STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY • GOVERNOR EDMUND G. BROWN JR.
Medical Board of California
BOARD OF PODIATRIC MEDICINE
2005 Evergreen Street, Suite 1300 Sacramento, CA 95815-3831
P (916) 263-2647 F (916) 263-2651 www.bpm.ca.gov

LICENSING COMMITTEE
August 17, 2016

SUBJECT: APPLICATIONS FOR CONTINUING MEDICAL EDUCATION (CME) PROGRAM APPROVAL

5

ACTION: REVIEW APPLICATION FOR APPROVAL

RECOMMENDATION

Review and approve subject to the guideline criteria provided in section 1399.671 of the California Code of Regulations.

ISSUE

A program organizer seeks continuing medical educational ("CME") course approval from the California Board of Podiatric Medicine ("BPM").

DISCUSSION

Program organizers offering educational courses or programs lacking previous approval for CME credit by the California or American Podiatric Medical Associations or their affiliated organizations or approval of Category 1 credit of the American or California Medical Associations or approval by the American and/or California Osteopathic Associations and neither offered by a government agency or an approved college/school of medicine may apply to BPM for CME course or program approval.

Accordingly, pursuant to the professional and vocational regulations contained in Title 16, California Code of Regulations, Division 13.9, Sections 1399.670 and 1399.671, BPM may extend approval to said educational courses or programs as qualified for CME credits upon submission of appropriate documentation and other evidence as needed to determine compliance with required criteria as set forth in the regulations which include the following benchmarks:

1) A faculty appointment in a public university, state college or private postsecondary education institution;

2) Clearly stated educational objectives that are realistically achievable within a course framework;

3) A delineated method of course instruction;

4) Maintenance of a record of attendance for all participants; and

5) Rationale and method for determining both the need for and content of the course offering.

FINANCIAL IMPACT

Approval of this item will not have a financial impact on the Board of Podiatric Medicine's FY 16/17 Budget. Ultimately, submission of an application for approval of a continuing medical education course or program generates fee revenue of one hundred dollars ($100) in accordance with the authority provided under section 2499.5 of the California Business and Professions Code.

POLICY IMPLICATIONS

Review and approval is consistent with the Board's regulatory authority as provided by Title 16, California Code of Regulations, Division 13.9, Sections 1399.670 and 1399.671.

NEXT STEPS

With Committee approval, staff will issue the required documentation to the course provider which appropriately reflects the decision of the Board.

ATTACHMENTS

A. 16 CCR §§ 1399.670 – 1399.671
B. Application for Continuing Medical Education (CME) Program Approval from *MD Trials, LLC/Podiatry Research Group*
C. Application for Continuing Medical Education (CME) Program Approval from *O'Connor Hospital Would Care Center*

Prepared by: Kia-Maria Zamora, Licensing Unit Coordinator

Kia-Maria Zamora
Licensing Unit Coordinator

Kathleen Cooper, JD
Interim Executive Officer

ATTACHMENT A

§ 1399.671. Criteria for Approval of Courses.
16 CA ADC § 1399.671
BARCLAYS OFFICIAL CALIFORNIA CODE OF REGULATIONS

Barclays Official California Code of Regulations Currentness
Title 16. Professional and Vocational Regulations
Division 13.9. Board of Podiatric Medicine of the Medical Board of California
Article 3. Continuing Competence

16 CCR § 1399.671

§ 1399.671. Criteria for Approval of Courses.

(a) Only those individuals, organizations or institutions seeking approval by the board of continuing education courses or programs under Section 1399.670, subdivision (f), shall apply for such approval on a form provided by the board. Those individuals, organizations and institutions approved under Section 1399.670, subdivisions (a) through (e), need not apply to the board for approval.

(b) Those individuals, organizations and institutions applying for approval of course or program offerings by the board under Section 1399.670, subdivision (f), shall submit such documents and other evidence as may be needed by the board to determine compliance with the criteria set forth below, including, but not limited to, catalogues, course descriptions, curricula plans and bulletins.

(c) Those courses or programs referred to in Section 1399.670, subdivision (f), shall meet the following criteria in order to be approved by the board on an hour-for-hour basis:

(1) Faculty -The course or program organizer(s) shall have a faculty appointment in a public university or state college or in a private postsecondary educational institution authorized or approved pursuant to Section 94310 of the Education Code. The appointment may be in disciplines other than medicine but directly related to the practice of podiatric medicine or medicine. The curriculum vitae of all faculty members and all other organizers shall be kept on file.

(2) Rationale -The need for the course and how the need was determined shall be clearly stated and maintained on file.

(3) Course Content -The content of the course and how the need was determined shall be clearly stated and maintained on file.

(4) Educational Objectives -Each course or program shall clearly state educational objectives that can be realistically accomplished within the framework of the course.

