CME Policy Guideline

Education on devices is a special use-case in accredited CME

(*presented as a scenario for application to special use devices*)

NEW (03/2009) 10) One of our CME courses is an intensive hands-on course that trains physicians to perform vascular interventions in a laboratory setting. The training is primarily about newer medical devices and equipment, their use, and practical training in how to perform the procedures. The course director has asked a couple of companies to provide both training equipment/devices to use and company personnel to operate the equipment. We will track this loaned equipment as in-kind commercial support. The course director has independently designed the activity, determined the procedures to be taught, instructs the technologists on their roles, and is present to oversee and participate in the instruction. The course director verifies that the training and comments provided by the device technologists are technical only about the use of the equipment, and do not favor a commercial product or compare products. Is this situation allowed under the ACCME® Standards for Commercial Support?

Education on devices is a special use-case in accredited CME. Some equipment contains "labeling requirements" set by the FDA that include the requirement for instruction prior to use. Each set of circumstances need to be taken on a case-by-case basis as the conflicts of interest of industry employees are irreconcilable in CME, so they can never take the usual role as teacher or author in accredited CME. Industry employees can demonstrate the operational aspects of the use of a device under the umbrella of a provider's ACCME accreditation - but they must only demonstrate the operational aspects. They can do this without contributing in any way to any decision making about the elements of SCS 1 of the ACCME® Standards for Commercial Support℠. It is also critical that the employees never expand their input into areas of clinical medicine while involved in accredited CME (e.g., never talk about indications for use, never talk about comparisons between competing products or comparisons between the device and/or invasive surgery and/or medical treatment.) This special use-case, if it is going to remain compliant, requires careful supervision by the accredited provider's faculty and staff and proper professional behavior by industry staff.