Red Tape Review Rule Report
(Due: September 1, 2023)

Department Name:	Health & Human Services (HHS)	**Date:**	9/1/2023	**Total Rule Count:**	74
IAC #:	641	**Chapter/ SubChapter/ Rule(s):**	154	**Iowa Code Section Authorizing Rule:**	124E
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PLEASE NOTE, THE BOXES BELOW WILL EXPAND AS YOU TYPE

What is the intended benefit of the rule?

This rule chapter implements a medical cannabidiol program for the in-state manufacture and dispensing of medical cannabis products for patients with qualifying debilitating medical conditions. Registration cards to purchase at a dispensary in Iowa are issued to patients who are at least eighteen years of age, permanent residents of Iowa, and for whom a health care practitioner determines suffer from a medical condition that qualifies for use of medical cannabidiol. Registration cards may also be issued to the primary caregivers of such patients.

The rule chapter defines licensing requirements for medical cannabidiol manufacturers and dispensaries, fees for application and licensure, safety protocols, marketing and advertising restrictions, and limits on manufacturing and dispensing. Manufacturers may only manufacture products in the forms recommended by the Medical Cannabidiol Board and approved by the Board of Medicine. The General Assembly maintains sole authority to revise the definition of medical cannabidiol.

HHS maintains a secure sales and inventory tracking system available to dispensaries 24 hours a day, seven days a week for the purpose of verifying that a person is lawfully in possession of a registration card and for tracking the date of the sale and quantity purchased. This system tracks products and inventory from creation by a manufacturer, transfers for testing and delivery, dispensing at a dispensary, and chain of custody; or "seed-to-sale."

Is the benefit being achieved? Please provide evidence.

Figures below are actuals incurred in the fiscal years shown.

Identified Impacts*

	SFY2019	SFY2020	SFY2021	SFY2022	SFY2023	5 Year Total
Costs						
HHS Implementation	$627,000	$898,000	$813,000	$809,000	$909,000	$4.056M
Benefits						
Registration Card Fees	$157,000	$305,000	$446,000	$827,000	$1,330,000	$3.065M
License & Application Fees	$675,000	$400,000	$333,000	$220,000	$125,000	$1.753M
Improved Outcomes for Patients	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative
Improved Public Health & Safety	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative
Net Value	+ $205,000	- $193,000	- $34,000	+ 238,000	+ 546,000	+ $762,000

*All monetary figures have been rounded to the nearest thousandth.
HHS has not conducted an observational study on patient outcomes. HHS focuses on customer service metrics, and strategies for improving the registration experience and processing time, which averages <1 day from submission to approval. Patient outcomes can also improve by reducing the cost of participation, by reducing compliance and regulatory costs, and annual license fees to the industry.

The physical security requirements, manufacturer and dispensary data requirements, testing protocols, and other safeguards defined in this rule chapter ensure medical cannabidiol facilities operate in a manner protective of public health and safety.

What are the costs incurred by the public to comply with the rule?

The Medical Cannabidiol Act is a fee-based program, receives no appropriation, and does not incur a specific cost on the public. The program is funded by license application and annual fees from manufacturers and dispensaries, and patient and caregiver application fees.

Licensed facilities pay an annual fee to the department to cover costs associated with regulation, inspection, and other expenses necessary for the administration of the program, which have been reduced each year. License Application and Annual Fee revenues are reflected in the table above. Patients issued registration cards are charged a fee of $100 per patient card, and primary caregivers are charged $25. Registration cards expire one year from the date of issuance. This revenue is reflected in the table above as “Registration Card Fees”.

What are the costs to the agency or any other agency to implement/enforce the rule?

HHS incurs personnel costs for team members to support the regulation of the medical cannabidiol program. Additional expenses are incurred, mainly IT and software, to also support the regulation of the program and registration of patients and caregivers. These costs are reflected in the table above as “HHS Implementation”.

The Iowa Department of Public Safety (DPS) incurs costs to conduct background investigations to support licensure of manufacturers and dispensaries, and are paid by the industry to conduct necessary background checks. There are unknown costs to law enforcement for education and training on medical cannabis. These costs are unknown and not reflected in the table above.

Do the costs justify the benefits achieved? Please explain.

The cost benefit analysis above reflects a net value of +$762,000 for FY19-FY23 and indicates improved outcomes for patients with qualifying medical conditions, and the industry that serves them. By investing in scalable IT solutions early on, the program has been able to limit traditional expenses as volume and revenue have increased.

Eliminating this rule chapter would prohibit existing medical cannabidiol manufactures and dispensaries of medical cannabidiol in Iowa from conducting legal business, remove the procedural clarification of administrative rule to support the program, and introduce general and widespread regulatory uncertainty. This would create confusion among licensed entities, and possibly the misapplication of state law. This could result in adverse health impacts for patients by eliminating their safe and legal access to products for the treatment of their qualifying condition.

Are there less restrictive alternatives to accomplish the benefit? ☒ YES ☐ NO
If YES, please list alternative(s) and provide analysis of less restrictive alternatives from other states, if applicable. If NO, please explain.

HHS implements the medical cannabidiol program in accordance with requirements of Iowa Code; overall, HHS implements the program as prescribed and has limited latitude in determining regulatory requirements. The Department maintains flexibility and authority for:

- Setting sampling protocols and testing procedures for the testing of medical cannabidiol produced;
- Determining the frequency of inspection of licensed facilities;
- Determining the method, type, and frequency of certain operational data;
- Setting specific criteria for the implementation of safety requirements; and
- Setting reasonable restrictions related to marketing, signage, display, packaging, and advertising of medical cannabidiol.

HHS believes the regulatory approach defined in this rule chapter is at the level necessary to ensure public health and safety. Should adjustments be made, less restrictive alternatives might include:

- Adjust sampling protocols to sample less frequently and/or sample for fewer contaminants;
- Inspect facilities less often than annually or on an ad hoc basis;
- Reduce the number or type of required safety elements such as physical property security systems and chain of custody;
- Reduce the manufacturing and dispensary data required to be transmitted to HHS; or
- Reduce restrictions related to marketing and other advertising of medical cannabidiol.

Does this chapter/rule(s) contain language that is obsolete, outdated, inconsistent, redundant, or unnecessary language, including instances where rule language is duplicative of statutory language? [list chapter/rule number(s) that fall under any of the above categories]

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This chapter contained both duplication with statutory language and duplication across the chapter itself. This second category of duplication was corrected by reorganizing the chapter to merge duplicate content and create an ease of flow to the information provided.

All rules in this chapter fall under this category: 154.1-154.76

RULES PROPOSED FOR REPEAL (list rule number[s]):

The reorganized content consists of 52 rules. Accordingly HHS seeks to repeal rules 154.53-154.76.

RULES PROPOSED FOR RE-PROMULGATION (list rule number[s] or include text if available):
154.1-154.52

For rules being re-promulgated with changes, please attach a document with suggested changes, if available.

METRICS

Total number of rules repealed:	24
Proposed word count reduction after repeal and/or re-promulgation	12,964
Proposed number of restrictive terms eliminated after repeal and/or re-promulgation	231

ARE THERE ANY RULES YOU WOULD RECOMMEND BE CODIFIED IN STATUTE?
None identified.