



Originating Office, Deputate or Bureau: Medical Marijuana Advisory Board

Subject:

Qualifying Medical Conditions for Medical Marijuana Research Application

Issue Date:
July 28, 2022

Effective Date:
July 28, 2022

Revision Date:
As needed

Rescission Date:
As needed

By Direction of:

Denise Johnson, MD, FACOG, FACHE, Acting Secretary of Health and Chair of the Medical Marijuana Advisory Board

Distribution: Certified Medical Marijuana Academic Clinical Research Centers (ACRC)

Policy location: Pennsylvania Department of Health, 625 Forster St, Health and Welfare Building, Harrisburg, PA, 17120

Scope: Medical Marijuana Advisory Board (MMAB)

Purpose: Pursuant to § 1201(j)(4) of the Medical Marijuana Act (35 P.S. § 10231.1201(j)(4)) , the MMAB is empowered to accept and review written comments from individuals and organizations about medical marijuana. This policy establishes a procedure for the MMAB to accept recommendations from Academic Clinical Research Centers (ACRCs) that a qualifying serious medical condition be added for Chapter 20 research purposes only. This policy further outlines the sequence of events following the submission of the “Qualifying Medical Conditions for Medical Marijuana Chapter 20 Research Application.”

Background: The Commonwealth of Pennsylvania recognizes qualifying serious medical conditions that provide for the use of medical marijuana by approved patients. As more research becomes available surrounding therapeutic or palliative use of medical marijuana, the MMAB hopes to expand the list of qualifying conditions for medical marijuana usage. However, the MMAB recognizes the potential need for research studies to be conducted prior to additional qualifying serious medical conditions being approved for use in Pennsylvania. Pursuant to 28 Pa. Code § 1211.21, research conducted under Chapter 20 of the Medical Marijuana Act can only study serious medical conditions that have been approved for use in the Commonwealth. Therefore, it is the MMAB’s intent to establish a process whereby ACRCs in the Commonwealth can petition the MMAB to approve a qualifying serious medical condition, limited to Chapter 20 research purposes only. In order to petition the MMAB, ACRCs must complete and submit to the MMAB the “Qualifying Medical Conditions for Medical Marijuana Chapter 20 Research Application.”

Discussion:

- (1) A member of a ACRC submitting a request to add a medical condition for medical marijuana Chapter 20 research must submit the Qualifying Medical Conditions for Medical Marijuana Chapter 20 Research Application via electronic submission to the MMAB’s Medical Review Subcommittee at the following email address: RA-dhmedicalcond@pa.gov.

- (2) The requester must submit the application request at least fifteen (15) days prior to the scheduled meeting of the MMAB.
- (3) The members of the MMAB's Medical Review Subcommittee will review the application request.
- (4) The subcommittee will deliberate and return a recommendation to the MMAB members with the application in advance of the board meeting for the full Board's consideration. The recommendation will be to a. approve, b. reject, or c. consider modifications. The recommendation will also contain rationale for the selection.
- (5) The application will then be presented before the MMAB for a vote.
- (6) The MMAB will approve or reject the application. Approval of an application by the MMAB does not automatically deem the condition a qualifying serious medical condition for Chapter 20 research purposes. Upon approval of a qualifying serious medical condition for Chapter 20 research, the MMAB must compile a report which presents its recommendation to the Secretary. The report will be presented at the next MMAB meeting, in accordance with the MMAB's reports policy.
- (7) Once a report containing the recommendation to add the condition as a qualifying serious medical condition for Chapter 20 research is adopted, the report will go to the Secretary for consideration. Pursuant to 35 P.S. § 10231.1202, the Secretary has 12 months from receipt of the report to effectuate the recommendation. Effectuation of any recommendation will be done via publication of a notice in the Pennsylvania Bulletin. Upon effectuation of a recommendation, the condition will be deemed approved for Chapter 20 research studies. Upon approval, ACRCs that wish to conduct a research study must comply with Office of Medical Marijuana's policies and procedures for Chapter 20 research studies on the approved research condition.
- (8) If rejected, the requester will receive a communication from the MMAB explaining the decision. The requester will then have the ability to request reconsideration by the Chairperson of the MMAB, in writing, set forth the reasons for the requested reconsideration. Upon a grant for reconsideration by the Chairperson, the requestor will be able to present their case directly to the MMAB. If reconsideration by the chairperson is denied or, after granting reconsideration, the request is rejected by the MMAB a second time, the requester's request will be deemed denied for one year, or until new scientific evidence is available.

If any ACRC's IRB cancels a study due to safety concerns, the MMAB will automatically reevaluate its approval of the condition for research and make a recommendation to the Secretary of Health.

Contact: If any concerns arise about this process, please email RA-dhmedicalcond@pa.gov with your question.