

Washington, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1019, tisha.washington@fda.hhs.gov no later than September 4, 2018.

Requests for Oral Presentations:

During online registration you may indicate if you wish to present at the public comment session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by September 5, 2018. All requests to make oral presentations must be received by the close of registration on September 4, 2018. If selected for presentation, any presentation materials must be emailed to Tisha Washington (see **FOR FURTHER INFORMATION CONTACT**) no later than close of business, September 6, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. The webcast link will be available on the following web page 5 days before the workshop at: <https://www.fda.gov/Drugs/NewsEvents/ucm611203.htm>.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the internet at <https://www.fda.gov/Drugs/NewsEvents/ucm611203.htm>.

Dated: August 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-17130 Filed 8-9-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

HHS Approval of Entities That Certify Medical Review Officers

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: This notice publishes a list of the Department of Health and Human Services (HHS) approved Medical Review Officers certification entities. The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines), applicable on October 1, 2017, addresses the role and qualifications of Medical Review Officers (MROs) and HHS approval of entities that certify MROs.

FOR FURTHER INFORMATION CONTACT:

Sean J. Belouin, Pharm.D., CAPT, United States Public Health Service, Senior Pharmacology and Regulatory Policy Advisor, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Room 16N06D, Rockville, Maryland 20857; Telephone: (240) 276-2716; Email: sean.belouin@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION: Subpart M—Medical Review Officer (MRO), Section 13.2 of the Mandatory Guidelines, “How are nationally recognized entities or subspecialty boards that certify MROs approved?” states as follows: “All nationally recognized entities or subspecialty boards which seek approval by the Secretary to certify physicians as MROs for federal workplace drug testing programs must submit their qualifications, a sample examination, and other necessary supporting examination materials (e.g., answers, previous examination statistics or other background examination information, if requested) (OMB Control No.: 0930-0158). Approval will be based on an objective review of qualifications that include a copy of the MRO applicant application form, documentation that the continuing education courses are accredited by a professional organization, and the delivery method and content of the examination. Each approved MRO certification entity must

resubmit their qualifications for approval every two years. The Secretary shall publish at least every two years a notice in the **Federal Register** listing those entities and subspecialty boards that have been approved. This notice is also available on the internet at <http://www.samhsa.gov/workplace/drug-testing>.”

HHS has completed its review of entities that certify MROs, in accordance with requests submitted by such entities to HHS.

The HHS Secretary approves the following MRO certifying entities that offer MRO certification through examination:

American Association of Medical Review Officers (AAMRO), P.O. Box 12873, Research Triangle Park, NC 27709, Phone: (919) 489-5407, Fax: (919) 490-1010, Email: bbrandon@aamro.com, website: <http://www.aamro.com/>.

Medical Review Officer Certification Council (MROCC), 3231 S. Halsted St, #167, Chicago, IL 60608, Phone: (847) 631-0599, Fax: (847) 483-1282, Email: mrocc@mrocc.org, website: <http://www.mrocc.org/>.

DATES: HHS approval is effective July 31, 2018.

Alex M. Azar II,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,