

Department of Health
Revised Statement Of Estimated Regulatory Costs (SERC)

Division: Office of Compassionate Use

Board:

Rule Number: 64-4.002

Rule Description: Initial Application Requirements for Dispensing Organizations

Contact Person: Patricia Nelson

Please remember to analyze the impact of the rule, NOT the statute, when completing this form.

A. Is the rule likely to, **directly or indirectly**, have an adverse impact on economic growth, private-sector job creation or employment, or private-sector investment in excess of \$1 million in the aggregate within 5 years after the implementation of the rule?

- | | | |
|--|------------------------------|------|
| 1. Is the rule likely to reduce personal income? | <input type="checkbox"/> Yes | X No |
| 2. Is the rule likely to reduce total non-farm employment? | <input type="checkbox"/> Yes | X No |
| 3. Is the rule likely to reduce private housing starts? | <input type="checkbox"/> Yes | X No |
| 4. Is the rule likely to reduce visitors to Florida? | <input type="checkbox"/> Yes | X No |
| 5. Is the rule likely to reduce wages or salaries? | <input type="checkbox"/> Yes | X No |
| 6. Is the rule likely to reduce property income? | <input type="checkbox"/> Yes | X No |

Explanation: The new regulatory structure established by this rule and the statute upon which it is based should have a positive impact on all of the items in this category.

If any of these questions are answered "Yes," presume that there is a likely and adverse impact in excess of \$1 million, and the rule must be submitted to the legislature for ratification.

B. Is the rule likely to, **directly or indirectly**, have an adverse impact on business competitiveness, including the ability of persons doing business in the state to compete with persons doing business in other states or domestic markets, productivity, or innovation in excess of \$1 million in the aggregate within 5 years after the implementation of the rule?

1. Is the rule likely to raise the price of goods or services provided by Florida business?
- Yes X No

Department of Health
Revised Statement Of Estimated Regulatory Costs (SERC)

2. Is the rule likely to add regulation that is not present in other states or markets?

Yes X No

3. Is the rule likely to reduce the quantity of goods or services Florida businesses are able to produce, i.e. will goods or services become too expensive to produce?

Yes X No

4. Is the rule likely to cause Florida businesses to reduce workforces?

Yes X No

5. Is the rule likely to increase regulatory costs to the extent that Florida businesses will be unable to invest in product development or other innovation?

Yes X No

6. Is the rule likely to make illegal any product or service that is currently legal?

Yes X No

Explanation: The answer to Question 2 could be yes, but only because the statute, and by extension the rule, are allowing activities that have previously been illegal in Florida and is still illegal in many other states. That fact necessitates regulation that is not present in other states. Given the new opportunities being created, the new regulations do not impact the competitiveness of Florida businesses.

If any of these questions are answered "Yes," presume that there is a likely and adverse impact in excess of \$1 million, and the rule must be submitted to the legislature for ratification.

C. Is the rule likely, **directly or indirectly**, to increase regulatory costs, including any transactional costs (see F below for examples of transactional costs), in excess of \$1 million in the aggregate within 5 years after the implementation of this rule?

1. Current one-time costs	0
2. New one-time costs	915,945
3. Subtract 1 from 2	915,945
4. Current recurring costs	0
5. New recurring costs	0
6. Subtract 4 from 5	0

Department of Health
Revised Statement Of Estimated Regulatory Costs (SERC)

7. Number of times costs will recur in 5 years	0
8. Multiply 6 times 7	0
9. Add 3 to 8	915,945

If 9. is greater than \$1 million, there is likely an increase of regulatory costs in excess of \$1 million, and the rule must be submitted to the legislature for ratification.

D. Good faith estimates (numbers/types):

1. The number of individuals and entities likely to be required to comply with the rule.

15. This number was reached by consensus of the Negotiated Rulemaking Committee on February 5, 2015. The growers on the Committee decided, based on their knowledge of their respective regions, the likely requirements for approval as a dispensing organization, and the statutory requirements, that approximately 15 nurseries that meet the requirements of section 381.986(5)(b)1., Florida Statutes, would apply for Department approval.

2. A general description of the types of individuals likely to be affected by the rule.

Nurseries that meet the requirements of section 381.986(5)(b)1., Florida Statutes, which requires possession of a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to section 581.131, Florida Statutes, for the cultivation of more than 400,000 plants, operation by a nurseryman as defined in section 581.011, Florida Statutes, and operation as a registered nursery in this state for at least 30 continuous years.

E. Good faith estimates (costs):

1. Cost to the department of implementing the proposed rule:

None. The department intends to implement the proposed rule within its current workload, with existing staff.

Minimal. The Department has implemented this statute using existing resources. Upon receipt of initial application fees, the Department will continue its implementation of the statute using available resources. The majority of the Department's resources are only used at licensure and renewal, allowing the Department to make judicious use of resources.

