



Operating Procedures for Program Funding

January 1, 2013

Meals, Educational Items and Charitable Donations

Professional Services

Educational Activities

General Program Support

Glossary

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Note: Government Customers frequently have policies and procedures that are stricter than those found in the OPPF.

Introduction

As part of your interactions with [Healthcare Professionals \(HCP\)/Customers](#), you may provide modest occasional meals and [Educational Items](#), as well as charitable donations, as allowed in these procedures.

Note: As you read this section, a word in purple text indicates that its definition is included in the Glossary section.

General Requirements

1. No [Quid Pro Quo](#). Funding may not be offered or given with the intent to induce, or in exchange for, an explicit or implicit agreement or understanding that Abbott products will be used, purchased, leased, ordered, prescribed, recommended, or arranged for or provided formulary or other preferential or qualifying status.
2. When interacting with [HCP/Customers](#), Abbott employees must determine whether the [HCP/Customers'](#) employer has a policy or procedure governing interactions with industry. Where such policies or procedures are stricter than the Operating Procedures for Program Funding, Abbott employees must comply with the stricter standard. **[Government Customers](#) frequently have policies and procedures that are stricter than those found in the OPPF.**
3. Entertainment and recreation are not allowed.
4. All meals (including [On-Site](#) and [Off-Site Meals](#) and [Snacks](#)), [Educational Items](#) and charitable donations must be submitted for reimbursement.
5. An employee **must not** personally pay for or allow an [HCP/Customer](#) to pay for an activity prohibited under these procedures.
6. Meals, [Snacks](#), and food at display/exhibit provided by Abbott must always be in conjunction with an informational or business discussion that provides scientific or educational value and only to [HCP/Customers](#) in attendance who have a legitimate interest in the discussion. All meals must be held in a business appropriate venue.
7. Meals must be modest as judged by local standards and provided on only an occasional basis (for example, no more than once per month per [HCP/Customer](#)) as a business courtesy.
8. Only [Educational Items](#) designed primarily to advance [Disease State](#) or [Treatment](#) education of patients/consumers or [HCP/Customers](#) may be offered and provided on only an occasional basis even if each [Educational Item](#) is appropriate.
9. No [Educational Items](#) are permitted if intended for the personal benefit of the [HCP/Customer](#).
10. Meals, [Snacks](#), food at displays/exhibits, [Educational Items](#) and receptions are not permitted for guests, spouses or family members of [HCP/Customers](#).
11. No cash, gift certificates or other cash equivalents are allowed, other than reasonable [Fee For Service](#) for [Professional Services](#).
12. [Educational Items](#) cannot be given to [Government Customers](#).
13. Any exceptions to these requirements must be approved by the [Ethics and Compliance Officer \(ECO\)](#) or delegate and in accordance with exception procedure B2-10-002.

Note: Any violation of the Operating Procedures or falsification of records submitted in connection with the procedures may result in disciplinary action up to and including termination.

Meal Category	Conditions	Required Forms
Off-Site Meals	<ol style="list-style-type: none"> 1. \$125 limit per HCP/Customer, including food, beverages, tax and gratuity. <ul style="list-style-type: none"> - Within the city limits of New York City, San Francisco and Las Vegas only, the limit per HCP/Customer, including food, beverages, tax and gratuity, is \$150. 2. Limit does not include room or audiovisual costs. 3. Unless in conjunction with a Speaker Program or an approved customer Product Training Program, no more than 5 HCP/Customers may attend per Abbott employee. 4. Meals in conjunction with a Speaker Program or approved Product Training Program must allow for significant interaction for a meaningful amount of time. 	<p>If expense report, then:</p> <ul style="list-style-type: none"> • Itemized receipt • List of attendees <p>If check request, then: Administrative Check Request (ACR) or Purchase Order (PO)</p> <ul style="list-style-type: none"> • Invoice • List of attendees • W-9 Form
On-Site Meals (e.g., In-Service, Lunch 'N' Learn)	<ol style="list-style-type: none"> 1. \$25 limit per HCP/Customer, including food, beverages, tax and gratuity. 2. Limit does not include delivery cost. 3. No limit on the number of HCP/Customers who attend. 4. No dropping off or arranging for pickup of food for later consumption. 	
Snacks at Office	<ol style="list-style-type: none"> 1. \$25 total value per office, including tax. 2. No dropping off or arranging for pickup of Snacks for later consumption. 	<p>If expense report, then:</p> <ul style="list-style-type: none"> • Itemized receipt • Provide a list of Snack recipients <p>If check request, then:</p> <ul style="list-style-type: none"> • ACR or PO • Provide a list of Snack recipients • Invoice • W-9 Form

Meal Category	Conditions	Required Forms
Food at Display/Exhibit	<ol style="list-style-type: none"> 1. \$10 per HCP/Customer. 2. Dollar amount based on estimated attendees at event or per serving cost. 3. Limit does not include vendor fees or equipment costs. 	<p>If expense report, then:</p> <ul style="list-style-type: none"> • Itemized receipt <p>If check request, then:</p> <ul style="list-style-type: none"> • ACR or PO • Invoice • W-9 Form
Receptions	<ol style="list-style-type: none"> 1. Abbott may sponsor a modest reception only at a Group Consulting Program or third-party educational or professional meeting if the following exists: <ul style="list-style-type: none"> - Commercial sponsorship is allowed by the independent third party holding the meeting or by the standards or guidelines of any applicable accrediting body - Any CME activities comprise only a part of the education or professional meeting - Reception is clearly separate from any CME portions of the meeting - Reception is clearly subordinate to the amount of time spent at other aspects of the meeting. 2. \$50 per HCP/Customer for food, beverages, tax and gratuity. 3. Dollar amount based on estimated attendees at event or per serving cost. 4. Limit does not include vendor fees, equipment costs, room rental and/or any audiovisual costs. 5. No limit on the number of HCP/Customers who may attend. 	<p>If expense report, then:</p> <ul style="list-style-type: none"> • Itemized receipt • List of attendees <p>If check request, then:</p> <ul style="list-style-type: none"> • ACR or PO • Invoice • W-9 Form • List of attendees

Meal Category	Conditions	Required Forms
Patient/ Consumer Meals	<ol style="list-style-type: none"> 1. \$10 per Patient/Consumer. 2. Dollar amount based on estimated attendees at event or per serving cost. 3. Limit does not include vendor fees or equipment costs. 	<p>If expense report, then:</p> <ul style="list-style-type: none"> • Itemized receipt <p>If check request, then:</p> <ul style="list-style-type: none"> • <u>ACR</u> or PO • Invoice • W-9 Form

Educational Items

Educational Items must be designed primarily to advance Disease State or Treatment education of patients/consumers or HCP/Customers.

