



DeBusk College of Osteopathic Medicine
LINCOLN MEMORIAL UNIVERSITY

Policy Order Number: DCOM CME Off-Label Use 1

Effective Date: June 1, 2016

Revised:

Signature on File
Dr. Brian A. Kessler, Dean

LMU-DCOM Office of CME Off-Label Use of Products Policy

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1. PURPOSE

To ensure the discussion of products in Continuing Medical Education (CME) educational activities are with sufficient evidence and accepted within the medical profession as having adequate justification for the proposed use in best serving patients.

2. POLICY

As a Category 1-A CME Sponsor Organization, and to ensure the independence of educational activities regarding off-label drug use, LMU-DCOM follows the Accreditation Requirements set forth by the American Osteopathic Association (AOA) and the Council on Continuing Medical Education (CCME) for Continuing Medical Education (CME) activities.

When an Off-label use of a product, or an investigational use not yet approved for any purpose, is discussed during an educational activity, the accredited sponsor shall require the speaker to disclose that the product is not labeled for the use under discussion, or that the

product is still investigational. Discussions of such uses shall focus on those uses that have been subject of objective investigation.

3. PROCEDURE

A. Course Directors, adjunct faculty, and/or program faculty speakers who may be representing Off-label drug use will need to verbally disclose and document or indicate on presentation slide, prior to presentation one of the following: 1) the content of my presentation will not include discussion of unapproved or investigational uses of products or devices or 2) the content of my presentation will include discussion of unapproved or investigational uses of products or devices as indicated. Documentation should be kept on file in respective departments and/or the CME Office.

B. Questions about the Office of CME Off-Label Use of Products Policy:

CME Office-LMU-DCOM
6965 Cumberland Gap Parkway
Harrogate, TN 37752
Phone: 423-869-6819 or fax: 423-869-7078

4. CONSEQUENCES OF NON-COMPLIANCE

CME Sponsor Accreditation Probation and/or Revocation

5. DURATION OF POLICY

This Policy is effective as of the date above and shall remain effective until amended or terminated by the Dean of LMU-DCOM.