Other. *(Please provide a reasonable explanation for the estimate used and methodology used for deriving the estimate).*

Department of Health
Revised Statement Of Estimated Regulatory Costs (SERC)

2. Cost to any other state and local government entities of implementing the proposed rule:

None. This proposed rule will only affect the department.

Minimal. *(Provide a brief explanation).*

Other. *(Please provide a reasonable explanation for the estimate used and methodology used for deriving the estimate).* Nothing in this regulatory structure requires implementation by other state and local government entities. If such entities choose to further regulate dispensing organizations, it is by choice and purely in addition to the state's regulation of dispensing organizations.

3. Cost to the department of enforcing the proposed rule:

None. The department intends to enforce the proposed rule within its current workload with existing staff.

Minimal. *(Provide a brief explanation).*

Other. *(Please provide a reasonable explanation for the estimate used and methodology used for deriving the estimate).*

4. Cost to any other state and local government of enforcing the proposed rule:

None. This proposed rule will only affect the department.

Minimal. *(Provide a brief explanation).*

Other. *(Please provide a reasonable explanation for the estimate used and methodology used for deriving the estimate).* See answer to E.2. above.

- F. Good faith estimates (transactional costs) likely to be incurred by individuals and entities, including local government entities, required to comply with the requirements of the proposed rule. *(Includes filing fees, cost of obtaining a license, cost of equipment required to be installed or used, cost of implementing processes and procedures, cost of modifying existing processes and procedures, additional operating costs incurred, cost of monitoring, and cost of reporting, or any other costs necessary to comply with the rule).*

None. This proposed rule will only affect the department.

Minimal. *(Provide a brief explanation).*

Department of Health
Revised Statement Of Estimated Regulatory Costs (SERC)

X Other. *(Please provide a reasonable explanation for the estimate used and methodology used for deriving the estimate).* See answer to C. above.

G. An analysis of the impact on small business as defined by s. 288.703, F.S., and an analysis of the impact on small counties and small cities as defined by s. 120.52, F.S. *(Includes:*

- *Why the regulation is needed [e.g., How will the regulation make the regulatory process more efficient? Required to meet changes in federal law? Required to meet changes in state law?];*
- *The type of small businesses that would be subject to the rule;*
- *The probable impact on affected small businesses [e.g., increased reporting requirements; increased staffing; increased legal or accounting fees?];*
- *The likely per-firm regulatory cost increase, if any).*

A small business is defined in Section 288.703, F.S., as "...an independently owned and operated business concern that employs 200 or fewer permanent full-time employees and that, together with its affiliates, has a net worth of not more than \$5 million or any firm based in this state which has a Small Business Administration 8(a) certification. As applicable to sole proprietorships, the \$5 million net worth requirement shall include both personal and business investments."

A small county is defined in Section 120.52(19), F.S., as "any county that has an unincarcerated population of 75,000 or less according to the most recent decennial census." And, a small city is defined in Section 120.52(18), F.S., as "any municipality that has an unincarcerated population of 10,000 or less according to the most recent decennial census."

The estimated number of small businesses that would be subject to the rule:

- 1-99 100-499 500-999
 1,000-4,999 More than 5,000
 Unknown, please explain:

X Analysis of the impact on small business: The impact of this rule on small business is largely the same as that on larger businesses. In this very specialized field, all businesses face tremendous risk that is not just financial. That risk is then augmented by the fact that the only businesses qualified are those that have been in business for at least 30 years with significant market recognition and good will at stake. Some impacts are greater for small business, i.e. the requirement of certified financials. Some impacts are lesser for small businesses, i.e. the difficulty retaining banking relationships, because the larger the business, the more likely it is to carry large amounts of debt. Overall, most impacts come from the statute, not the rule, and the impacts seem to be balanced vis-à-vis small and large businesses. Finally, the considerable interest in this opportunity exhibited by investors appears to be alleviating some of the financial impacts.

Department of Health
Revised Statement Of Estimated Regulatory Costs (SERC)

- There is no small county or small city that will be impacted by this proposed rule.
- A small county or small city will be impacted. Analysis:
- Lower impact alternatives were not implemented? Describe the alternatives and the basis for not implementing them.

H. Any additional information that the agency determines may be useful.

- None.
- Additional.

I. A description of any good faith written proposal for a lower cost regulatory alternative to the proposed rule which substantially accomplishes the objectives of the law being implemented and either a statement adopting the alternative or a statement of the reasons rejecting the alternative in favor of the proposed rule.

- No good faith written proposals for a lower cost regulatory alternative to the proposed rule were received.

X See attachment "A".

