1. PURPOSE

UCB, Inc. (“UCB”) contracts with HCPs, HCIs, and Patients/Caregivers to provide business counseling and advice, train UCB employees, educate other HCPs about our products, and provide other services to or on behalf of UCB. This procedure provides guidance for engaging a healthcare professional (“HCP”), Healthcare Institution (“HCI”), or Patient/Caregiver to perform legitimate and bona fide business, consulting, and/or advisory services for UCB.

UCB is subject to federal and state health care Anti-Kickback Statutes that prohibit giving or offering anything of value to HCPs, HCIs, or Patients/Caregivers to influence prescribing, recommending or purchasing pharmaceuticals. In addition, HCPs/HCIs are subject to laws and professional ethical standards prohibiting the receipt of remuneration from health care suppliers in connection with prescribing or treatment decisions. A violation of these laws can lead to penalties including criminal and/or civil fines for the company or individuals, imprisonment of individuals, and exclusion of UCB products from eligibility for reimbursement from Medicare and Medicaid.

2. SCOPE

This procedure applies to all UCB Business Units, functional areas, and departments who may engage and compensate HCPs/HCIs/Patients/Caregivers to perform specific and measurable activities and services for UCB. This procedure covers all fee-for-service arrangements generally; however, specific activity procedures may also apply and should be followed for the following arrangements:

- Advisory Boards (Commercial and Clinical)
- Educational presentations to UCB’s employees
- Investigator meetings
- Market research
- Peer-to-Peer speaker training
- Peer-to-Peer programs

This procedure does not apply to researchers and investigators involved in studies; these arrangements are covered by specific procedures for company sponsored clinical trials and investigator initiated studies.

3. HEALTH, SAFETY AND ENVIRONMENTAL PROTECTION

There are no significant hazards or special instructions relating to the arrangements described that need to be detailed in this SOP.
4. RESPONSIBILITIES

**Activity Organizer**
- Ensuring that the process for selecting and engaging HCPs, HCIs, and Patient’s/Caregivers is in compliance with UCB policies and procedures.
- Ensuring approval of HCPs/HCIs/Patients/Caregivers qualifications.
- Maintaining and/or submitting in the electronic platform all required fee-for-service engagement files, including written qualifications, ANFs, service agreements and final deliverables.
- Ensures prior to initiation of any provision of services that a fully executed written agreement and scope of work is created that defines all deliverables
- Identifying impacted stakeholders in other departments and ensuring that they are informed and provide input on the fee-for-service engagement as appropriate.
- Submitting fee-for-service engagement proposals to the appropriate internal departments for review and approval prior to submission to Sourcing and Contracting, as applicable.
- Provides a copy of the fully executed contract in the designated electronic system.
- Ensures that noncompliance of regulations and statutes are reported to the appropriate internal UCB departments as soon as possible.

**Compliance**
- Reviewing and providing approval for ANF.
- Assessing FMV for individual fee-for-service arrangements.
- Monitoring fee-for-service arrangements for compliance with UCB policies and procedures.

**Legal**
- Provides agreement templates, reviews any changes requested to standard templates as needed, and develops actions to mitigate potential risk areas.
- Reviews and approves all final fee-for-service contracts as needed. Reviewing and providing approval for selected ANFs.

**Medical**
- Review and approve a legitimate need for the activity.
- Reviews and approves HCPs/HCIs qualifications for the proposed activity.
5. PROCEDURE

5.1 Activity Notification Review and Approval Process

**HCPs and HCIs**

Once the identified need has been approved in the Semi-Annual Activity Budget Plan for HCPs/HCIs for UCB, Inc. only, the UCB activity organizer who is requesting the engagement of a HCP/HCI for a specific activity or service must submit an ANF. The ANF will serve as a needs assessment for the individual engagement as specified in the form.