Allowed Educational Items	Conditions	Examples	Required Forms
Educational Items Given to HCP/ Customers	<ol style="list-style-type: none"> \$100 limit, excluding tax and shipping. <ul style="list-style-type: none"> For anatomical models and medical textbooks only, the limit is \$250, excluding tax and shipping Items must have no value to <u>HCP/Customer</u> outside of his or her professional responsibilities. Any Abbott-generated or Abbott-branded items must be reviewed and approved in accordance with divisional approval processes. 	Anatomical heart model, medical textbook, medical journal subscription	<p>If expense report, then:</p> <ul style="list-style-type: none"> Name of recipient Itemized receipt <p>If check request, then:</p> <ul style="list-style-type: none"> Name of recipient <u>ACR</u> or PO Invoice W-9 Form
Educational Items Given to Patients/ Consumers	<ol style="list-style-type: none"> \$10 limit per patient per item, excluding tax and shipping. \$100 combined value per <u>HCP/Customer</u> if provided to <u>HCP/Customer</u> to give to patients. Any Abbott-generated or Abbott-branded items must be reviewed and approved in accordance with divisional approval processes. 	Informational sheets and brochures, patient self-assessment and tracking tools, written materials that inform patients about adherence to medicine regimens, healthy lifestyle materials, patient assistance program information	
Office/ Work-Related Items (including “Reminder” Items)	<p>PROHIBITED:</p> <ol style="list-style-type: none"> Even at third-party educational or professional meetings Even if accompanied by <u>Educational Items</u> 	Pens, notepads, magnets, calendars, mugs or “Reminder Items” with company or product logos	

Consumer Items

Allowed Consumer Items	Conditions	Examples	Required Forms
Consumer Items	1. Allowed per divisional procedure or ECO approval.	Diaper bags, cookbooks	Contact ECO or delegate for approval

Charitable Donations Additional Requirements

Follow these additional **requirements** when considering charitable donations for [Non-Profit Organizations](#) and [Non-Profit Providers](#). Request for charitable donations must be submitted in accordance with divisional procedure/guidance, including, as applicable, the use of an online system or centralized donations group.

1. Charitable donations must be paid by check payable to the organization and not payable in the [HCP's/Customer's](#) name.
2. Charitable donations cannot be used to support capital projects (e.g., building a wing for a hospital).
3. Charitable donations cannot be used to support lobbying efforts. Contact Abbott Government Affairs for information regarding appropriate lobbying process and approval.
4. Donated Abbott Products must follow Policy B2-03, "Providing No-Charge Products to Customers," and applicable division policies and operating procedures.
5. Sales and marketing personnel may provide input about the suitability of a Charitable Donation recipient or program, but may not control or unduly influence the decision of who should receive the amount.
6. Charitable Donations may not be given to For-Profit Providers.
7. Sales and marketing personnel and their management may not directly disburse the funds to the third-party recipient of the funded charitable donation.
8. All documentation must be completed prior to a program taking place.

Charitable Donations to Non-Profit Organizations

Allowed Donations	Conditions	Examples	Required Forms
Charity Events	1. Must not pay for or invite HCP/Customers to attend.	Golf fundraisers, galas, marathons, entertainment	<ul style="list-style-type: none"> • ACR or PO • Charitable Donation Form • Request letter for funding and/or program flyer/customer flyer • Current W-9 Form (note: may be maintained elsewhere, e.g., financial system)
Awards	<ol style="list-style-type: none"> 1. Abbott cannot control the selection of the award recipient. 2. Selection of the award recipient must not be based on the use or recommendation of Abbott Products. 3. An Abbott employee must not be on the Non-Profit Organization's board that is responsible for selecting the recipient. 	Humanitarian awards	
Attendance at Patient Educational Events	1. Must not include attendance costs for HCP/Customers .	Patient Disease State or Treatment education event	
Business Expense or General Office Support	1. Allowed unless provided as part of a clinical study and outlined in the clinical research budget.	Business equipment, open house, advertising of the Non-Profit Organization	
Other Purposes	1. Requires written pre-approval by ECO or delegate or in accordance with divisional process.	Programs supporting Non-Profit Mission	

Charitable Donations to Non-Profit Organizations (cont.)

For example [Non-Profit](#) hospitals or clinics or foundations affiliated with [HCP/Customers](#).

Allowed Donations	Conditions	Required Forms
Donations Supporting Only the Non-Profit Mission	<ol style="list-style-type: none">1. Programs must support:<ul style="list-style-type: none">– Low-income families.– Indigent homeless families.– Underserved or uninsured.2. Requires written pre-approval by ECO or delegate or in accordance with divisional process.	<ul style="list-style-type: none">• ACR or PO• Charitable Donation Form• Request letter for funding and/or program flyer/customer flyer• Current W-9 Form (note: may be maintained elsewhere, e.g., financial system)

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Note: Government Customers frequently have policies and procedures that are stricter than those found in the OPPF.

Introduction

Abbott may obtain services from a [HCP/Customer](#), including individuals, to meet the company's legitimate need for information, services and advice.

Note: As you read this section, a word in purple text indicates that it is defined in the Glossary section.

General Requirements

When hiring individuals for [Professional Services](#), the following requirements apply:

1. No [Quid Pro Quo](#). Funding may not be offered or given with the intent to induce, or in exchange for, an explicit or implicit agreement or understanding that Abbott products will be used, purchased, leased, ordered, prescribed, recommended, or arranged for or provided formulary or other preferential or qualifying status.
2. When interacting with [HCP/Customers](#), Abbott employees must determine whether the [HCP/Customer's](#) employer has a policy or procedure governing interactions with industry. Where such policies or procedures are stricter than the Operating Procedures for Program Funding, Abbott employees must comply with the stricter standard. **[Government Customers](#) frequently have policies and procedures that are stricter than those found in the OPPF.**
3. The legitimate need for [Professional Services](#) must be clearly identified in advance of requesting the services and entering into any agreement with the prospective [Consultants](#) or [Speakers](#).
4. All arrangements for [Professional Services](#) must be reflected in one of the standard agreements on the Office of Ethics and Compliance (OEC) website or some other agreement approved by Legal.
 - The agreement must specify the nature of the [Professional Services](#) to be provided and the basis for payment of those services.
 - The agreement must include a provision requiring [Consultants](#) and [Speakers](#) to disclose the existence and nature of their relationship with Abbott to any formulary or clinical guideline committee of which they are members in advance of their participation in those formulary or clinical guideline committee meetings, and to follow the formulary or clinical guideline committee's policies and procedures, including, for example, an obligation to recuse themselves from decisions related to the Abbott Products for which they provided [Professional Services](#), for at least two years beyond the termination or expiration of their agreement with Abbott.
 - Any changes made to the standard agreement or some other agreement approved by Legal (including use of a third party's form) must be pre-approved by Legal.
 - The agreement must be signed by all parties before [Professional Services](#) are provided.
 - Signature grade level on agreements must be based on the total fee under that [Consultant's](#) or [Speaker's](#) agreement and must be approved in accordance with Corporate Financial Manual 0060, "Commitment and Expenditure of Funds – Approval Levels," and applicable division policies and/or operating procedures.
5. Individual(s) must be chosen based on defined criteria directly related to the identified [Professional Services](#), such as general medical expertise and reputation, knowledge and experience regarding a particular therapeutic area, and communication skills.
6. The number of [HCP/Customers](#) retained must be limited to the number reasonably required to obtain the information, services or advice needed.
7. All [HCP/Customers](#) must be qualified to perform the services and must be selected by an individual who has the necessary expertise to determine that the [HCP/Customer](#) meets the defined criteria to qualify to perform the services.
8. Sales personnel and their management cannot hire [HCP/Customers](#) as Consultants (e.g. Advisors [Product Trainers](#), Speakers and Internal Speakers). Sales personnel and their management may provide input into the suitability of a proposed consultant, but may not control or unduly influence the decision of whether to engage a particular [HCP/Customer](#) as a consultant.
9. Sales and marketing personnel and their management may not directly disburse the Fee-For-Service payment to the Consultant (e.g. Advisors, [Product Trainers](#), Speakers and Internal Speakers).

