

September 13, 2021

Dear Members of Interim Rules Review Committee:

Thank you for the opportunity to present the Department of Health's (DOH) proposed rules to establish and implement a medical cannabis program in South Dakota to the Interim Rules Review Committee. As I am sure you can appreciate, the rules represent months of work between the DOH, patients, the industry, and interested stakeholders to develop rules that represents the will of the voters to provide for access to medical cannabis while ensuring the program protects the health and safety of South Dakotans.

The DOH appreciated the opportunity to meet with staff from the Legislative Research Council (LRC) as the rules were developed to address their questions and concerns. This letter is in response to the recommendations made by LRC staff on September 7th to the final rules presented to the Interim Rules Review Committee. In addition to the technical corrections noted, the DOH also made the revisions below.

Use of Term "Cannabis Extract" – LRC indicates that they recommended that the reference to "cannabis extract" be struck in any list with "cannabis products," because SDCL 34-20G-1(3) defines "cannabis extract" as a "cannabis product" and to split them out separately suggests that "cannabis extract" is not a "cannabis product". (§§ 44:90:01:01 (pgs. 4-6, 44:90:04:12 (pg. 48), 44:90:04:14 (pg. 50), 44:90:04:19 (pg. 52), 44:90:04:20 (pg. 53), 44:90:04:21 (pg. 54), 44:90:04:22 (pg. 54), 44:90:04:23 (pg. 55), 44:90:09:08 (pg. 89), 44:90:10:08 (pg. 98), and 44:90:10:13 (pg. 100))

DOH Response: LRC's initial recommendation on August 9th was as stated "[a] revision should be made so that "cannabis extract" and "concentrated cannabis" do not overlap in their definitions and then appropriate changes made when these terms are used throughout the article." The DOH modified the definitions of both "cannabis extract" and "concentrated cannabis" in response to this recommendation. LRC's subsequently recommended that the reference to "cannabis extract" be struck. While the DOH believes the use of the term "cannabis extracts" provides needed clarity to ensure the industry and patients have a clear understanding of what constitutes a cannabis product, the reference has been struck.

Practitioner Authorization for Home Cultivation by Patients and Caregivers – LRC staff have stated that SDCL 34-20G-29 and 34-20G-72(5) are not sufficient authority to require practitioners to authorize patients and caregivers to cultivate cannabis and that the "health and safety regulations" cited by the DOH are limited to medical cannabis establishments. (§§ 44:90:02:03 (pg. 12-13), 44:90:02:06 (pg. 15), 44:90:02:08 (pg. 17))

DOH Response: The DOH believes a plain reading of the statute provides the general authority for this rule. SDCL 34-20G-72(4) provides the DOH the authority "[g]overning the manner in which the department shall consider applications for and renewals of registry identification cards, that may include creating a standard written certification form." ARSD 44:90:02:03 governs what information will be required to be completed by the physician on the practitioner's certification form. Additionally, the DOH's authority must be read in conjunction with SDCL 34-20G-1(1)(c) which provides that for home cultivation, an "allowable amount" is "three cannabis plants minimum or as prescribed by a physician;". This rule is detailing the information that will be required on the certification form if home grown is indicated. We have updated the general authority accordingly.

While the vast majority of LRC staff comments from August 9th and September 7th were incorporated, there are several areas where the DOH differs with LRC and we formally appeal to the Interim Rules Review Committee to make a final determination. The LRC objections and the DOH response are summarized below.

Program Fees – LRC Fiscal staff believe that because revenues exceed expenditures, particularly in year 2 and ongoing, that the fee turns into a tax that the DOH cannot impose. (§§ 44:90:02:19 (pgs. 23-34) and 44:90:03:17 (pg. 40))

DOH Response: SDCL 34-20G provides the Department of Health with clear authority to establish fees related to the medical cannabis program and the statute in no way prohibits total fees from generating projected revenue that is greater than the projected expenses, particularly in the case of a newly established program.

