CMP-HC Glossary of Terms

Accreditation Council for Continuing Medical Education (ACCME) – ACCME is the overseeing body for institutions and organizations that provide continuing medical education (CME) activities. It sets standards in physician continuing education (lifelong learning) in the United States and, through a voluntary self-regulated system and a peer-review process, certifies that institutions and organizations meet them. The council was established in 1980 by seven organizations: the American Board of Medical Specialties (ABMS), the American Hospital Association (AHA), the American Medical Association (AMA), the Association of American Medical Colleges (AAMC), the Association for Hospital Medical Education (AHME), the Council of Medical Specialty Societies (CMSS), and the Federation of State Medical Boards (FSMB).

Accredited provider – An organization that demonstrates to ACCME and its member organizations that its programs, operations, and administration of continuing education consistently meet the standards outlined in the ACCME rules and regulations.

AdvaMED – The Advanced Medical Technology Association (AdvaMed) is a trade association representing companies that produce medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed represents 80 percent of medical technology firms in the United States. (See *EuroMed*.)

AdvaMED Code of Ethics on Interactions with Health Care Professionals – The AdvaMed Code of Ethics clarifies appropriate activities between health care professionals (HCPs) and representatives of AdvaMed member companies. Companies can serve the interests of patients through beneficial collaborations with HCPs to advance medical technologies, ensure the safe and effective use of these technologies, encourage research and education, and foster charitable donations and giving. To ensure that these collaborative relationships meet the highest ethical standards, they must be conducted with appropriate transparency and in compliance with applicable laws, regulations, and government guidance.

Aggregate spend – The process used to aggregate and monitor the total amount spent by health care manufacturers on individual health care professionals and organizations; for example, through payments, gifts, honoraria, and travel expenses.

American Board of Medical Specialties (ABMS) — A not-for-profit organization that oversees the certification of physician specialties in the United States. ABMS comprises 24 medical specialty member boards. Its primary function is to help the boards develop and implement educational and professional standards to evaluate and certify physician specialists.

American Medical Association (AMA) – The AMA is one of the largest associations of medical doctors and medical students in the United States. Its mission is to promote the art and science of medicine and the improvement of public health.

American Medical Association Physician's Recognition Award (AMA PRA) Category 1 Credit –

The AMA PRA Category 1 Credit system has become the CME standard for licensing boards and specialty organizations nationwide and is recognized by all U.S. jurisdictions, which simplifies the medical relicensure process. Thirty-nine states/territories accept the AMA PRA certificate or the AMA-approved AMA PRA application as proof of having met the CME requirements for licensure.

Americans with Disabilities Act (ADA) – The ADA provides civil rights protections for people with disabilities similar to those provided for individuals on the basis of race, sex, national origin, and religion. It guarantees equal opportunity for people with disabilities in employment, public accommodations, transportation, state and local government services, and telecommunications.

Attendee registration report – A report on the disciplines, specialties, and demographics of attendees at a meeting or event.

Anti-kickback statute of the Medicare and Medicaid Patient Protection Act – In the Medicare and Medicaid Patient Protection Act of 1987, as amended, the "anti-kickback statute" provides criminal penalties for certain acts that affect reimbursable services of Medicare and state health care (e.g., Medicaid). It prohibits offering or accepting remuneration in return for referrals to or recommending purchase of supplies or services that are reimbursable under government health care programs.

C-arms – An imaging scanner intensifier. C-arms have radiographic capabilities, although they are used primarily for fluoroscopic imaging during surgical, orthopedic, critical care, and emergency care procedures.

Call for papers (CFP) – A CFP is a method used in academic and other contexts to collect book or journal articles or conference presentations. The CFP is usually sent to interested parties and describes the occasion and the broad theme, what kind of abstract or summary must be submitted and to whom, and the deadline for submission.

Clinical investigator (CI) – The CI is responsible for ensuring that a clinical trial is conducted according to the signed investigator statement, the investigational plan, and applicable regulations. The CI is also responsible for protecting the rights, safety, and welfare of trial subjects and for the control of drugs under investigation. The CI must meet requirements set forth by the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMEA), and other regulatory bodies. The CI's qualifications must be outlined in a current resume and readily available for auditors. See also *principal investigator*.

Clinical trial – A clinical trial is a test that generates information about the efficacy of a drug or other health intervention, as well as any adverse effects. Clinical trials are also called studies or protocols. The four common types of clinical trials are:

Phase I trials: Researchers test an experimental drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects. Most often this phase is completed at one or two sites and would not be a good trial candidate for meeting planning services.

