshments. 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 meals or refreshments 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.
- Spouses and other guests of healthcare professionals should not be invited to the hospitality event.
- K-C may not provide or pay for any entertainment.
- If the third-party sponsor of the conference has additional or conflicting rules regarding hospitality provided during the conference, those rules must be observed.

## Tab C

### 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 provide a meal to a healthcare professional as long as the meal complies with these guidelines. The meal should be incidental to the bona fide presentation of scientific, educational or business information and provided in a manner conducive to the presentation of such information. Meals should typically occur at a health care professional's place of business such as an office or hospital, but meals may occur elsewhere such as at modest restaurants if the healthcare professional's place of business is not conducive to, or appropriate for, discussions for such reasons as space, timing, confidentiality, or it is impractical to have the meal at the place of business. The meal should not be part of an entertainment or recreational event. 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 provide a meal in a healthcare professional's place of business or take a healthcare professional out for a meal, the following guidelines must be observed:

- Meals can be provided only occasionally meaning, once per quarter per physician. Diligently track how often you provide a meal to a particular healthcare professional and be prepared to provide this documentation to your team leader.
- Meals can be provided only to healthcare professionals that actually attend the meeting. For example, meals cannot be provided to an entire office staff where everyone does not attend the meeting.
- Merely dropping off food without conducting a product-related presentation (sometimes called "dine and dash") is not allowed.
- The meal must be "modest" in relation to local standards. In any event, 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).
- 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.

- 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.
- The restaurant chosen must be conducive to discussions. Loud, flashy restaurants with bands or entertainment would not be appropriate.
- 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.

### **Reimbursement Guidelines**

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

## Tab E

### Gifts

#### 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 two categories of appropriate gifts.

Category 1 – gifts valued under \$100 that benefit patients or serve a genuine educational function for health care professionals. This would include, for example, educational posters and graphs for a patient examination room.

Category 2 – medical textbooks and anatomical models. 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:

- Gifts, regardless of category, can be given only occasionally, meaning once every quarter per healthcare professional. Diligently track how often you give a gift, including which category of gift, to a particular health care professional and be prepared to provide this documentation to your team leader.
- All gifts must benefit the recipient's patients or be related to the recipient's practice. Gifts that are capable of use by the healthcare professional for non-educational or non-patient-related purposes are never appropriate (for example, DVD players or I-Pods).
- Non-educational, branded promotional items such as, coffee mugs, pens and pads are not permitted even if the item is of minimal value, related to the healthcare professional's work or may benefit patients.
- 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, gift baskets, wine, flowers and candy.
- Gifts to government employees are never appropriate.
- 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.

## Tab F

### Coverage and Reimbursement Assistance

#### Introduction

K-C supports the accurate and responsible billing for our products by providing timely, accurate and objective coverage, reimbursement and health economic information to healthcare professionals, professional organizations, patient organizations, and payors. K-C also supports collaboration with healthcare professionals, organizations and patients to achieve payor coverage decisions, guidelines, policies, and adequate reimbursement levels to allow greater access to our products. However, there is a limit to the types of coverage and 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.

#### Guidelines for Coverage and Reimbursement Assistance

As a general rule, K-C personnel should only provide factual information (e.g., HCPCS Code) and K-C approved marketing collateral. However, K-C personnel may provide truthful, objective and balanced information learned and obtained through K-C's 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](http://www.cms.gov).

As further described in K-C's training, permissible activities involving providing coverage, reimbursement and health economic assistance include:

- Identifying the clinical value of our products and services and procedures in which they are used
- Collaborating with healthcare professionals, professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement and health economic issues
- Promoting accurate Medicare and other payor claims by providing accurate and objective information and materials to healthcare professionals regarding K-C's products, including identifying applicable coverage, codes and billing options
- Providing accurate and objective information about the economically efficient use of K-C's products, including where and how they can be used within the continuum of care
- Providing information on reimbursement revenues and associated costs
- Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use of K-C's products.
- Facilitating patient access to K-C's products by providing healthcare professionals with assistance in obtaining patient coverage decisions 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.

- Remind the customer to confirm any information with the payor, as payor policies are subject to change.

It is never appropriate for a K-C employee to interfere with a healthcare professional's independent clinical decision-making or provide coverage, reimbursement or health economic support in exchange for receiving the healthcare professional's business.

## Tab G

### Healthcare Professional Consultants

#### 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 make certain healthcare professionals especially knowledgeable, credible and effective 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 of it, when entering into consulting arrangements with healthcare professionals. 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 the 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 to meet the defined need. 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. Consultancies that relate to disease state, potential clinical trials or research, or other medical or technical-related functions include those involving KOL's (Key

Opinion Leaders), Advisory Board members, Speaker Board members and Investigators. Each of these categories is described below:

KOL: A recognized expert in a specific field of medicine as demonstrated by academic appointment, publications in the field, editorial and congress board participation and experience in presentations on related topics.