(5) Method of Instruction -Teaching methods for each course or program shall be described, e.g., lecture, seminar, audio-visual simulation, etc.

(6) Attendance -Course organizers shall maintain a record of attendance of each participant.

Note: Authority cited: Section 2496, Business and Professions Code. Reference: Section 2496, Business and Professions Code.

HISTORY

1. Amendment of subsection (a) filed 8-4-83; effective thirtieth day thereafter (Register 83, No. 32).

2. Renumbering of former Section 1399.672 to Section 1399.671 and renumbering and amendment of former Section 1399.671 to Section 1399.670 filed 3-8-84; effective thirtieth day thereafter (Register 84, No. 10).

3. Change without regulatory effect of subsections (a)-(c) (Register 87, No. 15).

4. Change without regulatory effect amending subsections (a)-(c) and Note filed 9-3-2015 pursuant to section 100, title 1, California Code of Regulations (Register 2015, No. 36).

This database is current through 4/8/16 Register 2016, No. 15

16 CCR § 1399.671, **16 CA ADC § 1399 . 671**

END OF DOCUMENT

© 2016 Thomson Reuters. No claim to original U.S. Government Works.

ATTACHMENT B

STATE OF CALIFORNIA
BOARD OF
PODIATRIC
MEDICINE

CH#: 1010
$100
2/11/2016

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

APPLICATION FOR CONTINUING MEDICAL EDUCATION (CME) PROGRAM APPROVAL

FOR BPM USE ONLY			
Fee paid:	100	Receipt #:	RI-0387
Date Cashiered:	3/4/16	Cashier's Initials:	[illegible]
Date Approved:		Date Denial:	
Approved Initial:			

~~[illegible]~~ E4182
CH#: 366 857

Only those individuals, organizations or institutions seeking approval by the board for continuing medical education programs per Section 1399.670(f) of the California Code of Regulations must complete this form:

Please print or type. Illegible applications will be returned.

Name of Program: CLINICAL TRIALS FELLOWSHIP

Location(s) Given: ONLINE TRAINING MODULE, Date: 2/5/2016

Requested number of CME hours: 25

1. Program organizer with faculty appointment in a public university, state college or private post-secondary educational institution approved under Section 94310 of the California Education Code. (Please attach a curriculum vitae).[1]

Name: Michael Alex DPM Title: Director

University/College: MOT TRIALS / PODIATRY RESEARCH GROUP

Department: CLINICAL

Address: 557 Promontory DRIVE WEST E4182
NEWPORT BEACH CA 92660

Telephone: 415 824 2000

Email:

[1] Faculty appointment may be in a discipline other than medicine but must be directly related to the practice of podiatric medicine.

Application for CME Program Approval

2. Clearly state the rationale for the program and how the need was determined.

CLINICAL TRIALS ARE A STANDARD IN ALLOPATHIC EDUCATION AND DURING RESIDENCY TRAINING. PODIATRISTS ARE NOT EXPOSED TO THE OPPORTUNITY OF CONDUCTING CLINICAL TRIALS. AS A RESULT, NEW, INNOVATIVE DRUGS/DEVICES ARE DELAYED. PODIATRISTS ARE PHYSICIANS AND MUST BE GIVEN THE OPPORTUNITY TO CONDUCT CLINICAL TRIALS

3. Has a need survey of the podiatric medical community been utilized?

Yes X No _____

4. Course Content: Please provide a complete breakdown of topics with designated times to be given. Supplemental attached documents should include but are not limited to catalogues, course descriptions, curricula plans, bulletins and brochures. SEE ATTACHED

5. List the educational objectives of the program(s):

UPON COMPLETION OF THIS PROGRAM, PODIATRISTS WILL UNDERSTAND THE DRUG DEVELOPMENT PROCESS. IN ADDITION, TO HAVING THE KNOWLEDGE TO CONDUCT OFFICE BASED CLINICAL TRIALS.

6. What is the method of instruction?

Lecture _____ Workshop _____ Audio-visual simulation X

Other _____

Please explain:

THE COURSE IS ~~18~~ 12 MODULES OF ONLINE TRAINING; CONTAINING ~~15~~ 15 HOURS OF CONTENT.

PLEASE SEE ENCLOSURE.

Application for CME Program Approval

7. Are you providing each participant a self-assessment evaluation?

Yes X No _____

8. Are you maintaining records of attendance on each participant?

Yes X No _____

For how long? 7 years

This form must be mailed to the board at the address below with a $100 processing fee.

Application submitted by:

Name: Michele Alex, DPM Title: Director

Address: 557 Promontory Drive West

Telephone: 415 824 2000

Email: michele@podiatryresearchgroup.com

Signature: Date: 2/5/16

Dear Board Of Podiatric Medicine:

Below is a description of the course content for the clinical trial fellowship training:
Each module is 1-2hours. Modules CRx19, CRx20, CRx21, CRx22, CRx23,CRx24, CRx26, CRx27, CRx28 have a self assessment quiz consisting of 30-50 questions each.