Phase II trials: The experimental study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety. It is important to note that not all Phase II studies progress to Phase III. This is usually the stage where a drug manufacturer will decide if the results within the Phase II will warrant progresses into a full-fledged Phase III study.

Phase III trials: The experimental study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.

Phase IV trials: Post-marketing studies delineate additional information including the drug's risks, benefits, and optimal use. Often times, Phase IV trials are Investigator Initiated Studies (IIS), which are studies that individual investigators suggest to the manufacturer. As in Phase I studies, these studies are usually performed at a single site or sometimes over 1-3 sites, but would not require meeting planning services.

Code on Interactions with Health Care Professionals (PhRMA Code) – Pharmaceutical Research and Manufacturers of America (PhRMA) represents pharmaceutical and biotechnology companies that develop and market medicines. In 2002, PhRMA adopted voluntary guidelines to ensure that marketing practices and informational activities comply with the highest ethical and professional standards. The code was revised in 2009.

Competency-based medical education (CBME) – CBME is based on a determination of the competencies and assessment tools required of physicians and sets appropriate curricula for residents and physicians in practice.

Conseil National de l'Ordre des Médecins (CNOM) – CNOM is legally responsible for upholding the principles of morality, integrity, competence, and dedication necessary for the practice of medicine by all physicians in France. The CNOM code of medical ethics guarantees the quality of care provided to patients and preserves the uniqueness of the doctor-patient relationship.

Continuing medical education (CME) – CME refers to educational activities that maintain, develop, or increase the knowledge, skills, and professional performance and relationships a physician uses to provide services for patients, the public, or the profession.

Corporate integrity agreement (CIA) – A CIA is an enforcement tool used by the Department of Health and Human Services Office of Inspector General (HHS OIG) to improve the quality of health care and promote compliance with health care regulations. It is usually part of a civil settlement with an entity that has been found guilty of fraud in connection with Medicare, Medicaid, or any other federal health care program. An integrity agreement (IA) is used for smaller providers, such as individual physicians.

Current good manufacturing practice (cGMP) – A GMP is a production and testing practice that helps ensure the quality of a drug or medical device and thus safeguard the health of patients. In many countries, pharmaceutical and medical device companies are legally required to follow GMP guidelines, which are general principles, not specific instructions on how to manufacture products. Regulatory agencies (including the FDA in the United States) perform both routine and unannounced inspections, as well as preapproval inspections.

Didactic lecture – A form of teaching that involves the conveyance of perceived facts from a teacher to a student in a lecture format. This form of instruction often does not invite questions or discussion.

Dosimitry badges – A radiation-sensitive material, such as film, worn in a small package on a person's clothing to record accumulated radiation exposure over a period of time. For example, these badges are used to monitor the exposure of workers in a nuclear power plant to ionizing radiation.

European Accreditation Council for Continuing Medical Education (EACCME) – The European Union of Medical Specialists (UEMS) established EACCME in January 2000 to encourage high standards in the development, delivery, and harmonization of continuing medical education (CME) through the international accreditation of CME events and the establishment of a system for the international acceptance of CME credits. EACCME accredits approximately 1,400 meetings a year for international CME. In 2009, the council introduced a system to accredit elearning materials.

European Federation of Medical Suppliers (EucoMed) – An organization that represents designers, manufacturers, and suppliers of medical technology used in the diagnosis, prevention, treatment, and amelioration of disease and disability. EucoMed represents 11,000 legal entities in Europe.

European Medicines Agency (EMA) – Based in London, this agency was established in 1995 by the European Union and pharmaceutical industry to work in conjunction with (and not a replacement for) European medicine regulatory bodies. Its purpose is to promote human and animal health by conducting scientific evaluation and monitoring of medicinal products.

FARMAINDUSTRIA Code of Ethics – In Spain, a code of practice that establishes the proper relationship between the pharmaceutical industry and health care professionals, as well as between the industry and patient associations, with regard to the promotion of drugs and medical devices for human use.

Faculty and Planning Committee Disclosure Declaration – ACCME requires accredited CME providers to have a method in place to acquire information on all faculty and planning committee members' financial relationships with commercial interests for an activity that could affect the content of CME about the products or services of a specific commercial interest.

Health Insurance Portability and Accountability Act of 1996 (HIPAA) – Title I of HIPAA protects health insurance coverage for workers and their families when they change or lose their jobs. Title II of HIPAA (known as the administrative simplification provisions) mandates the establishment of national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers.