Professional Services (cont.)

10. The venue and circumstances of any meeting with Consultants (e.g., Advisors, [Product Trainers](#), Speakers and Internal Speakers) must be conducive to the intended [Professional Services](#) and the activities related to the [Professional Services](#) must be the primary focus of the meeting. Venues such as resorts, 5-star hotels, and any location that has entertainment or recreation as the primary focus are not appropriate.
11. Abbott must maintain records of, and make appropriate use of, [Professional Services](#) provided.
12. Payments may be made for [Professional Services](#) provided and actual out-of-pocket expenses incurred, such as travel (coach class, if by air), food and lodging, directly in conjunction with providing those Professional Services, but not for guests, spouses or family members of [Consultants](#) or [Speakers](#).
 - Value of [Fee For Services](#) must be reasonable, based on [Fair Market Value](#) and be provided in accordance with any applicable divisional limits.
 - For Agreements executed on or after January 1, 2011, a determination that proposed compensation is consistent with Fair Market Value must be made using the Fair Market Value Assessment Tool (“FMV Tool”) available on the OEC website at <http://oec.abbott.com/OEC/fmvtool.html> except to the extent noted under Market Research. The FMV Tool provides a standardized approach for determining the fair market value of services based on the HCP/Customer Consultant’s specialty/area of expertise, qualifications, and experience. If the proposed compensation exceeds the maximum compensation calculated by the FMV Tool due to the HCP’s unique qualifications, or if the HCP/Customer’s specialty is not listed in the FMV Tool, the FMV Process Exception Form must be completed. The FMV Process Exception Form is available on the OEC website at <http://oec.abbott.com/OEC/fmvtool.html>.
 - [Third-Party Expense Reimbursement](#) associated with travel outside the U.S. must follow International Procedures.
13. Payments to U.S. [HCP/Customers](#) must **ONLY** be made by check or wire transfer through the accounts payable department in the U.S. or Puerto Rico. No payment may be made in exchange for [HCP/Customer](#) participation in, or attendance at, a promotional presentation/meeting about Abbott products, including a promotional detailing session.
14. Entertainment and recreation are not allowed.
15. An employee **cannot** personally pay for or allow an [HCP/Customer](#) to pay for an activity prohibited under these procedures.
16. Any exceptions to these requirements must be approved by the [Ethics and Compliance Officer \(ECO\)](#) or delegate and in accordance with exception procedure B2-10-002.
17. Any arrangement with an [HCP/Customer](#) that may result in a royalty payment to the [HCP/Customer](#) must be pre-approved by Legal.
18. All documentation must be completed prior to a program taking place.

Note: Any violation of the Operating Procedures or falsification of records submitted in connection with the procedures may result in disciplinary action up to and including termination.

Speaker Programs and Product Training Programs

Allowed Activity	Conditions	Required Forms
<p>Speaker Programs/ Product Trainer Programs</p>	<ol style="list-style-type: none"> 1. <u>Speaker Program</u> requirements: <ul style="list-style-type: none"> – All <u>HCP/Customers</u> that speak on behalf of Abbott must be trained in compliance with the “Speaker/Product Trainer Training” section. – All Speakers and their presentations and materials used for <u>Speaker Programs</u> must be within <u>Labeling</u>, meet divisional review/approval requirements and clearly identify that Abbott is the program sponsor, that the Speaker is presenting on behalf of Abbott and that the content is in compliance with any applicable FDA requirements. 2. Value of <u>Fee For Service</u> must be reasonable and based on <u>Fair Market Value</u>. 3. Incidental expenses may be provided for room/facility rental, rental of tables and chairs, audiovisual equipment rental, etc. 4. For meals, see “Meals, Educational Items and Charitable Donations.” 5. When an Abbott employee is acting as an <u>Approved Speaker</u>, see divisional procedures. 	<ul style="list-style-type: none"> • <u>Administrative Check Request (ACR)</u> or Purchase Order (PO). • List of attendees • Professional Services Request Form (PSRF) or other mechanism (e.g., on-line system) approved by Divisional OEC that captures-materially similar information as required in the PSRF • FMV Tool Worksheet (and FMV Process Exception Form, if required) • Applicable Professional Services agreement (e.g., <u>Speaker Agreement</u>) or other • Agreement approved by Legal • W-9 Form • Invoice or other documentation detailing services provided

Speaker Programs and Product Training Programs

Allowed Activity	Conditions	Required Forms
<p>Product Training Programs</p>	<ol style="list-style-type: none"> 1. Product Training Programs that include presentations regarding Abbott products or related Disease States must comply with the following requirements: <ul style="list-style-type: none"> – All HCP/Customers who speak on behalf of Abbott must be trained in compliance with the OPPF “Speaker/Product Trainer Training” section. – All presentations and materials used for Product Training Programs must be within Labeling, meet divisional review/approval requirements and clearly identify that Abbott is the program sponsor, that the Product Trainer is presenting on behalf of Abbott and that the content is in compliance with any applicable FDA requirements. 2. Value of Fee For Service must be reasonable and based on Fair Market Value. 3. Incidental expenses may be provided for room/facility rental, rental of tables and chairs, audiovisual equipment rental, etc. 4. For meals, see OPPF “Meals, Educational Items and Charitable Donations” requirements. 5. If permitted by divisional procedures or guidelines, sales representatives can attend Product Training Programs, including an accompanying meal, for purposes of assisting the Product Trainer with logistics or for their own training and professional development. 6. Sales activities are not allowed at the Product Training Programs. 	<ul style="list-style-type: none"> • ACR • List of attendees • Professional Services Request Form (PSRF) or other mechanism (e.g., on-line system) approved by Divisional OEC that captures-materially similar information as required in the PSRF • FMV Tool Worksheet (and FMV Process Exception Form, if required) • Product Training Services Agreement or other agreement approved by Legal • W-9 Form • Invoice or other documentation detailing services provided.

Speaker Programs and Product Training Programs (cont.)

