

**DRAFT**  
**REGULATORY ANALYSIS**  
for

**Proposed Amendments to Rules and Regulations Pertaining to  
Medical Use of Marijuana (5 CCR 1006-2), Regulation 6 – Debilitating Medical Conditions and  
the Process for Adding New Debilitating Medical Conditions  
August 18, 2010**

- 1. A description of the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.**  
Patients and physicians who have submitted a petition to have a condition added to the list of debilitating medical conditions for the Medical Marijuana Registry.
- 2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.**  
This proposed rule formalizes the department’s process of reviewing petitions to add debilitating medical conditions to the Medical Marijuana Registry. The department would solicit input from an ad hoc medical advisory panel in instances where the condition that is the subject of the petition is both supported by peer-reviewed randomized controlled studies showing efficacy in humans, as well as peer-reviewed published evidence of harms other than those associated with smoking, and for which there are no alternative, conventional treatments for the condition. The proposed rule further establishes when the department shall deny petitions to add debilitating medical conditions without benefit of a rulemaking hearing. Finally, the proposed rule specifies when an action of the department or Board of Health with respect to a petition constitutes final agency action subject to judicial review. As this proposed rule is procedural in nature, the department does not anticipate any change in the number of petitions to add debilitating medical conditions.
- 3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.**  
The Medical Marijuana Registry may see an increase in applications with the expansion of the number of qualifying debilitating medical conditions. The Medical Marijuana Registry has no way to estimate how many new applications may be received based upon this change, but anticipates that the application fees will be sufficient to cover the costs of the increased number of applications.
- 4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.**  
Article XVIII, Section 14 of the Colorado Constitution requires the state health agency responsible for administration of the Medical Marijuana Registry to accept petitions from patients and physicians to add debilitating medical conditions to the list of qualifying debilitating medical conditions for the program, either approve or deny such petitions with (180) days of receipt, and set a rulemaking hearing if the state health agency deems such hearing to be appropriate. C.R.S. § 25-1-106 tasks the department with administering the Medical Marijuana

Registry. Setting forth in rule the process by which debilitating medical conditions may be added to the Medical Marijuana Registry provides petitioners with certainty about the methods used by the department in reviewing and deciding upon their petitions. While the Colorado Constitution does not require rulemaking to establish this review process, failure to promulgate rules could lead to uncertainty amongst those interested in petitioning to add debilitating medical conditions in regard to the process they must follow and the standard that must be met. The department anticipates minimal costs associated with this proposed rule, to the extent that ad hoc medical advisory committees must be convened to review specific petitions.

**5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.**

The department considered continuing to review petitions to add debilitating medical conditions in accord with its policy for such review, but determined that promulgating rules provided more certainty to the regulated community as to the process for such review.

**6. A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule.**

As described above, the rules proposed establish a procedural framework for the review and determination of approval or denial for petitions to add conditions to the list of debilitating medical conditions for which an individual can apply to the Medical Marijuana Registry. The only alternative method considered was to continue reviewing petitions in accord with department policy, and the department chose not to do so in order to provide certainty to the process of reviewing petitions.

**7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.**

The department considered receipt of past petitions, and the potential for future petitions, to add debilitating medical conditions to the Medical Marijuana Registry, and determined that setting forth a one process that applied to all petitions received, approved by the Board of Health, would best serve the interests of both the petitioners and the department.