Health care congress (HCC) – "Congress" usually refers to general sessions of delegates who belong to a particular organization or a body engaged in general studies. Also used to mean a full membership meeting of an organization.

Health care provider (HCP) – A person or institution that provides preventive, curative, promotional, or rehabilitative health care services in a systematic way to individuals, families, or communities.

Honorarium – A payment for professional services.

Industry prospectus – In the field of CME, a document that describes the features of an upcoming educational program or conference, including support and exhibit opportunities.

International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code — IFPMA was founded in 1968 to ensure that pharmaceutical companies throughout the world use ethical practices in promoting and marketing medicines. The federation created a code of practice in 1981; it has been updated frequently. The 2012 revision of the code expands beyond marketing practices to cover interactions with health care professionals, medical institutions, and patient organizations.

International Pharmaceutical Congress Advisory Association (IPCAA) – IPCAA is a global nonprofit membership organization that focuses on standards and protocols for medical meetings. The association provides guidance for medical societies, meeting organizers, and the health care industry in the form of codes of conduct and ethics focusing on choice of venue; sponsorship levels for accommodations, travel, and hospitality; and so on.

Key opinion leaders (KOLs) – KOLs, also known as thought leaders, are the experts on whom society depends for original research leading to disease understanding and new therapies. KOLs have become intimately entwined with the marketing of pharmaceuticals and medical devices, not only to lend credibility to claims of efficacy and safety but also to promote anecdotal and off-label use of these medications to increase industry profits.

Letter of agreement (LOA) – An LOA can be used for a simple agreement that does not require a contract. With regard to ACCME, an LOA describes the terms, conditions, and purposes of a commercial support grant to provide continuing medical education (CME). It is signed by the commercial supporter and the accredited provider.

Medicare and Medicaid Patient Protection Act of 1987 – See anti-kickback statute.

Mdeon Code of Ethics – Mdeon is a common ethical platform comprising associations of physicians, pharmacists, veterinarians, dentists, nurses, as well as the pharmaceutical and medical device industries. The Mdeon Code of Ethics is a framework to ensure that scientific events organized, sponsored, or supported by manufacturers, importers, or wholesalers of drugs and medical devices and attended by health care practitioners are conducted ethically in terms of the promotion of medicinal products and medical devices.

Medical license number – The identification number assigned by a government-approved professional association or a government agency to a medical practitioner who has completed all requirements for a medical license (usually testing or examination by a medical board). In the United States, individual states grant medical licenses.

Modest meals – Various regulations and guidelines define the sort of meal or refreshment a pharmaceutical or medical device manufacturing company may provide or pay for in connection with informational or educational meetings or presentations to health care practitioners. AMA guidelines attach a dollar figure to other gifts, such as textbooks, but they do not provide a dollar limit on meals.

Open payment program – The Patient Protection and Affordable Care Act of 2010 requires the establishment of a transparency program to increase public awareness of financial relationships between drug and device manufacturers and certain health care providers. Covered manufacturers and group purchasing organizations (GPOs) must submit annual reports to the Centers for Medicare and Medicaid Serves (CMS) regarding their financial relationships with providers such as physicians and teaching hospitals. CMS will collect this data, aggregate it, and publish it on a public website. (See *U.S. Physician Payments Sunshine Act.*)

National provider identifier (NPI) – The NPI is a Health Insurance Portability and Accountability Act (HIPAA) administrative simplification standard. It is a 10-digit identifier for covered health care providers. The numbers do not carry other information about health care providers, such as the state in which they live or their medical specialties.

Needs assessment/gap analysis – A needs assessment is a systematic process for determining and addressing needs or gaps between current conditions and desired conditions.

New drug application (NDA) number – The FDA assigns a six-digit number to each application for approval to market a new drug in the United States. A drug can have more than one application number if it has different dosage forms or routes of administration.

Off-label use – In the United States, physicians may prescribe approved medications for other than their intended indications. The FDA further defines off-label use as "use for indication,

dosage form, dose regimen, population, or other use parameter not mentioned in the approved labeling."

Principal investigator (PI) – The PI is the lead scientist or engineer for a particular science or other research project, such as a laboratory study or clinical trial. The title is also used as a synonym for head of the laboratory or research group leader. (See *clinical investigator*.)

Product life cycle – A set of common stages in the life of commercial products; for example, introduction, promotion, growth, maturity, and decline.

