



## **Challenging Proposed Regulations for Lack of Necessity**

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One way to challenge California's proposed medical cannabis regulations is to argue that the record of rule making fails to establish the need for a particular regulation.

California Government Code § 11349(a) defines **necessity** in the context of proposed regulations: "Necessity" means the record of the rulemaking proceeding demonstrates by substantial evidence the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific, taking into account the totality of the record. For purposes of this standard, evidence includes, but is not limited to, facts, studies, and expert opinion."

In other words, if the record of the rule making proceeding fails to show, by substantial evidence, the need for a particular regulation, that regulation is susceptible to a necessity challenge.

For an example of a proposed California medical cannabis regulation which may be susceptible to a necessity challenge, the manufacturing ISOR does little to establish the necessity of the categorical prohibition on cannabis-infused caffeine products set forth in proposed Section 40300. The ISOR states:

"The recommendation that caffeine not be allowed as an additive comes from the FDA determination that caffeine (stimulant) in certain alcoholic (depressant) beverages is an "unsafe food additive" due to the unpredictable negative effects of the two substances. The mixing of stimulants with depressants may lead to dangerous cardiac events. A similar lack of definitive information exists as well for the safety of caffeine as an additive to cannabis."

The ISOR cites no facts, studies, or expert opinions to establish the necessity of the ban on caffeine, and the record of the rule making proceeding at this juncture appears insufficient to establish by substantial evidence the necessity of a categorical prohibition on caffeine.

Another example is the ten-foot outdoor "canopy" separation in proposed Section 8000(d)(3). The proposed section reads: "Canopy may be noncontiguous but each unique area included in the total canopy calculation shall be separated by an identifiable boundary such as an interior wall or by at least 10 feet of open space." The ten feet seems arbitrary, and the ISOR does not indicate that alternatives were considered or cite any facts or studies which would support the necessity of a ten-foot separation.

Comments submitted to the regulating agencies should be specific and raise necessity challenges where appropriate. If you have questions about the administrative rulemaking process, the public comment period, the proposed regulations in general, or the permitting and licensing process, please contact our office at (707) 829-0215.

*The above information is provided for informational purposes only and is not intended as legal advice.  
Please contact a lawyer for legal counsel.*

*If you would like legal assistance in advocating for changes to the proposed regulations,  
please get in touch with us at (707) 829-0215 or at (415) 489-0420.*