CRx19 - The History of Clinical Research
CRx20 - Participant Recruitment for Beginners
CRx21 - Advanced Participant Recruitment
CRx22 - Clinical Research Site Study Close Out
CRx23 - Investigator Responsibilities in Clinical Research
CRx24 - Regulatory Document Submission
CRx25- Staff Training
CRx26 - Ethics In Clinical Research
CRx27 - Site Selection and Initiation Procedures
CRx28 - Building a Successful Clinical Research Site
CRx29- Contract and Budget Negotiations
CRx30- How to partner with MDs to conduct clinical trials

Michelle Alex, D.P.M.

Newport Beach, CA

THERAPEUTIC EXPERIENCE:
Oncology, Hematology, Vascular, Gastroenterology, Renal, Cardiology, Neurology(Stem Cell) Neurology, Imaging, Pediatrics, Infectious Disease, Endocrinology, Respiratory, Orthopedics/Surgical, Urology, Analgesics, Rheumatology, Dermatology, Respiratory

PROFESSIONAL:

MDTrials, LLC/Podiatry Research Group Director
1-2013-Present

Reno Clinical Trials, Director
3/2010-2013

San Francisco Clinical Research Center, Clinical Research Center Director
4/2009-1/2010

Bay Area Foot Care, San Francisco, CA
Podiatric Medical Director
1997-2009

EDUCATION:
San Francisco General Hospital, San Francisco, Ca
Podiatric Medical Resident
1996-1997

- Successfully completed the following rotations: Endocrinology, Internal Medicine, Emergency Medicine, Trauma, Dermatology, Orthopedic Surgery.
- Researched, wrote and presented to the Department of Endocrinology, an independent paper titled "Dysfunction of Lipid Metabolism."

Ohio College of Podiatric Medicine, Cleveland, OH
Doctor of Podiatric Medicine (D.P.M.)
1992-1996

- Completed 2 years of clinical rotations through all departments of medicine.
- Completed 2 years of basic sciences (biochemistry, physiology, microbiology,pharmacology, microbiology, immunology, gross anatomy, cell biology).

1/28/16

University of Akron, Akron, OH
Major: Biology
1988-1992

PROFESSIONAL TRAINING:

*2015: CITI GCP Trianing
2010: Rx Trial Institute, The Hidden Costs of Conducting Clinical Research
2009: Duke University Health System, Keys to Building a Successful Research Site
2008: PRI, Auditing Clinical Trials for GCP Compliance
2007: GSK, RECIST Workshop
2005: PRI, Auditing for GCP Compliance
2004: PhaseForward, Certified Electronic Data Capture (EDC) Trainer Version 4.0
2003: HIPPA Training
2002: University of California Santa Cruz, Certification in Clinical Trials Design/Management
1999: Barnett International Seminar, Medical Writing for Clinical Research

AFFILIATIONS:

- Drug Information Association
- Society of Quality Assurance
- American Medical Writers Association
- Association of Clinical Research Professionals

Zamora, Kia-Maria@DCA

From: Michelle Alex <researchdrugs@aol.com>
Sent: Tuesday, June 07, 2016 2:21 PM
To: Zamora, Kia-Maria@DCA
Subject: Re: CME program

Dear Kia-Maria,

The training consist of a live 2.5 day training in Newport Beach, CA in combination with the 12 online modules. that would exceed 25 hours in training.

Thank you,

Michelle Alex
415-824-2000

-----Original Message-----
From: Michelle <researchdrugs@aol.com>
To: Zamora, Kia-Maria@DCA <Kia-Maria.Zamora@dca.ca.gov>
Sent: Mon, Feb 22, 2016 2:16 pm
Subject: Re: CME program

Mia

I wanted to check on the status of the CmE application I submitted. Thank you
Michelle

On Jan 20, 2016, at 10:44 AM, Michelle <researchdrugs@aol.com> wrote:

> Than you Mia for he follow up
> When do I have to renew the original course?
>
> Sent from my iPhone
>
> On Jan 20, 2016, at 10:36 AM, Zamora, Kia-Maria@DCA <Kia-Maria.Zamora@dca.ca.gov> wrote:
>
> > Hello Dr. Alex,
> >
> > Please accept my apologies for the delayed response. As I'm sure with you, it has been extremely busy.
> >
> > With regards to your CME program, unfortunately, if no documentation was provided for the additional 5 hours, then I am unable to approve the continuance of this program with the additional hours. I recommend reapplying for this program with the request of the additional hours and it will be presented to our Education Committee for review. On the same note, if anything in the curriculum has changed or been updated, that information needs to be provided to the board as such.