Allowed Activity	Conditions	Required Forms
Speaker / Product Trainer Training	<p>Training Speakers or Product Trainers:</p> <ol style="list-style-type: none"> All HCP/Customers that speak on behalf of Abbott must be trained, and Abbott must maintain training records and records of services. HCP/Customers may be offered reasonable Fee For Service based on Fair Market Value for their time, and be offered reimbursement for actual out-of-pocket expenses, such as travel, lodging and meal expenses. At least one engagement must take place within 12 months following training, if the prospective Speaker or Product Trainer is compensated for his/her time spent on training. Training must be provided on company products or other specific topics to be presented and, as applicable, on compliance with FDA regulatory requirements. Training must be held in appropriate venues. Resorts are not appropriate venues. See “Group Consulting Program Requirements” when Speaker or Product Trainer training is provided to multiple Speakers or Product Trainers at a group training meeting. 	<ul style="list-style-type: none"> ACR or PO Approved Application for Group Consulting Program for Speaker or Product Trainer Training provided to multiple Speakers or Product Trainers at a group training meeting Professional Services Request Form (PSRF) or other mechanism (e.g., on-line system) approved by Divisional OEC that captures-materially similar information as required in the PSRF When the Speaker/Product Trainer is compensated for his/her time spent training, FMV Tool Worksheet (and FMV Process Exception Form, if required) Applicable Professional Services agreement (e.g., Speaker Agreement) for each Speaker or Product Trainer, other agreement approved by Legal W-9 Form Invoice or other documentation detailing the services provided, if the HCP/Customer is compensated for the time spent training

Individual Consultants

Individuals may be hired to provide the following services for Abbott:

Type of Professional	Types of Services	Conditions	Required Forms
Consultant /Advisor	<ol style="list-style-type: none"> Provides information, services or advice for a topic/subject as requested by Abbott (includes, for example, Speakers, Product Trainers, Advisors, etc.). Includes investigators/researchers acting as Consultants/Advisors for services not otherwise provided under a Clinical Research Agreement. 	<ol style="list-style-type: none"> The value of the Fee For Service must be reasonable and based on Fair Market Value. 	<ul style="list-style-type: none"> ACR or PO Professional Services Request Form (PSRF) or other mechanism (e.g., on-line system) approved by Divisional OEC that captures-materially similar information as required in the PSRF FMV Tool Worksheet (and FMV Process Exception Form, if required) Professional Services Agreement, or other agreement approved by Legal W-9 Form Invoice or other documentation detailing the services provided.
Internal Speaker	<ol style="list-style-type: none"> Provides education for Abbott employees at sales training or other employee meetings. 	<ol style="list-style-type: none"> The value of the Fee For Service must be reasonable and based on Fair Market Value. 	<ul style="list-style-type: none"> ACR or PO Professional Services Request Form (PSRF) or other mechanism (e.g., on-line system) approved by Divisional OEC that captures-materially similar information as required in the PSRF FMV Tool Worksheet (and FMV Process Exception Form, if required) Speaker Agreement, if only speaking, or Professional Services Agreement, if speaking plus other activities, or other agreement approved by Legal W-9 Form Invoice or other documentation detailing the services provided.

Group Consulting Program Requirements

Follow the [Professional Services](#) general requirements and these requirements when arranging all [Group Consulting Programs](#):

1. The scope and structure of the [Group Consulting Program](#) should be designed to facilitate and encourage active participation and feedback to Abbott during the program. [Group Consulting Programs](#) **cannot** be developed, managed or paid for by the sales force or their management.
2. The number of individuals selected for a [Group Consulting Program](#) must be limited to that number reasonably necessary to obtain meaningful feedback.
3. Modest meals and/or receptions may be provided at an [Group Consulting Program](#), in accordance with “Meals, Educational Items and Charitable Donations” requirements.
4. Prior to extending invitations to a [Group Consulting Program](#) to an [HCP/Customer](#) must complete an Application for [Group Consulting Program](#) and submit for prior approval of the [ECO](#) or delegate.
5. Once an Application for [Group Consulting Program](#) has been approved, no change to the scope or purpose of the program, including changes to the agenda, or the professional fees associated with it, may be made without prior approval of the [ECO](#) or delegate.

Group Consulting Programs

Activity	Types of Services	Conditions	Required Forms
Group Consulting Programs, Consulting Meetings, Advisory Boards, Strategic Advisory Committees	<ol style="list-style-type: none"> 1. Programs established to meet Abbott's legitimate need for information, services and advice. 	<ol style="list-style-type: none"> 1. See "Group Consulting Program Requirements" and "Group Consulting Procedure." 2. Must be approved by ECO or delegate prior to extending invitations. 	<ul style="list-style-type: none"> • ACR or PO • Approved Application for Group Consulting Program • Professional Services Request Form for each individual Consultant • FMV Tool Worksheet (and FMV Process Exception Form, if required) • Professional Services Agreement, for each Consultant, or • Other agreement approved by Legal • W-9 Form • Invoice or other documentation detailing services provided
Investigator Meetings, Data Safety Monitoring Board/ Independent Data Monitoring and Steering Committee Meetings Relating to Clinical Research Programs	<ol style="list-style-type: none"> 1. Acting in a capacity covered under a Clinical Research Agreement or directly related to the Study/ Committee Charter. 	<ol style="list-style-type: none"> 1. No separate contract is required with the investigator covered by a Confidentiality Disclosure Agreement or a Research Agreement. 2. Meals, receptions and Educational Items for these activities must comply with "Meals, Educational Items and Charitable Donations" requirements. 3. Reimbursement of reasonable expenses (travel, lodging, meals and incidental personal expenses) incurred by a clinical investigator participating in an Abbott sponsored investigator meeting, must comply with OEC's Abbott Support of Scientific Research Policy #B2-07 and applicable division procedures. 	<ul style="list-style-type: none"> • No Application for Group Consulting Program required • Follow divisional process • Invoice or other documentation detailing the services provided

Market Research

Market research may be conducted only in accordance with applicable division policies and/or operating procedures.

Market Research Where...	Conditions	Required Forms
Abbott Is Not Identified or Identifiable	<ol style="list-style-type: none"> 1. Research is conducted by third party. 2. No patient/consumer contact. 	<ul style="list-style-type: none"> • ACR or PO • W-9 Form • Market Research Provider Agreement, between the third-party market research provider and Abbott or • Other form approved by Legal
Abbott Is Identified or Identifiable – by Abbott	<ol style="list-style-type: none"> 1. Research is conducted by Abbott. 2. Follow “Professional Services Requirements and Group Consulting Program Requirements.” 3. No patient/consumer contact. 	<ul style="list-style-type: none"> • ACR or PO • W-9 Form • Market Research Agreement between Abbott and each HCP/Customer or • Other form approved by Legal • Application for Group Consulting Program • FMV Tool Worksheet (and FMV Process Exception Form, if required)
Abbott Is Identified or Identifiable – by Third Party	<ol style="list-style-type: none"> 1. Research is conducted by third party. 2. No patient contact. 	<ul style="list-style-type: none"> • ACR or PO • W-9 Form • Market Research Provider Agreement, between the third-party market research provider and Abbott and • Market Research Participant Agreement – Third Party between the market research provider and each HCP/Customer or • Other form approved by Legal • FMV Tool Worksheet (and FMV Process Exception Form, if required) or other documented divisional FMV Processes
Patient/Customer Contact Occurred (regardless of Abbott identification)	<ol style="list-style-type: none"> 1. Patient/customer contact, or 2. Use of patient identifiable information. 	<ul style="list-style-type: none"> • Must be approved by ECO or delegate

Representative Preceptorship

Representative [Preceptorships](#) are intended to be an educational opportunity for appropriate Abbott employees with [HCP/Customers](#).