Advisory Board: A group of recognized experts in a specific field of medicine who are gathered at a single time or at recurrent intervals to provide guidance to K-C are on product development (R & E Advisory Board) or clinical practice (Medical Advisory Board) or both. Typically, an Advisory Board is comprised of around 4 to 8 individuals at any one meeting.

Speaker Board: A group of healthcare providers who are good public speakers and users of K-C products who are invited to speak on our behalf to other healthcare providers at informal meetings. A standard slide deck is developed with the assistance of the speaker board members, and all members are trained by K-C on specific product features, benefits and clinical data to support use. The slide deck must go through the yellow folder process for claim substantiation.

Investigator: A person who performs a study, including a clinical trial, involving K-C products. An investigator might initiate the idea for a study and seek funding from K-C to conduct it, or K-C could initiate the idea and fund it. If the investigator initiates the study, it is called simply an Investigator Initiated Study.

Any K-C employee, including employees in the Sales & Marketing department, may suggest that K-C hire a KOL, an Advisory Board member, a Speaker Board member or an Investigator, but before K-C actually engages the consultant, the Director of Global Clinical Affairs, Healthcare's Medical Director or one of their direct reports must first approve engaging that consultant. If a K-C employee suggests that K-C hire a specific consultant, he or she should keep in mind the anti-kickback laws and not base the suggestion on the volume of purchases made or likely to be made by the potential consultant. Past experience with, usage of or familiarity with a product is an appropriate qualification for a potential consultant, but the suggestion of an expert cannot be to reward past usage of the product.

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.

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 consulting agreement must 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.

If the consultant is expected to make or has made a significant or innovative contribution to the development of a K-C product or process, K-C may arrange for the payment of royalties to the healthcare professional. The Legal Department should be consulted before a decision is made to make royalties payments.

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 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 royalty payments or provide examples of past compensation amounts. Compensation, including payment of any royalty fees, 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 Consulting 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 consulting agreement for this purpose, which must be reviewed and approved by the Legal Department. The consulting 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 consulting agreements signed. This file will be used to confirm that all consulting agreements comply with applicable law and K-C policies and to avoid duplicate service and duplicate payment arrangements.

## **Consultant/Advisory Board 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? Each of 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.
- 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?

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 refreshments 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 meals or refreshments should be subordinate in time and focus to the consultant meeting. As in other contexts, K-C may not provide or pay for the entertainment of any healthcare professional. Any gift given in connection with a consultant meeting must comply with the provisions of Tab E.

## Tab H

### Grants

#### 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. K-C may not make educational grants to individual healthcare professionals.

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 bona fide charitable organization, or in certain circumstances, to an individual engaged in genuine charitable activities, certain governmental entities, such as a public university, as well as medical societies and civic organizations with a bona-fide charitable mission. K-C should exercise diligence to ensure the bona fide nature of the charitable organization or charitable mission. 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 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.

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 or marketing efforts for our products.

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 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 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 K-C

employee or appropriate designee must complete an Application for Grant Funding, which is available from the Legal department, and submit the completed application to the Legal Department for consideration by the Grants Committee. If additional information is needed about the potential recipient, the Grants Committee will request it.

2. 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 will 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.

3. 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.

4. 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.

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

6. 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.

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

## Tab I

### Evaluation and Demonstration of Products

#### Introduction

K-C recognizes that providing our products to healthcare professionals at no charge for evaluation or demonstration purposes offers many benefits, including improving patient care by facilitating the safe and effective use of our products.

#### Guidelines for Evaluation and Demonstration of Products

K-C employees may provide reasonable quantities of single use and multiple use products at no charge to healthcare professionals for the purpose of evaluation or demonstration.

**Evaluation.** Products provided for evaluation are typically expected to be used in patient care.

- *Single Use Products.* The number of single use products provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation of the products.
- *Multiple Use Products.* Multiple use products provided without transfer of title for evaluation purposes should be furnished only for a period of time that is reasonable to allow an adequate evaluation. The terms of an evaluation for multiple use products should be documented in writing.

**Demonstration.** Demonstration products are typically unsterilized single use products or mock-ups of such products that are used for training and education. For example, a healthcare professional may use a demonstration product to show a patient the type of device that will be used during an operation. Demonstration products typically are not intended to be used in patient care. Demonstration products should always be identified as not intended for patient use with such designations as “Sample,” “Not for Human Use,” or other suitable designation on the product, product packaging, or accompanying documentation.

**Documentation.** K-C employees should work with the Legal Department to develop appropriate documentation regarding the terms of the evaluation or demonstration prior to providing healthcare professionals with products intended for such purposes.