

POLICY NUMBER: 602.4

POLICY TITLE: Office of CME Off-Label Use Policy

I. PURPOSE

This policy is 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.

II. POLICY STATEMENT

As a Category 1-A 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. Discussion of such uses shall focus on those uses that have been subject of objective investigation.

III. DEFINITIONS

CME = Continuing Medical Education

IV. AUDIENCE

This policy applies to all activity directors, planners, course directors, committee members, and presenters participating in any LMU-DCOM-sponsored CME program.

V. COMPLIANCE

N/A

VI. ROLES AND RESPONSIBILITIES

LMU-DCOM Administration: The mission of the Office of Continuing Medical Education (CME) at LMU-DCOM will remain consistent with the mission of the DeBusk College of Osteopathic Medicine in its commitment to prepare outstanding osteopathic physicians who are committed to the premise that the cornerstone of meaningful existence is service to humanity.

Responsible Office: LMU-DCOM Office of Continuing Medical Education
Responsible University Officer: LMU-DCOM Director of CME
Policy Oversight Committee: LMU-DCOM Policy Process Committee

VII. STANDARDS

N/A

VIII. PROCEDURE

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.

Consequences of non-compliance include CME sponsor accreditation probation and/or revocation.

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

IX. CONTACT INFORMATION

For more information regarding this policy, please contact the LMU-DCOM Director of Alumni Services and CME at 423-869-6252.

X. DOCUMENT HISTORY

Policy Order Number: DCOM CME Off-Label Use 1 Effective Date June 1, 2016

Version S23.1:

Approved by LMU DCOM Policy Process Committee 06/02/23

Approved by LMU Legal 06/15/23

XI. FORMS

<http://dcomcme.LMUnet.edu>

<https://www.lmunet.edu/debusk-college-of-osteopathic-medicine/do/office-of-cme-preceptor-development/preceptor-faculty-development/index>