If an engagement was not described in an approved Semi-Annual Activity Budget Plan for HCPs/HCIs or deviates and/or modified from the description for the engagement set forth in an approved Semi-Annual Activity Budget Plan for HCPs/HCIs, the then the Activity Organizer must include a written explanation for the deviation or the modification. The explanation should be provided within the ANF.

**Patients/Caregivers**

Once the need business need has been identified, the UCB activity organizer who is requesting the engagement of a Patient/Caregiver for a specific activity or service, must submit an ANF. The ANF will serve as a needs assessment for the individual engagement as specified in the form.

5.1.1 Fair Market Value Analysis

**HCP/HCI**

The activity owner requesting the HCP/HCI engagement will propose reasonable compensation rates based on the fair market value of the activity. These proposed rates for HCPs will take into account the following criteria:

a) HCP Type: All HCPs must be classified by type (i.e., physician or non-physician).

b) HCP Specialty: All HCPs must then be classified by specialty within their type.
   – UCB personnel should use the UCB FMV Analysis to review a full listing of specialties for both physicians and non-physicians.
c) HCP Tier: All HCPs must then be classified as a KOL or non-KOL. KOLs are physicians who influence their peers’ medical practice through their status in the medical community.

- Determination of a KOL can include, but is not limited to, the following: years in a given specialty, number/type of scholarly publications, number/type of academic appointments, experience running clinical trials, and speaking/teaching capabilities.

- Determination of KOL status should be documented through the collection of specific documents related to that HCP. These documents could include, but are not limited to: CVs or resumes, speaking evaluations, lists or copies of authored articles, information on clinical trial experience, or through historical usage where similar criteria and expertise were required, which can be confirmed by the medical/scientific team.

d) Level of Effort: The level of effort associated with the type of service to be provided should be determined.

- The Activity Organizer should provide information on the type of service that the HCP will be performing (e.g., presentation to sales force).

- The Activity Organizer should also indicate the number of hours or the daily amount associated with the service (e.g., 1 hour, ½ day, 1 day).

FMV rates for HCIs will follow similar criteria.

For some types of arrangements with HCPs (e.g., speaker programs, consultants, advisory boards, research,) UCB maintains a centrally managed, pre-determined rate structure called a Fair Market Value Analysis, which is overseen by the Compliance Department. The Fair Market Value Analysis is based on the fair market value of the services to be provided. In those circumstances, compensation is paid in accordance with this rate structure, and any deviations from this rate structure must be documented and approved in advance by Compliance.

U.S. Compliance and Medical will review (and discuss with the Activity Organizer, if necessary) the information provided by the Activity Organizer to validate: (1) that the type and specialty is correct, (2) that there is sufficient documentation to demonstrate a KOL determination (if applicable), and (3) if applicable, that the rate matches the service and level of effort indicated in the FMV Analysis or the reason for any deviation is accurately documented and supported.

**Patients/Caregivers**

Rates for engaging Patients/Caregivers in activities will be determined on a case-by-case basis, considering level of effort and duration of activity.
5.1.2 Review and Approval

Each ANF will be reviewed and approved by U.S. Compliance and U.S. Medical Affairs for any activity involving U.S. HCPs or conducted on U.S. soil. Market Research ANF’s will be reviewed and approved by Compliance and impacted departments, based on the type of research to be conducted. Prior to engagement of any HCP/HCI/Patient/Caregiver, all required approvals must be obtained. Legal can review activities that were modified or not included in the Semi-annual HCP/HCI Activity Budget Plan.

It is not permissible to commit any fees or guarantees to a HCP/HCI/Patient/Caregiver in advance of activity approval.

5.2 Engagement of HCPs/HCIs/Patients/Caregivers

Upon approval of an activity, the activity owner is responsible for ensuring that all UCB requirements specified in any applicable policies and procedures are met (e.g., sop-009645 U.S. Advisory Boards).