Activity	Types of Services	Conditions	Required Forms
Representative Preceptorship	<ol style="list-style-type: none"> Provides educational opportunity for appropriate Abbott employees to learn from HCP/Customers. 	<ol style="list-style-type: none"> Fee must be reasonable and based on Fair Market Value. May only be done with ECO or delegate approval or in accordance with divisional procedure. 	<ul style="list-style-type: none"> ACR W-9 Form FMV Tool Worksheet (and FMV Process Exception Form, if required) Professional Services Request Form

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Note: Government Customers frequently have policies and procedures that are stricter than those found in the OPPF.

Educational Activities

Introduction

Abbott may provide financial support to legitimate entities for bona fide [Educational Programs/Activities](#). This support may only be provided for [Educational Programs/Activities](#) that foster increased understanding of scientific, clinical or healthcare issues that contribute to the enhancement of patient care.

Requests for proposed educational grants must be submitted in accordance with divisional procedure/guidance including, as applicable, the use of an online system.

Note: As you read this section, a word in purple text indicates that it is defined in the Glossary section.

General Requirements

Follow these requirements when funding [Educational Programs/Activities](#):

1. No [Quid Pro Quo](#). Funding may not be offered or given with the intent to induce, or in exchange for, an explicit or implicit agreement or understanding that Abbott products will be used, purchased, leased, ordered, prescribed, recommended, or arranged for or provided formulary or other preferential or qualifying status.
2. When interacting with [HCP/Customers](#), Abbott employees must determine whether the [HCP/Customers'](#) employer has a policy or procedure governing interactions with industry. Where such policies or procedures are stricter than the Operating Procedures for Program Funding, Abbott employees must comply with the stricter standard. **[Government Customers](#) frequently have policies and procedures that are stricter than those found in the OPPF.**
3. Appropriate, well-defined programs may be supported.
4. Funding may be provided to help defray legitimate expenses incurred in carrying out [Educational Programs/Activities](#) (e.g., audiovisual rental, faculty fees).
5. An employee **cannot** personally pay for or allow an [HCP/Customer](#) to pay for an activity prohibited under these procedures.
6. Funding cannot directly or indirectly cover costs for travel, lodging or other expenses for non-faculty attendees, including guests, spouses or family members of faculty [HCP/Customers](#), at [Educational Programs/Activities](#), and must not be used to compensate for the non-faculty attendee's time or for any other payment to non-faculty attendees (e.g., [Fee For Service](#) or reimbursement for expenses), other than what is allowed under "Funding for HCP in Training."
7. Educational grants, including funding for educational materials, may not be provided to an individual [HCP/Customer](#).
8. Entertainment and recreation are not allowed.
9. Any exceptions to these requirements must be approved by the [Ethics and Compliance Officer \(ECO\)](#) or delegate and in accordance with exception procedure B2-10-002.
10. Consistent with divisional policy, procedure, or guidance, sales personnel and their management may provide input about the suitability of an educational grant recipient or program, but may not control or unduly influence the decision of whether a particular [HCP](#) or institution will receive the grant or the amount.
11. Sales personnel and their management may not directly disburse the funds to the third-party recipient of the funded educational activity.

Note: Any violation of the Operating Procedures or falsification of records submitted in connection with the procedures may result in disciplinary action up to and including termination.

Funding of Educational Programs for HCP/Customers (Including Patients/Consumers)

Accredited [Continuing Medical Education \(CME\)](#) programs by an independent third party, where that third party has control over the content, implementation and selection of faculty.

Allowed Activity	General Requirements	Required Forms and Approvals
<p>Accredited Continuing Medical Education (CME)</p>	<ol style="list-style-type: none"> 1. Decisions to make a grant to support an accredited CME program must be made separately from divisional sales and marketing departments and be based on predetermined objective criteria. 2. Program must be provided by an independent third party (i.e., Medical Education Provider or accrediting body). 3. Funding/grant must be provided to an independent third party and must comply with the accrediting body's standards. 4. The independent third party must maintain full responsibility for, and control over, the selection of content, faculty, educational methods, materials and venue. <ul style="list-style-type: none"> - Whether requested or not by the independent third party, Abbott must not provide any advice or guidance regarding topics, content or faculty. - If requested by the independent third party, Abbott may disseminate invitations, business reply cards, "save-the-date" cards or brochures about the event, provided that ultimate selection of audience members is controlled by the independent third party. 5. At the independent third party's discretion, grant may include funding for modest meals and receptions for all participants held in conjunction with the medical education activity. 6. No promotional activities may take place in the room where the Educational Program/Activity occurs. 7. Abbott MAY NOT: <ul style="list-style-type: none"> - Disseminate accredited materials - Arrange or provide for HCP/Customer access to the accredited presentations (e.g., CME enduring materials and webcasts), unless provided by non-commercial 	<ul style="list-style-type: none"> • ACR • Current W-9 Form (note: may be maintained elsewhere, e.g., financial system) • LOA including: <ul style="list-style-type: none"> - Description of the program - Detailed budget for use of the funds • LOA must include approvals from these parties: <ul style="list-style-type: none"> - Appropriate representative of the independent third party - Appropriate Abbott business representative - ECO or delegate • The ECO or delegate must approve any modifications to the LOA • No more than one LOA may be signed for each event

personnel in response to an unsolicited request for information in accordance with applicable divisional procedures or guidance.

- Directly provide meals or receptions at the [Educational Program/Activity](#)

Funding of Educational Programs for HCP/Customers (Including Patients/Consumers) (cont.)

Non-CME programs conducted by an independent third party where the third party has control over the content, implementation and selection of faculty.

Allowed Activity	General Requirements	Required Forms and Approvals
<p>Accredited Continuing Education (CE/CPEU) and Patient Health-Related Programs</p> <p>and</p> <p>Non-Accredited Third-Party Educational/Professional Meetings</p>	<ol style="list-style-type: none"> 1. Funding must be provided to an independent third party. 2. The independent third party must provide the program and maintain full responsibility for, and control over, the selection of content, faculty, educational methods, materials and venue. 3. Must comply with, as applicable, the standards or guidelines of the accrediting body and the independent third party and may, to the extent permitted: <ul style="list-style-type: none"> – Provide advice or guidance, including selection of topics, content or faculty, to the independent third party. If the program includes discussion of use of Abbott Products, then the materials must go through the appropriate divisional review/approval process. – Disseminate invitations, business reply cards, “save-the-date” cards or brochures about the event, provided that ultimate selection of audience members is controlled by the independent third party. 4. Abbott may directly or indirectly fund modest meals and receptions (such as by providing funds to a restaurant or caterer, or by providing funds to a vendor that organizes the meeting/event) to the extent it is consistent with the standards of the accrediting body and independent third party, as applicable, and consistent with the OPPF “Meals, Educational Items and Charitable Donations” requirements. 	<ul style="list-style-type: none"> • ACR • Current W-9 Form (note: may be maintained elsewhere, e.g., financial system) • LOA including: <ul style="list-style-type: none"> – Description of the program – Detailed budget for use of the funds • LOA must include approvals from these parties: <ul style="list-style-type: none"> – Appropriate representative of the independent third party – Appropriate Abbott business representative – ECO or delegate • The ECO or delegate must approve any modifications to the LOA • No more than one LOA may be signed for each event

Funding of Educational Programs for HCP/Customers (Including Patients/Consumers) (cont.)

