

FORM 14**REGULATORY IMPACT ANALYSIS**

1. Specify the content revised in this rulemaking by ARSD article, chapter, and section following the examples provided below; if essentially revising an entire article or chapter, just specify the article or chapter:

NEW	AMENDING	REPEALING
44:90:01:01 (24)	44:90:01:01 (5), (7), (14), (15), (40)	
	44:90:02:07	
	44:90:02:10	
	44:90:02:11	
	44:90:02:12	
	44:90:02:13	
	44:90:02:15	
	44:90:02:17	
	44:90:03:02	
	44:90:03:05	
	44:90:03:07	
	44:90:03:16	
	44:90:04:08	
	44:90:04:09	
	44:90:04:10	
	44:90:04:13	
	44:90:04:14	
	44:90:04:15	
	44:90:04:16	
	44:90:04:19	
	44:90:04:20	
	44:90:04:26	
	44:90:06:01	
	44:90:06:04	
	44:90:06:05	
	44:90:06:07	
	44:90:07:04	
	44:90:08:03	
	44:90:09:02	
	44:90:09:06	
	44:90:09:07.01	
	44:90:09:11	
	44:90:10:01.01	
	44:90:10:04	
	44:90:11:06	
	44:90:12:03	
	44:90:12:11	

2. Does this rulemaking constitute a "major rule" pursuant to SDCL 1-26-1 (please check one below):

☒ No - please summarily explain: This rulemaking consists primarily of amendments to clarify existing rules and to match current program procedures.

☐ Yes - please summarily explain:

3. Does the rulemaking agency assert that the Legislature provided sufficient authority and intention for this proposed rulemaking to occur despite it being a major rule* (please check one below):

☒ No or Not Applicable.

☐ Yes - please provide a narrative explanation in support:

4. Provide a narrative explanation for the need for these proposed rules to be promulgated at this time; if the need is substantively different depending on the rule section(s) contained in this rulemaking, please give a more specific explanation of each need and specify the rule sections to which the explanation applies:

The Department of Health conducted an industry stakeholder meeting in October 2025 to hear feedback on the rules in chapter 44:90, including which rules need further clarification and which rules conflict with industry standards and current processes.

Additionally, the Department conducted an internal review of the rules to determine which rules need further clarification and which rules do not align with current industry standards and processes.

5. Has the rulemaking agency verified that the rule sections to be amended, created, or repealed in this rulemaking have sufficient General Authority (i.e., express statutory authority to promulgate rule in the given subject area) and the rule sections to be amended or created have sufficient Law Implemented (i.e., intelligible standards to guide the rulemaking):

☒ Yes - and we have no concerns.

☐ Yes - and there may be concerns with the following sections (list each section by section number and denote page number in packet, explaining the concern for each):

* The Legislature provides sufficient authority and intention for the proposed rulemaking to occur despite it being a major rule when the Legislature either (1) directs in statute the propounding of particular rule language; or (2) authorizes or requires that rule be propounded and that rule could not be reasonably executed in a manner that would place the rule below the major rule cost threshold.

6. Provide a narrative explanation of any alternative options and why they were not pursued in this rulemaking; please provide a bulleted list of each alternative (if there were no other alternatives, please explain why):

- No alternative exists. This rule change clarifies existing rules and amends them to match current practices and industry standards.

7. Estimate the primary or direct benefits of these proposed rules and provide the basis of the estimate, including any key assumptions and sources of uncertainty:

Primary benefits would be increased compliance with rules due to clarification and alignment with current practices.

8. Estimate the cost savings or financial benefits to businesses, individuals, other nongovernmental entities, or units of local government, as a result of these proposed rules and provide the basis of the estimate, including any key assumptions and sources of uncertainty:

The amendment to 44:90:12:11 changes the penalty for a first offense for a category 4 violation and category 5 violation from a fine to a corrective action plan. This saves businesses from paying a fine for the first offense in these categories.

9. Explain in detail the estimated costs of implementation or compliance incurred by or passed along to businesses, individuals, other nongovernmental entities, or units of local government, as a result of these proposed rules and provide the basis of the explanation, including any key assumptions and sources of uncertainty:

N/A- There is no cost associated with these rule changes.

10. Estimate the secondary or indirect costs for businesses, individuals, other nongovernmental entities, and units of local government, as a result of these proposed rules and provide the basis of the estimate, including any key assumptions and sources of uncertainty:

N/A- There is no cost associated with these rule changes.

11. Estimate the opportunity cost of compliance as a result of the removal of private capital from the market brought on by these proposed rules and provide the basis of the estimate, including any key assumptions and sources of uncertainty:

N/A

12. List the sources consulted in preparing this regulatory impact analysis:

Department of Health staff

13. Describe the proposed rules' impact on small businesses (i.e., 25 or fewer FTEs) by:

a. Specifying what type of small businesses are likely to be impacted:

Medical Cannabis businesses, including cultivators, manufacturers, testing facilities, and dispensaries

b. Estimating the number of small businesses that would be impacted (check one):

☐ 1-99 ☒ 100-499 ☐ 500-999 ☐ 1,000-4,999 ☐ More than 5,000

☐ Unknown - please briefly explain:

c. Providing a description of any of the impacts of the proposed rules that uniquely impact small businesses:

Medical cannabis businesses are already complying with the rules of this chapter. These rule updates do not add burden or costs as they are not additional requirements.

d. Projecting whether there are any recordkeeping or reporting requirements as a result of these proposed rules:

☐ Yes ☒ No

i. If "yes," how many annual reports must a small business submit to the state:

ii. If "yes," how much ongoing recordkeeping within the business is necessary:

iii. If "yes," what type of professional skills would be necessary to prepare the reports or records (check one):

☐ The average owner of a small business should be able to complete the reports or records with no assistance.

☐ It is likely that a bookkeeper for a small business should be able to complete the reports or records.

☐ It is likely that a small business person would need the assistance of a CPA to complete the reports or records.

☐ It is likely that a small business person would need the assistance of an attorney to complete the reports or records.

☐ Unknown or other - please explain:

August 19, 2016
[Date]

[Authorized Signatory - Chief Officer of Rulemaking Agency]

Department of Health
[Rulemaking Agency Name]