Payments may be made to an HCP/HCI/Patient/Caregiver for approved legitimate fee-for-service activities only if an approved written agreement has been entered into between UCB and the individual or HCI prior to the provision of services. The fee-for-service agreement must specify at a minimum the following information using an approved legal template; however, the written agreement for certain types of arrangements may require additional mandatory language, which is set forth in the applicable SOPs.

- Date of engagement;
- Nature and scope of work to be performed, including any required deliverables;
- Timeframe within which work is to be completed (term of contract) and schedule of services to be provided;
- Compensation rate to be paid;
- Business travel and expense reimbursement guidelines;
- Requirement for the HCPs to make any necessary disclosures and notifications to superiors based on the HCP’s affiliation with all Formulary/ P&T committees, committees associated with the development of treatment protocols or standards or that are required by any health care institution, medical committee, or other medical or scientific organization with which the HCP is affiliated;
- Certification that local law allows for the HCP or HCI to perform identified services and that he or she is not restricted by other contractual arrangements with third parties, or employer agreements in performing fee-for-service activities for UCB;
- Obligation to comply with all federal and state laws, and regulations; and
- Requirement to report any actual or suspected incidences of noncompliance to the Compliance Departments.
5.2.1 Verification of Non-Exclusion/Debarment Status

Operational Excellence or UCB Compliance must verify that proposed HCPs and HCIs do not appear on the FDA, OIG or SAM federal healthcare programs exclusion or debarment lists. Receiving a contractual representation from the HCP or HCl does not constitute verification. Vendors may perform these website verifications if documentation of the results of such verification is provided to the Activity Organizer.

- SAM (System for Award Management)
  http://www.sam.gov/portal/public/sam

- OIG List of Excluded Individuals and Entities
  http://oig.hhs.gov/fraud/exclusions.html

- FDA List of Debarred Persons or Firms:
  http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/default.htm

5.3 Payment to HCPs/HCIs/Patients/Caregivers

All fees must be paid directly to the HCP/HCl/Patient/Caregiver who is contracted to render services for UCB. Payments may not be made to third-party organizations (corporation or charity) as an alternative to paying the HCP/HCl/Patient/Caregiver directly.

In rare cases, an HCP’s terms of employment may require that funds be paid to his employer. UCB will consider these on an exception basis and will require written documentation from the HCP and the employer. If accepted, the contract will be jointly executed with the employer.

If appropriate, UCB may pay for the reasonable travel, lodging, and meal expenses of contracted HCPs/HCIs/Patients/Caregivers as set forth in the Policy for Reimbursement included with each contract. UCB will not pay for the travel, incremental lodging, meals, or other expenses of anyone accompanying the contracted person.

Meals provided in coordination with a fee-for-service arrangement should be generally modest by local standards and should not exceed the following limits, inclusive of beverage, tax and tips, unless documented approval is received in advance:

- Breakfast: $25 per person
- Lunch: $50 per person
- Dinner: $125 per person

Recreation and entertainment of any type is strictly prohibited in connection with fee-for-service arrangements.
5.4 Documentation, Record Maintenance and Retention
All records, information and deliverables related to this procedure will be retained for a period of six (6) years or longer if required by applicable law, contract or regulatory requirement. Records related to this procedure will be maintained by the activity owner unless otherwise specifically directed by the Legal Department. For GxP records retention refer to Corporate SOP Retention Periods for GxP Records
Payments to HCPs and HCIs and associated expenses will be disclosed as required by federal and state law. HCPs and HCIs may not condition their agreement to perform services for or on UCB’s behalf on the nondisclosure of this information.

5.5 Compliance Monitoring
The Compliance Department shall implement monitoring activities to assess compliance with this SOP. Such monitoring activities shall be revised from time to time as determined by the Compliance Department and will include live monitoring of activities and document reviews.
Specific fee-for-service arrangements are subject to specific monitoring requirements, which are set forth in the SOPs governing those arrangements.

6. ABBREVIATIONS AND DEFINITIONS
Abbreviations and definitions, used in this document, are in accordance with the UCB Glossary. To the extent that these definitions differ from those contained in the UCB Glossary, these definitions will take precedence for the purpose of this policy / procedure.