Allowed Activity	General Requirements	Required Forms and Approvals
	<p>5. No promotional activities may take place in the room where the Educational Program/Activity occurs, except to the extent permitted by standards of the accrediting body and/or independent third party, as applicable.</p>	

Funding of Educational Programs for HCP/Customers (Including Patients/Consumers) (cont.)

CE programs conducted by either Abbott or a third party on behalf of Abbott, where Abbott has any **control** over the content, implementation and selection of faculty.

If **Abbott has any control** over the topic(s), content, implementation or selection of faculty, the following apply:

Allowed Activity	General Requirements	Required Forms and Approvals If Third Party Provider
Accredited Continuing Education (CE/CPEU)	<ol style="list-style-type: none"> 1. Must comply with the accrediting body's standards. 2. Abbott may suggest, select and develop topics, content and/or faculty for CE program/activity, including activities managed by an education provider, if and to the extent it is consistent with the standards of the accrediting body and the rules regarding control by Abbott, including the corresponding promotional restrictions and review processes, stated below: <ul style="list-style-type: none"> - CE program/activity cannot include discussion of any off-label use of Abbott Products. - All materials must be reviewed in accordance with the divisional review/approval process. 3. CE program/activity may include funding for modest meals and receptions held in conjunction with the CE program/activity if and to the extent funding is consistent with the standards of the accrediting body and consistent with the OPPF "Meals, Educational Items and Charitable Donations" requirements. 	<ul style="list-style-type: none"> • ACR • W-9 Form • LOA (short form) including: <ul style="list-style-type: none"> - Description of the program - Detailed budget for use of the funds • LOA (short form) must include approvals from these parties: <ul style="list-style-type: none"> - Appropriate representative of the third party - Appropriate Abbott business representative - ECO or delegate • The ECO or delegate must approve any modifications to the LOA (short form) • No more than one LOA (short form) may be signed for each event
Patient Health-Related Programs	See "Speaker Programs" requirements.	

Funding of Educational Programs for HCPs in Training

Allowed Activity	General Requirements	Required Forms and Approvals
Scholarships to Educational Conferences	<ol style="list-style-type: none"> 1. Funding attendance at educational conferences may only be provided to residents, fellows, medical students and other HCPs in training. 2. Funds must be given to a university, medical school, Non-Profit Organization, third-party educational program sponsor or other entity approved by ECO or delegate. 3. Funds may be used to allow HCPs in training to attend major educational, scientific or policy-making meetings of national, regional or specialty medical associations. 4. Abbott must not have influence over the selection of the individuals receiving the funding. 5. Funds must be designated “for HCP in training educational conference use only” and not for obtaining or maintaining an HCP/Customer’s license. 	<ul style="list-style-type: none"> • ACR • General Program Support Form • W-9 Form
Fellowship Programs	<ol style="list-style-type: none"> 1. Funding for fellowship programs must only support educational or research activities of HCPs in training. 2. Funds must be given to a university, medical school, Non-Profit Organization or other entity approved by ECO. 3. Funds may be used to cover reasonable stipend/salary and textbooks for the individual receiving the fellowships, but may not be used to cover expenses for tools and equipment. 4. Any benefit to the individual recipient’s workforce must be incidental and minimal and must be approved by ECO or delegate. 5. Abbott must not have any influence in the selection of the individual receiving the fellowship. 	

Funding for Educational Materials

Refer to the following table for general requirements for funding educational materials in connection with Abbott promotional programs or patient health-related programs, as well as the required documents and approvals needed for each activity.

Allowed Activity	General Requirements	Required Forms and Approvals
Educational Materials	<ol style="list-style-type: none"> 1. Funding may be provided for the following educational materials: <ul style="list-style-type: none"> - Materials for Speaker Programs or non-speaker programs, such as multimedia patient health-related educational materials. - HCP/Customer newsletter limited to clinical and healthcare topics. - Textbooks for use by residents at a library that supports a residents' program or for individual residents not selected by Abbott. - Funding may not be provided to an individual HCP. 	<ul style="list-style-type: none"> • Division regulatory approval of any materials that identify Abbott products • ACR • General Program Support Form • W-9 Form

General Program Support Table of Contents

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Note: Government Customers frequently have policies and procedures that are stricter than those found in the OPPF.

Introduction

As part of Abbott's business, Abbott provides funding for a range of activities.

Note: As you read this section, a word in purple text indicates that it is defined in the Glossary section.

General Requirements

Follow these requirements for general program support:

1. No **Quid Pro Quo**. Funding may not be offered or given with the intent to induce, or in exchange for, an explicit or implicit agreement or understanding that Abbott products will be used, purchased, leased, ordered, prescribed, recommended, or arranged for or provided formulary or other preferential or qualifying status.
2. When interacting with **HCP/Customers**, Abbott employees must determine whether the **HCP/Customers'** employer has a policy or procedure governing interactions with industry. Where such policies or procedures are stricter than the Operating Procedures for Program Funding, Abbott employees must comply with the stricter standard. **Government Customers frequently have policies and procedures that are stricter than those found in the OPPF.**
3. Payment must be reasonable and based on **Fair Market Value**.
4. For programs provided to an individual **HCP/Customer** (including clinical investigators and their staff), payment must be made directly to the vendor.
5. Except as specifically provided in this procedure, funds must not be offered to pay **HCP/Customer** expenses to attend programs/activities or for an **HCP's/Customer's** time at a program/activity.
6. Entertainment and recreation are not allowed.
7. An employee **cannot** personally pay for or allow an **HCP/Customer** to pay for an activity prohibited under these procedures.
8. Nothing in these procedures prohibits Abbott from purchasing legitimately needed products (e.g., specimens), data or certain services from its customers at **Fair Market Value** including non-patient/consumer-identified prescriber data to facilitate communications with an **HCP/Customer** in compliance with applicable divisional procedures regarding the appropriate use and confidentiality of such prescriber data. (See applicable division policies and/or operating procedures.)
9. Any exceptions to these requirements must be approved by the **Ethics and Compliance Officer (ECO)** or delegate and in accordance with exception procedure B2-10-002.
10. All documentation must be completed prior to a program taking place.

Note: Any violation of the Operating Procedures or falsification of records submitted in connection with the procedures may result in disciplinary action up to and including termination.

General Program Support Activities

Refer to the following table for details on activities for which Abbott provides general program support.