ATTACHMENT C

STATE OF CALIFORNIA
BOARD OF
PODIATRIC
MEDICINE

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

APPLICATION FOR CONTINUING MEDICAL EDUCATION (CME) PROGRAM APPROVAL

FOR BPM USE ONLY			
Fee paid:		Receipt #:	
Date Cashiered:		Cashier's Initials:	
Date Approved:		Date Denial:	
Approved Initial:			

Only those individuals, organizations or institutions seeking approval by the board for continuing medical education programs per Section 1399.670(f) of the California Code of Regulations must complete this form:

Please print or type. Illegible applications will be returned.

Name of Program: Center of Excellence Clinical Experience in Wound Care

Location(s) Given: 125 Gro Ave
San Jose CA 95128

Date: Monthly August 15 2014

Requested number of CME hours: 5

1. Program organizer with faculty appointment in a public university, state college or private post-secondary educational institution approved under Section 94310 of the California Education Code. (Please attach a curriculum vitae).[1]

Name: Bruce Leeman

Title: Director

University/College: Oconnor Hospital Wound Care Center

Department: Wound Care Out Patient

Address: 125 Gro Ave SJ CA 95128

Telephone: 408 947-2804

Email: LEEMAN.BRUCE1@GMAIL.COM

[1] Faculty appointment may be in a discipline other than medicine but must be directly related to the practice of podiatric medicine.

Application for CME Program Approval

2. Clearly state the rationale for the program and how the need was determined.

Wound care has become extremely specialized. New technology and diagnostics are available. We provide training & education on indications, application protocol, logarithms in proper diagnostics. Please see enclosed agenda

3. Has a need survey of the podiatric medical community been utilized?

Yes ✓ No _____

4. Course Content: Please provide a complete breakdown of topics with designated times to be given. Supplemental attached documents should include but are not limited to catalogues, course descriptions, curricula plans, bulletins and brochures. enclosed

5. List the educational objectives of the program(s):

Education on Regenerative Medicine
Exposure to vascular diagnostics Venous + Arterial
Education on how to Run a wound care center

6. What is the method of instruction?

Lecture ✓ Workshop ✓ Audio-visual simulation _____

Other _____

Please explain:

Morning lecture followed by Clinical Experience
Finish with questions answered.

Application for CME Program Approval **Page 3**

7. Are you providing each participant a self-assessment evaluation?

Yes ✓ No _____

8. Are you maintaining records of attendance on each participant?

Yes ✓ No _____

For how long? We have records past 4 years.

This form must be mailed to the board at the address below with a $100 processing fee.

Application submitted by:

Name: Bruce Lerman DPM FACFAS Title: Director WCC

Address: 125 Ciro Ave
SAN JOSE CA 95128

Telephone: 408 947 2804

Email: LERMAN.BRUCEF@GMAIL.COM

Signature: _____ Date: 7/11/2016.

Bruce Lerman, DPM, FACFAS
Medical Director
O'Connor Hospital Wound Care Clinic
125 Ciro Ave, Suite 201, San Jose, CA 95128-1471
408-947-2804 | Fax: 408-947-3480
www.oconnorhospital.org

Part of Verity Health System

ATTACHMENT C

Wound Care Clinic
O'Connor Hospital

125 Ciro Avenue, Suite 201
San Jose, California 95128
(408) 947-2804
(408) 947-3480 Fax

CH#: 6006 5002.65
$100.00
7/13/2016
R1-012
E 2996 CH#: 271423

Clinical Agenda for Visiting Physicians.

8:30 Morning meeting including breakfast

Discuss agenda for the day and what to expect for the next four hours

Includes discussion on paperwork, Wound Expert, Patient intake and New Patient Procedures, procedures required for authorization of bioengineered products , HBOT, insurance verification and designation of patient to the appropriate physician based on specialty and insurance provider requirements.

9:00-1:00 Clinic

- Patient Cases
- HBOT
- Vascular Arterial Evaluation:
  -doppler, laser doppler, TCOM
  -Luna
  -CT angiogram and MRA
- Venous Evaluation:
  -Duplex Scans, Reflux Scans ,Iliac Scans
- Bioengineered Products and Regenerative Medicine
  -Amnion Products Grafix and Epifix
  -Skin Substitutes including Apligraf, Dermagraft, Graft Jacket
  -Acellular Material Skin Temp Puraply, other collagen based products, Acell and others
- Debridements both surgical and nonsurgical
  -Mist Therapy
  -Wound debridements Surgical
  -Ultrasound debridement
- Negative Pressure therapy, care of Venous Disease
  -Wound Vacs Snap, PICO, others
  -Alternative Venous dressings and compression therapy

1:00-2:00 Lunch

- Closing discussion regarding Clinical Experience.
- Complete evaluation forms