

DRAFT
STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY 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

Basis and Purpose.

The Colorado Department of Public Health and Environment (department) is the state health agency responsible for the administration of the medical marijuana registry. Pursuant to Article XVIII, Section 14 of the Colorado Constitution, the department must accept or deny petitions from patients and physicians to add debilitating medical conditions to the list of conditions for which an applicant may submit an application to the medical marijuana registry for a medical marijuana registration card. The department has received several petitions to add debilitating medical conditions since the inception of the registry in 2000, and to date has referred one such petition for rulemaking to the Board of Health, namely, a petition to add Tourette's syndrome as a debilitating medical condition. The department seeks to implement through rules the process by which such petitions are reviewed and either brought before the Board of Health for rulemaking, or else denied.

Specific Statutory Authority.

These rules are promulgated pursuant to the following statutes:
C.R.S. § 25-1.5-106 and Colo. Constitution article XVIII, section 14.

Major Factual and Policy Issues Encountered.

The department has developed a process of reviewing petitions to add debilitating medical conditions to the list of conditions that may qualify an applicant for the medical marijuana registry, and seeks to now formalize that process through rule. The Colorado Constitution requires that the department determine which petitions to add debilitating medical conditions should be brought before the Board of Health for rulemaking. Until recently, the department had not received any petitions for which it determined that rulemaking was appropriate. At this time, a petition to add Tourette's syndrome is pending before the Board.

The proposed rules require that a petition to add a debilitating medical condition have scientific evidence of efficacy in order to be added to the list of debilitating medical conditions for the program. Specifically, the department will search medical literature for peer-reviewed published literature of randomized controlled trials concerning the use of marijuana for the condition that is the subject of the petition. The department will convene an ad hoc medical advisory panel for further review and advice when there are both peer-reviewed published evidence of efficacy in humans and peer-reviewed evidence of harms other than those associated with smoking, and there are no alternative, conventional treatments for the condition. The ad hoc medical advisory panel shall make recommendations to the executive director, and the executive director shall determine whether to request a rulemaking hearing to add the condition.

The proposed rules also set the parameters concerning when a petition to add a debilitating medical condition shall be denied by the department without benefit of a hearing by the Board of Health. Denials of petitions are final agency action subject to judicial review.

Alternative Rules Considered and Why Rejected.

No alternative rules were considered.