Type of Activity	Requirements	Required Forms
Customer Product Training or Product Education	<ol style="list-style-type: none"> 1. Reasonable and necessary travel and other expenses may be reimbursed if pre-approved by Ethics and Compliance Officer (ECO) or delegate. No travel or other expenses may be paid for uninvited guests, spouses or family members of HCP/Customer attendees. 2. Meals for customer product training or product education may be provided in accordance with “Meals, Educational Items and Donations” section of the OPPF. Note: meals may not be paid for uninvited guests, spouses or family members of HCP/Customer attendees. 3. Primary purpose is for product training or product education. 4. Product training must be on approved uses of Abbott products. 5. Product training must be held at a training facility, medical institution, lab, Abbott facility or other appropriate facility and be conducted by individuals with proper qualifications and expertise. 6. Providing travel expenses for HCP/Customers to attend customer product training programs requires a justification by the requestor that it is not possible to hold the training at the HCP/Customer location. 7. Product education includes the evaluation of Abbott’s products, technology or manufacturing capabilities. 8. Providing travel expenses for HCP/Customers to attend customer product education programs requires a justification by the requestor that it is not possible to hold the product education at the HCP/Customer location (e.g., due to the non-portability of the product or the fact that the product education includes a manufacturing tour). 9. Obtain approval from the ECO or delegate prior to finalizing arrangements. 10. Abbott must not compensate attendees for their time. 	<ul style="list-style-type: none"> • Administrative Check Request (ACR) or Purchase Order (PO) • W-9 Form • ECO or delegate pre-approval • Application for Customer Product Training or Product Education

General Program Support Activities (cont.)

Type of Activity	Requirements	Required Forms
Exhibit/ Display Fees	<ol style="list-style-type: none"> 1. May be provided, where participation is open to multiple companies and where the exhibit/display is not at the facility of an individual HCP (including clinical investigators and their staff), group practices, physician practices, management companies, provider medical groups. 2. Food may be provided in accordance with “Meals, Educational Items and Charitable Donations.” 3. Funding may not be provided to an individual HCP or HCP group practice. 	<ul style="list-style-type: none"> • ACR • W-9 Form • General Program Support Form and • Exhibit letter or application form
Screening Programs and Health Fairs	<ol style="list-style-type: none"> 1. The provision of Abbott products for screening or health fairs must comply with Abbott’s OEC Compliance Policy, “Providing No-Charge Product to Customers, Policy #B2-03” and applicable division policies and/or operating procedures. 2. HCP/Customer must not bill the patient or any third party for the screening activity or for screening-related items and services received free from Abbott. 3. When offered on-site at HCP/Customer, may be offered no more than on an occasional basis. 4. If the screening is not part of a regular office visit, an office visit must not be billed. 5. HCP/Customer (but not Non-Profit Organization) must submit receipts for actual costs. 6. HCP/Customer cannot be retained by Abbott to provide Professional Services without prior ECO approval. 	<ul style="list-style-type: none"> • ACR or PO • General Program Support Form • Receipts (as applicable) • W-9 Form • Applicable Professional Service Agreement for Abbott-hired HCP
Corporate Membership or Sponsorship Fee	<ol style="list-style-type: none"> 1. Allowed only for Abbott membership in or sponsorship of a Non-Profit Organization. 2. Sponsorship requires prior approval of ECO or delegate or in accordance with divisional procedure. 3. Funding may not be provided to an individual HCP or HCP group practice. 	<ul style="list-style-type: none"> • ACR • General Program Support Form and • Letter/Application from Non-Profit Organization • W-9 Form

Printing

Type of Activity	Requirements	Required Forms
Informational Materials	<ol style="list-style-type: none"> 1. Funding may only be offered to cover the actual cost to publish and distribute informational materials intended for patient use, such as Treatment guidelines. 2. For any material related to Abbott products, follow divisional promotional review/approval requirements. 3. Must be in compliance with requirements for “Educational Items Given to Patients.” 	<ul style="list-style-type: none"> • ACR or PO • Vendor invoices • Receipts • List of HCP recipients • W-9 Form
Formulary	<ol style="list-style-type: none"> 1. Funding may only be offered to cover the actual cost to publish and distribute a formulary for the purpose of adding or changing Abbott product information that would not otherwise be published. 2. Materials must follow divisional review and approval requirements. 3. Funding may not be provided to an individual HCP or HCP group practice. 	<ul style="list-style-type: none"> • ACR or PO • Vendor invoices • Receipts • W-9 Form

Prohibited Expenses

Salaries	<ol style="list-style-type: none"> 1. Salary, either directly or indirectly, for employees or agents of an HCP/Customer cannot be funded.
Customer Expenses	<ol style="list-style-type: none"> 1. Funding for personal expenses, travel, hotel, parking or registration fees is not allowed for attending any of the following: <ul style="list-style-type: none"> – Medical education events – Promotional programs – Non-CME patient or health-related programs – Non-faculty member attending educational meetings to present the results of a study (e.g., poster presentation on non-Abbott supported research) – Entertainment and recreation are not allowed

Glossary

Introduction

This Glossary contains definitions of terms related to the Operating Procedures for Program Funding (OPPF).

A word in purple text in the operating procedures indicates that its definition is included in this section. Understanding key terms and their meanings will help you interpret the guidelines correctly.

A

Administrative Check Request (ACR)

Financial form required when Abbott generates a check for a third party.

Advisor

Individual retained to perform defined activities or provide knowledge or opinion(s) for a topic/subject as requested by Abbott. (See *Consultant*.)

C

Consultant

Individual retained to perform defined activities or provide knowledge or opinion(s) for a topic/subject as requested by Abbott. (See *Advisor*.)

Continuing Education (CE)

Accredited educational program awarding CE credit(s) to HCP/Customers upon completion.

Continuing Medical Education (CME)

Accredited medical education program awarding CME credit(s) to HCP/Customers upon completion.

D

Disease State

Status and conditions of a specific disease, where patient treatment is being conducted or considered.

E

ECO

Ethics and Compliance Officer.

Educational Items

Items designed primarily to advance disease state education or treatment education of the patient/consumer or other HCP/Customers. The value of these items is the price that Abbott pays for them (excluding tax and shipping).

Educational Programs/Activities

Programs/activities that foster increased understanding of scientific, clinical or healthcare issues that contribute to the enhancement of patient care. Educational Programs/Activities include grand rounds, symposia and journal clubs on clinical topics for HCP/Customers.

F

Fair Market Value (FMV)

The price or compensation negotiated in an arm's-length transaction where neither party is required to buy or sell and when both have reasonable knowledge of the relevant facts.

Fee For Service

A specified and reasonable amount of compensation, based on Fair Market Value, paid for an activity/service performed by a person who has specific training and/or experience related to the professional services provided that cannot vary based upon the volume or value of that party's usage/referral of Abbott products or on the value of any business generated between that party and Abbott.

G

Government Customer

A Government Customer includes a Healthcare Professional (HCP)/Customer employed by any level of government, including, but not limited to, federal, state, county and local government. Some governmental agencies may consider even part-time workers and HCPs in training (e.g. medical students, interns, residents and fellows) to be employees of the government.

Examples of a Government Customer include, but are not limited to, an individual employed as a(n):

- Cardiologist at a Veterans Affairs Medical Center.
- Laboratory Director employed by a state university hospital system.
- Nurse in a county-owned jail or prison facility.
- Contracting officer responsible for awarding and administering healthcare product contracts at a Department of Defense facility.
- Executive of a hospital owned and operated by the Indian Health Service.

Grand Rounds

Educational programs/activities that take place within a hospital or other institution with an open invitation to all hospital/institution staff. The programs may or may not be CME/CE-accredited.

Group Consulting Program

A type of program that includes consulting meetings, advisory boards (including investigator meetings where investigators/researchers are acting in an advisory capacity not associated with services otherwise provided under a clinical research agreement), speaker training meetings, market research conducted directly by Abbott, and data and safety monitoring boards.

