

1 **DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

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3 **Health and Environmental Information and Statistics Division**

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5 **MEDICAL USE OF MARIJUANA**

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7 **5 CCR 1006-2**

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9 **Regulation 6: Debilitating medical conditions and the process for adding new debilitating**
10 **medical conditions**

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12 A. Debilitating medical conditions are defined as cancer, glaucoma, and infection with or
13 positive status for human immunodeficiency virus. Patients undergoing treatment for such
14 conditions are defined as having a debilitating medical condition.

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16 B. Debilitating medical condition also includes a chronic or debilitating disease or medical
17 condition other than HIV infection, cancer or glaucoma; or treatment for such conditions,
18 which produces for a specific patient one or more of the following, and for which, in the
19 professional opinion of the patient's physician, such condition or conditions may
20 reasonably be alleviated by the medical use of marijuana: cachexia; severe pain; severe
21 nausea; seizures, including those that are characteristic of epilepsy; or persistent muscle
22 spasms, including those that are characteristic of multiple sclerosis.

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24 C. Patients who have had a diagnosis of a debilitating medical condition in the past but do
25 not have active disease and are not undergoing treatment for such condition are not
26 suffering from a debilitating medical condition for which the medical use of marijuana is
27 authorized.

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29 D. ~~Beginning June 1, 2001, the~~ THE department shall accept physician or patient petitions
30 to add debilitating medical conditions to the list provided in paragraphs A and B of this
31 regulation, AND SHALL FOLLOW THE FOLLOWING PROCEDURES IN REVIEWING
32 SUCH PETITIONS: ~~The department shall determine if a public rulemaking hearing to~~
33 ~~modify this regulation is appropriate, and if so, shall petition the Board of Health to set a~~
34 ~~date for such hearing within one hundred twenty days of receipt of the patient or~~
35 ~~physician petition. If the department determines that a public rulemaking hearing is not~~
36 ~~appropriate, it shall notify the petitioner of its action within one hundred eighty days of~~
37 ~~receipt of submission of the petition. In making its determination, the department will~~
38 ~~consider whether there is information that the proposed condition is chronic, debilitating,~~
39 ~~and may be specifically diagnosed, and whether there is scientific evidence that~~
40 ~~treatment with marijuana may have a beneficial effect.~~

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42 1. RECEIPT OF PETITION; REVIEW OF MEDICAL LITERATURE. UPON
43 RECEIPT OF A PETITION, THE EXECUTIVE DIRECTOR, OR HIS OR HER
44 DESIGNEE, SHALL REVIEW THE INFORMATION SUBMITTED IN SUPPORT
45 OF THE PETITION AND SHALL ALSO CONDUCT A SEARCH OF THE
46 MEDICAL LITERATURE FOR PEER-REVIEWED PUBLISHED LITERATURE
47 OF RANDOMIZED CONTROLLED TRIALS CONCERNING THE USE OF
48 MARIJUANA FOR THE CONDITION THAT IS THE SUBJECT OF THE
49 PETITION USING PUBMED, THE OFFICIAL SEARCH PROGRAM FOR THE
50 NATIONAL LIBRARY OF MEDICINE AND THE NATIONAL INSTITUTES OF
51 HEALTH.

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53 2. AD HOC MEDICAL ADVISORY PANEL.
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- a. THE DEPARTMENT SHALL ESTABLISH AN AD HOC MEDICAL ADVISORY PANEL TO REVIEW PETITIONS IF BASED UPON THE REVIEW CONDUCTED IN THIS PARAGRAPH (D)(1) THERE ARE BOTH PEER-REVIEWED PUBLISHED EVIDENCE OF EFFICACY IN HUMANS AND PEER-REVIEWED PUBLISHED EVIDENCE OF HARMS OTHER THAN THOSE ASSOCIATED WITH SMOKING SUCH AS OBSTRUCTIVE LUNG DISEASE OR LUNG CANCER, AND THERE ARE NO ALTERNATIVE, CONVENTIONAL TREATMENTS FOR THE CONDITION.

 - b. COMPOSITION OF THE AD HOC MEDICAL ADVISORY PANEL SHALL BE AS FOLLOWS:
 - i. ONE MEDICAL EXPERT IN THE APPROPRIATE FIELD FOR THE CONDITION REQUESTED TO BE ADDED THAT IS RECOMMENDED BY THE *PETITIONER* WHO MEETS APPROPRIATE QUALIFICATIONS WITH NO OBJECTIVE EVIDENCE OF BIAS.

 - ii. ONE MEDICAL EXPERT IN THE APPROPRIATE FIELD FOR THE CONDITION REQUESTED TO BE ADDED THAT IS RECOMMENDED BY THE *DEPARTMENT* WHO MEETS APPROPRIATE QUALIFICATIONS WITH NO OBJECTIVE EVIDENCE OF BIAS.