Request for proposal (RFP) – An RFP is a solicitation made to potential suppliers by an agency or company that is interested in procuring a commodity or service. The RFP sets out preliminary requirements for the commodity or service, and may dictate to varying degrees the exact structure and format of the supplier's response. The RFP process brings structure to the procurement decision and allows the risks and benefits to be clearly identified up front.

Request for Research Grants (RRG) – A grant program offered to pediatric residents by the American Academy of Pediatrics.

Royal College of Surgeons/Royal Surgical College – These organizations are found in many countries that are or were members of the British Commonwealth. They are responsible for training surgeons and setting their examinations.

RPPS – Répertoire Partagé des Professionnels de Santé. A collective database of health professionals in France. The RPPS number is the French equivalent of the U.S. NPI number, which identifies health care providers.

Satellite symposium – An event or meeting held in conjunction with an annual meeting and intended to complement the content of the larger meeting.

Serology – The scientific study of blood serum and other bodily fluids. The term usually refers to the diagnostic identification of antibodies in the serum, but serological tests can alo be performed on other bodily fluids, such as semen and saliva.

Serovar or serotype – A group of closely related microorganisms within a species of bacteria or viruses or among immune cells. These microorganisms, viruses, or cells are classified together based on their cell surface antigens, allowing the epidemiologic classification of organisms to the subspecies level. A group of serovars with common antigens is called a serogroup.

Skills-based simulation workshop – A type of experiential learning, primarily in adult professional education, in which the learner has the opportunity to practice new skills in a structured situation that often includes analysis and feedback.

Sarbanes-Oxley Act (SOX) – The Sarbanes-Oxley Act of 2002 is a U.S. law that sets higher standards for all public company boards, management, and public accounting firms. SOX mandates that top management must individually certify the accuracy of financial information and sets severe penalties for fraudulent financial activity. The Act increases the independence of outside auditors who review corporate financial statements and increases the oversight role of boards of directors.

Stark law – The Stark law is actually a series of provisions in various Acts that regulate physician referrals to designated health services (DHS) for Medicare and Medicaid patients if the physician (or an immediate family member) has a financial relationship with that entity. Covered services include clinical lab services, imaging, physical therapy, medical equipment and supplies, home health services, and prescription drugs.

State license number – *See medical license number*.

Transfer of value (TOV) –TOVs are payments or other forms of remuneration from pharmaceutical and medical device manufacturers to health care providers, including physicians and teaching hospitals. Under the Affordable Care Act, these transfers must be reported to CMS, unless they total less than \$10 each or less than \$100 over a calendar year (2013 limits).

U.S. Centers for Medicare and Medicaid (CMS) – CMS is the U.S. Department of Health and Human Services (HHS) agency that runs the national Medicare program and works with states to run the Medicaid program.

U.S. Food and Drug Administration (FDA) – The FDA is the HHS agency responsible for ensuring the safety and efficacy of foods, human and veterinary drugs, vaccines and other biological products, and medical devices. The FDA also regulates electronic product radiation, cosmetics and dietary supplements, and tobacco products.

U.S. Patient Protection and Affordable Care Act – Commonly called the Affordable Care Act (ACA) or Obamacare, this federal statute was signed into law by President Barack Obama on March 23, 2010. Together with the Health Care and Education Reconciliation Act, it represents the most significant government expansion and regulatory overhaul of the country's health care system since the passage of Medicare and Medicaid in 1965. The ACA aims to increase the quality, affordability, and rate of health insurance coverage for Americans, and reduce the costs of health care for individuals and the government. On June 28, 2012, the U.S. Supreme Court upheld the constitutionality of most of the ACA in *National Federation of Independent Business v. Sebelius*; however, the Court held that states cannot be forced to participate in the ACA's Medicaid expansion under penalty of losing Medicaid funding.

U.S. Physician Payments Sunshine Act – The Sunshine Act is a section of the Affordable Care Act of 2010 that requires pharmaceutical and medical device companies to report to the federal government on certain payments they make to physicians and teaching hospitals. (See *open payment program*.)

U.S. Department of Health and Human Services, Office of Inspector General (HHS OIG) – The mission of HHS OIG is to protect the integrity of U.S. Department of Health and Human Services programs, as well as the health and welfare of program beneficiaries. Since its establishment in 1976, the office has been at the forefront of the nation's efforts to fight waste, fraud, and abuse in Medicare, Medicaid, and more than 300 other HHS programs. It is the largest inspector general's office in the federal government. The majority of its resources go toward oversight of Medicare and Medicaid, but it also covers other HHS institutions, including the Centers for Disease Control and Prevention, the National Institutes of Health, and the Food and Drug Administration.