- SDCL 34-20G-72(10)(a) states “[a]pplication fees for medical cannabis establishments may not exceed five thousand dollars, with this upper limit adjusted annually for inflation[.]” In addition, SDCL 34-20G-72(10)(b) states “[t]he total fees collected shall generate revenues sufficient to offset all expenses of implementing and administering this chapter[.]”
- SDCL 34-20G-72(10)(d) states “[t]he fees charged to qualifying patients, nonresident cardholders, and caregivers shall be no greater than the costs of processing the application and issuing a registry identification care or registration[.]”. Total program expenditures estimated for year 1 are \$1,367,609. Removing the “Seed to Sale” costs (\$303,500) and the Inspection Pool costs (\$421,140) leaves expenditures of \$642,969 for the remainder of the program. During year 1, the DOH estimates that \$353,633 (55%) of the remaining expenditures will support administration of the patient/caregiver card process which will be offset by the \$355,865 in estimated revenue from patient/caregiver fees.

As we have shared with LRC Fiscal staff throughout the process, all of the assumptions related to program expenditures and revenues are based on information that we have at this time based on experiences in other states. These assumptions will be refined as the program is implemented and we have South Dakota-specific data to make more accurate projections. Given this is a new program in an entirely new industry in the state, the DOH anticipates there will be differences in the projected vs. actual revenues received and we believe it makes sense to err on the side of ensuring revenues are sufficient to offset expenses. The DOH will assess expenditures and revenues after year 1 and make any adjustments necessary in year 2.

Disqualifying Felony Offense by Principal Officers and Board Members – LRC contends that “disqualifying felony offense” applies only to employees of establishments, not “principal officers or board members” as DOH provided for in § 44:90:03:14 and that the DOH response (that this information would be used to score the application was insufficient because the scoring rule (§ 44:90:03:15(3)) only addresses nonviolent crimes (e.g., fraud, false statements). (§ 44:90:04:14 (pg. 37))

DOH Response: The DOH disagrees with this interpretation. SDCL 34-20G-72(3)(c) provides the DOH with rulemaking authority to analyze, “[t]he character, veracity, background, qualifications, and relevant experience of principal officers and board members”. An inquiry into an individual’s criminal history is clearly within the scope of assessing the “character,” “veracity,” or “background” of one involved in a medical cannabis business. The DOH firmly believes that prohibiting principal officers and board members from having a felony offense is an integral part of ensuring a safe and effective medical cannabis program in South Dakota.

Inspection of Vehicles Transporting Cannabis – LRC contends that SDCL 34-20G-69 related to inspections applies to establishments only during business hours and does not apply to vehicles transporting medical cannabis. (§ 44:90:04:22 (pg. 54))

DOH Response: The DOH disagrees with this interpretation. The transport of medical cannabis is done under the auspices of a licensed establishment to another licensed establishment. The vehicle being used is property that is part of the establishment’s operation and is subject to the same regulation as any other “brick and mortar” part of the establishment. To suggest otherwise defeats the purpose of establishment inspections. In DOH’s view, any time an establishment’s vehicle is transporting cannabis it would clearly be doing so during the course of that establishment’s business and thus during “business hours.” Clearly, it would therefore be subject to inspection.

Debilitating Medical Condition – LRC believes the DOH did not follow the petition process required by 34-20G-26 and 34-20G-72(1) when adding additional qualifying medical conditions including public notice and an opportunity to comment in public hearings on the petitions and that the DOH does not have a rule that specifies the public notice required for the public hearing. (§§ 44:90:13:01 (pg. 122) and 44:90:13:03 (pgs. 123-124))

DOH Response: The DOH disagrees. To remove the list from the current proposed rules will unnecessarily delay access to medical cannabis to qualified patients. The DOH released a draft of the administrative rules on June 24, 2021 to the public and hosted two tele-townhalls to receive public input on the draft. The tele-townhalls were advertised throughout the state and over 254 individuals participated. The vast majority of those participating were advocating for the addition of specific conditions to the list of debilitating medical conditions. Based on comments received, the DOH revised the list of conditions in § 44:90:13:01. On July 27, 2021, the DOH initiated the formal rules promulgation process and the public had the opportunity to provide input on the revised list of condition as part of the public hearing required by SDCL 1-26. In addition, the DOH added

language to the proposed rules indicating the addition of other debilitating conditions would be done through the rules promulgation process, which by law includes a required public notice and hearing. The DOH believes we have met both the intent and letter of the law with an approach that is patient-focused and responsive to their hope for immediate relief through South Dakota's medical cannabis program.

Thank you again for the opportunity to respond. We appreciate the Rules Review Committee's favorable consideration of the state's medical cannabis program rules so that patients can access medical cannabis consistent with the requirements of SDCL 34-20G.

Sincerely,



Kim Malsam-Rysdon
Secretary of Health

cc: Justin Goetz, Code Counsel