Healthcare Professional/Customer (HCP/Customer)

Healthcare Professional/Customer is a non-employee of Abbott defined in all of the following ways (includes Government Customers):

- **Healthcare providers** include physicians (medical doctors, osteopaths and naturopathic physicians), nurses, pharmacists, physician assistants, dentists, dietitians, pathologists, cath lab staff, nurse clinicians, case managers, and techs (e.g., lab, x-ray, medical, emergency medicine and dental), medical students, medical interns, veterinarians, Ph.D. researchers, optometrists, midwives, podiatrists, physical therapists, respiratory therapists and social workers.
- **Business associates** include those individuals involved in the healthcare providers' business (e.g., purchasing agents, business managers, office managers, lab managers and employees, material managers, ICU administrators).
- **Employees of non-healthcare businesses and healthcare-related businesses**, whose businesses buy and use Abbott products, such as drug screening devices (e.g., airlines, firehouses, probation courts, insurance companies).
- **Patients/consumers.**
- **Employees of businesses that supply products** who are not practicing healthcare providers, who **may** seek reimbursement from Medicare, but are not directly involved in healthcare (e.g., employees of retail chain drug stores, mail order drug stores and home medical equipment, and durable medical equipment dealers and suppliers).
- **Employees of businesses that supply products** who are not practicing healthcare providers, who are not directly involved in healthcare and **do not** seek reimbursement from Medicare (e.g., employees of drug wholesalers and other distributors, food service companies [distributors and those that run cafeterias], state surveyors, CROs, group purchasing organizations).
- **Association leadership** consists of elected officials (presumably healthcare professionals) and mixed groups (staff and elected).
- **Insurer/managed care organizations** include formulary members and health benefit plan administrators.

In-Service

A meeting or presentation where there is significant interaction with HCP/Customers for a meaningful amount of time and at which an on-site meal is provided. (Also known as *Lunch 'N' Learn.*)

Journal Club

A type of educational program/activity where HCP/Customers meet to discuss professional articles.

L

Labeling

The use of a product in connection with a disease state, condition or symptom for which the product has been approved or cleared as being safe and effective in its prevention or treatment, or as being accurate in its diagnosis, by the U.S. Food and Drug Administration (FDA) or other authorized government agency.

Letter of Agreement (LOA)

Documented agreement between Abbott and an independent third party, including an accrediting body and/or Medical Education Provider, outlining terms and conditions for the payment of funds or educational grants, which includes a description of the defined educational program (i.e., CME, CE, patient health-related programs, and/or third-party educational or professional meetings) and a detailed budget for use of the funds or grants.

Lunch ‘N’ Learn

A meeting or presentation where there is significant interaction with HCP/Customers for a meaningful amount of time and at which an on-site meal is provided. (Also known as an *In-Service*.)

M

Medical Education Provider

The organization that arranges an educational program/activity.

N

Non-Profit Mission

The Non-Profit Mission of a provider or foundation (affiliated with an HCP/Customer that is for-profit or non-profit) is a service of planned activities carried on that does not contribute to the organization’s bottom line or profit. They cost money; they do not bring in money. These programs must support low-income, indigent or homeless families or persons, or other underserved or uninsured populations.

Non-Profit Organization

A tax-exempt organization whose objective is to support or engage in activities of public interest without any commercial or monetary profit. Examples include associations, patient advocacy groups, societies and foundations not affiliated with an HCP/Customer, but do NOT include non-profit hospitals, clinics or other provider entities, or foundations affiliated with an HCP/Customer.

Non-Profit Provider

Non-profit hospital, medical school or hospital-like entity (e.g., state mental institution, free clinic), or a non-profit foundation affiliated with any HCP/Customer.

Off-Site Meal

Meal, in conjunction with an informational meeting or presentation, at a restaurant or other venue (not the premises of an HCP/Customer), conducive to scientific or educational communications.

On-Site Meal

Meal, in conjunction with an informational meeting or presentation, on the premises of an HCP/Customer (e.g., office, hospital or place of business). On-Site Meals may be referred to as Lunch 'N' Learns, breakfast presentations and In-Services.

Preceptorship

Training or education for sales representatives provided by a subject-matter expert, typically a leading or specialty healthcare professional. Training is conducted as a half- to one-day shadowing of a healthcare professional or classroom training. Used for any of the following circumstances:

- New representative (no more than 180 days in the field)
- New product (no more than 180 days after FDA approval)
- New indication for an existing product (no more than 180 days after FDA approval)
- New market for the representative (no more than 180 days from alignment)

Product Trainer

An HCP/Customer engaged to train and/or educate other HCP/Customers on the safe and effective use of Abbott products. Training must be conducted in accordance with the requirements of policy *B2-10, Federal Healthcare Program Requirements – United States – Promotion of Abbott Products*.

Product Training Program

A program involving an HCP/Customer retained directly by Abbott for purposes of having the appropriately trained HCP/Customer train other HCP/Customers on the approved, safe and effective use of Abbott products. Training must be conducted in accordance with the requirements of policy *B2-10, Federal Healthcare Program Requirements – United States – Promotion of Abbott Products*.

Professional Services

Services performed by an HCP/Customer on behalf of Abbott to meet Abbott's need for information, services and advice, such as consulting with Abbott regarding product or market issues or participating in consulting meetings, advisory boards and speaker training meetings.

Promotional Speaker/Presenter

See *Speaker*.

Quid Pro Quo

Offering or giving anything of value with the intent to induce or in exchange for an explicit or implicit agreement or understanding that Abbott products will be used, purchased, leased, ordered, prescribed, recommended, or arranged for or provided formulary or other preferential or qualifying status.

S

Snacks

Purchased food items (e.g., cookies) provided on the premises of an HCP/Customer (e.g., office, hospital or place of business) in conjunction with an informational meeting or presentation.

Speaker

An appropriately trained third-party consultant engaged by Abbott via a Professional Services Agreement or Speaker Agreement or other agreement approved by Legal to perform a Speaker Program. An Abbott employee per divisional procedure may act as an Approved Speaker.

Speaker Agreement

A contract with an HCP/Customer hired by Abbott for Speaker Programs (including patient/health-related programs that do not discuss Abbott products), presentations to Non-Profit Organizations not related to healthcare or Abbott employee meetings.

Speaker Programs

A program involving an HCP/Customer retained directly by Abbott for purposes of having the appropriately trained HCP/Customer present materials reviewed/approved in compliance with applicable divisional procedures and/or FDA requirements to other HCP/Customers (including patients/consumers), whether regarding the benefits, risks and/or appropriate uses of Abbott Products, relevant disease state, or treatment options. Also includes a program involving an Abbott employee per divisional procedures.

Symposia

A series of educational programs on specific topics all related to a general topic. Symposia usually take place in a convention hall or as a sidebar to an association meeting.

T

Third-Party Expense Reimbursement

Expense reimbursement for the actual cost of reasonable meals, travel (coach class if by air, consistent with Abbott's travel policy), lodging and incidental personal expenses incurred as part of rendering professional services and/or approved customer visits.

Treatment

Includes prevention of illness and/or care of a person's health and wellness.