 - iii. ONE PHYSICIAN WHO RECOMMENDS MEDICAL MARIJUANA IN HIS OR HER PRACTICE, WHO MAY BE RECOMMENDED BY THE PETITIONER;

 - iv. ONE EXPERT IN ADDICTION MEDICINE; AND

 - v. THE STATE CHIEF MEDICAL OFFICER

 - c. THE AD HOC MEDICAL ADVISORY PANEL SHALL REVIEW THE PETITION INFORMATION PRESENTED TO THE DEPARTMENT AND ANY FURTHER MEDICAL RESEARCH RELATED TO THE CONDITION REQUESTED, AND MAKE RECOMMENDATIONS TO THE EXECUTIVE DIRECTOR, OR HIS OR HER DESIGNEE, REGARDING THE PETITION.

 - d. IF THE DEPARTMENT IS UNABLE TO RECRUIT PARTICIPANTS FOR THE AD HOC MEDICAL ADVISORY PANEL, THE DEPARTMENT SHALL SEEK INFORMAL CONSULTATION FROM INDIVIDUALS MEETING THE CRITERIA LISTED IN THIS PARAGRAPH (2)(a).
3. DEPARTMENT DENIAL OF PETITIONS.
- a. THE DEPARTMENT SHALL DENY A PETITION TO ADD A DEBILITATING MEDICAL CONDITION WITHIN (180) DAYS OF RECEIPT OF SUCH PETITION WITHOUT ANY HEARING OF THE BOARD IN ALL OF THE FOLLOWING CIRCUMSTANCES:
 - i. IF THERE ARE PEER-REVIEWED PUBLISHED STUDIES WHERE A RESEARCHER CONCLUDES THAT MARIJUANA USE IS OR COULD BE HARMFUL TO A PERSON WITH THE CONDITION THAT IS THE SUBJECT OF THE PETITION, AND

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NO PEER-REVIEWED PUBLISHED STUDIES OF
RANDOMIZED CONTROLLED STUDIES SHOWING
EFFICACY IN HUMANS.

- ii. IF THERE ARE PEER-REVIEWED STUDIES SHOWING EFFICACY IN HUMANS FOR THE CONDITION THAT IS THE SUBJECT OF THE PETITION, IF THERE ARE STUDIES THAT SHOW HARM AND THERE ARE ALTERNATIVE, CONVENTIONAL TREATMENTS AVAILABLE FOR THE CONDITION.
 - iii. IF THE PETITION SEEKS THE ADDITION OF AN UNDERLYING CONDITION FOR WHICH THE ASSOCIATED SYMPTOMS THAT ARE ALREADY LISTED AS DEBILITATING MEDICAL CONDITIONS FOR WHICH THE USE OF MEDICAL MARIJUANA IS ALLOWED, SUCH AS SEVERE PAIN, ARE THE REASON FOR WHICH MEDICAL MARIJUANA IS REQUESTED, RATHER THAN FOR IMPROVEMENT OF THE UNDERLYING CONDITION.
- d. THE DEPARTMENT SHALL DENY A PETITION TO ADD A DEBILITATING MEDICAL CONDITION WITHIN (180) DAYS OF RECEIPT OF SUCH PETITION IF A MAJORITY OF THE AD HOC MEDICAL ADVISORY PANEL RECOMMENDS DENIAL OF THE PETITION.
4. DEPARTMENT REQUESTS FOR RULEMAKING HEARINGS ON PETITIONS TO ADD DEBILITATING MEDICAL CONDITIONS. WITHIN (120) DAYS OF RECEIPT OF A PETITION TO ADD A DEBILITATING MEDICAL CONDITION, THE DEPARTMENT SHALL PETITION THE BOARD FOR A RULEMAKING HEARING TO ADD THE CONDITION TO THE LIST OF DEBILITATING MEDICAL CONDITIONS IN ALL OF THE FOLLOWING CIRCUMSTANCES:
- a. IF THERE IS PUBLISHED EVIDENCE OF EFFICACY IN HUMANS FROM RANDOMIZED CONTROLLED TRIALS AND NO PUBLISHED EVIDENCE OF HARMS TO PERSONS WITH THE CONDITION.
 - b. IF THE AD HOC MEDICAL ADVISORY PANEL RECOMMENDS APPROVAL OF THE PETITION TO ADD THE CONDITION.
5. FINAL AGENCY ACTION. THE FOLLOWING ACTIONS ARE FINAL AGENCY ACTIONS, SUBJECT TO JUDICIAL REVIEW PURSUANT TO C.R.S. § 24-4-106:
- a. DEPARTMENT DENIALS OF PETITIONS TO ADD DEBILITATING MEDICAL CONDITIONS.
 - b. BOARD OF HEALTH DENIALS OF RULES PROPOSED BY THE DEPARTMENT TO ADD A CONDITION TO THE LIST OF DEBILITATING MEDICAL CONDITIONS FOR THE MEDICAL MARIJUANA PROGRAM.