6.1 Abbreviations
ANF Activity Notification Form
CV Curriculum Vitae
FMV Fair Market Value
HCI Healthcare Institution
HCP Healthcare Professional
P&T Pharmacy and Therapeutics

6.2 Definitions
| Semi-Annual Activity Budget Plan for HCPs/HCIs | Identifies the business need for and the estimated numbers of various fee-for-service engagements and activities with HCPs/HCIs to occur during the following semi-annual period. These plans also identify the budgeted amounts to be spent on fee-for-service-related activities. |
**Bona fide**  
*Bona fide* means the fact of being genuine, or made in good faith without fraud or deceit. Therefore, the contracted service that the HCP or HCI is being asked to perform must be legitimate and necessary.

**Caregiver**  
A non-HCP who provides direct patient care (e.g. family member, friend, fee-for-service caretaker).

**Fair Market Value**  
The price, expressed in terms of “cash equivalents”, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arm’s length in an open and unrestricted market, whether neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts.

**Fair Market Value Analysis**  
A centrally managed reference tool consisting of pre-determined rates determined by UCB management to represent FMV compensation for certain types of activities performed by HCPs and HCIs for or on behalf of UCB. The rate structure is based on certain factors such as HCP type (i.e., physician or non-physician), specialty (e.g., primary care practitioner, gastroenterologist, rheumatologist), tier type (i.e., KOL or non-KOL), service type (e.g., Advisory Boards, Speaker Training, Research), and program length of time.

**Healthcare Institution**  
Any legal entity that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) through which one or more HCPs provide or receive services.

**Healthcare Professional**  
Any person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may directly or indirectly prescribe, purchase, supply, recommend, administer or arrange for the use of a medicinal product.

**Level of Effort**  
The level of effort for a HCP contracted service is the total amount of time needed to complete the service based on three variables: preparation time, travel time, and time spent performing the service. UCB takes into account all three variables when determining the proper compensation.

**Key Opinion Leader**  
HCPs that influence their peers’ medical practice through their status in the medical community. Criteria used to define a KOL include number of years in a given specialty, number and type of
scholarly publications, number and type of academic appointments, experience running clinical trials, and speaking/teaching capabilities.

Patient  A person receiving or registered to receive medical treatment.

7. RELATED DOCUMENTS

7.1 Associated Documents

N/A

7.2 References

- sop-008510, Contracts with Healthcare Professionals and Consultants for Cross-Border Activities
- sop-009342, Retention Periods for GxP Records
- sop-009645, Advisory Boards
- sop-009647, Promotional Speaker Programs
- sop-009648, Speaker Training
- sop-011598, Preceptorships
- sop-014113, U.S. False Claims Act and Anti-Kickback Statute

8. LIST OF APPENDICES

N/A

9. SOP HISTORY

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<td>sop-014111 v1.0</td>
<td>‘Preceptorships with Institutions’ was removed from Scope. 6.1 was changed to show that a written explanation should be included on the ANF.</td>
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<td>sop-014111 v2.0</td>
<td>SOP updated to include contracting with Patients/Caregivers. Section 4, added: Medical; Sales and Marketing Services. Section 5.1, added: ‘Semi-Annual Activity Budget Plan for</td>
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<td>HCP/HCIs.</td>
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<td>Section 5.1.1, added: ‘Activity Organizer’.</td>
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<td></td>
<td>Section 5.1.2, added: Compliance and impacted departments to review and approve.</td>
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<tr>
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<td>SOP updates: Global update to include contracting with Caregivers</td>
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<td>Section 6.2 modified definitions for HCP, HCI, and Caregiver</td>
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# Document Approval Electronic Signatures

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U.S. Compliance – Engaging Healthcare Professionals (HCPs), Healthcare Institutions (HCIs), and Patients/Caregivers in Fee-for-Service Arrangements