- Adopted in entirety.
- Adopted / rejected in part. *(Provide a description of the parts adopted or rejected, and provide a brief statement of the reasons adopting or rejecting this alternative in part).*

X Rejected in entirety. *(Provide a brief statement of the reasons rejecting this alternative).* The portion of the Lower Cost Regulatory Alternative that addresses the performance bond was rejected for four reasons: 1. The bond is a statutory requirement; 2. Any specific bond requirements placed in the bond form are not required as stated in rule 64-4.002(5)(g), Initial Application Requirements for Dispensing Organizations, therefore, any costs associated are not required; 3. The department believes that adding specific instances when the department could make a claim actually would reduce the cost of the bond by reducing uncertainty; and 4. The Final Order in the previous rule challenge clearly states that the two suggested claims, destruction of remaining product and selection of a new dispensing organization, would be unacceptable.

The portion of the Lower Cost Regulatory Alternative that addresses the application fee was rejected for two reasons: 1. The process suggested is far too speculative and uncertain to be feasible for both applicants. The department does not believe that eligible nurseries would put forth the significant effort

Department of Health
Revised Statement Of Estimated Regulatory Costs (SERC)

required by this application without knowing the application fee in advance. 2. The process suggested is far too speculative and uncertain to be feasible for the department. The department has used the most reliable information it has obtained to estimate the number of applicants. The eligible nurseries present at the negotiation helped reach the number used by the department. This number was based on the collective knowledge of all five regions by nurserymen from and with knowledge of those regions. The only other estimates the department has received are pure conjecture with no basis in fact. Because the department is statutorily required to set a fee “that is sufficient to cover the costs of administering [section 381.986, F.S.],” the department must use the most reliable method possible to set the application fee.

- See attachment “B”.
 - Adopted in entirety.
 - Adopted / rejected in part. *(Provide a description of the parts adopted or rejected, and provide a brief statement of the reasons adopting or rejecting this alternative in part).*
 - Rejected in entirety. *(Provide a brief statement of the reasons rejecting this alternative).*
- See attachment “C”.
 - Adopted in entirety.
 - Adopted / rejected in part. *(Provide a description of the parts adopted or rejected, and provide a brief statement of the reasons adopting or rejecting this alternative in part).*
 - Rejected in entirety. *(Provide a brief statement of the reasons rejecting this alternative).*
- See attachment “D”.
 - Adopted in entirety.
 - Adopted / rejected in part. *(Provide a description of the parts adopted or rejected, and provide a brief statement of the reasons adopting or rejecting this alternative in part).*
 - Rejected in entirety. *(Provide a brief statement of the reasons rejecting this alternative).*
- See attachment “E”.
 - Adopted in entirety.
 - Adopted / rejected in part. *(Provide a description of the parts adopted or rejected, and provide a brief statement of the reasons adopting or rejecting this alternative in part).*

Department of Health
Revised Statement Of Estimated Regulatory Costs (SERC)

Rejected in entirety. *(Provide a brief statement of the reasons rejecting this alternative).*

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Attachment A

February 26, 2015
Patricia Nelson, Director
Office of Compassionate Use
4052 Bald Cypress Way, Bin A-02
Tallahassee, Florida 32399-1703

Re: Statement of Estimated Regulatory Costs for Compassionate Medical Cannabis Act of 2014 Rules

Dear Ms. Nelson,

This letter represents a good faith proposal for a lower cost regulatory alternative under Florida Statute 120.541 to the Department's proposed rules implementing the Compassionate Medical Cannabis Act of 2014. This proposal is being submitted within 21 days after publication of the February 6 Notice of Proposed Rule.

Generally speaking, we would like to applaud the efforts of the Department of Health and your office. We realize that implementation of this important legislation is a daunting responsibility. Our comments are meant to help improve the process, not to condemn the progress that has been made thus far.

There are two specific areas that we would like to address:

\$5 Million Performance Bond

Although the requirement that a successful applicant post a \$5 million performance bond is contained in statute, the terms of the performance bond contained in proposed rule 64-4.002 and incorporated into Form DH8008-OCU-2/2015 unnecessarily increase regulatory costs for potential applicants. Specifically, the terms fail to specify with sufficient particularity the damages, costs, and expenses that will be covered by the bond and the specific activities that will trigger this coverage. This lack of specificity increases the risks undertaken by the surety and—necessarily—the cost of the performance bond to potential applicants.

This regulatory approach imposes significantly greater expenses on applicants than is necessary to accomplish the objectives of the statutory performance bond requirement. Finally, imposing unnecessary expenses on dispensing organizations will ultimately increase the cost of low-THC cannabis for qualified patients, which directly contradicts the objectives of the statute.

The financial impact of the proposed rule's bond language is magnified by the uncertainty surrounding the potential for use of low-THC cannabis at this point in time.

Two specific challenges and scenarios come to mind:

Attachment A

Scenario A – After the Department has approved a dispensing organization, the federal government changes its enforcement priorities and proceeds to shut down cannabis cultivation, processing, or dispensing facilities. The proposed rule would require revocation and forfeiture of the performance bonds of the approved dispensing organizations that, in good faith and in compliance with Florida law and *current* federal operating procedure, have sought to offer low-THC cannabis under the Act. The Department’s Form DH8008-OCU-2/2015 appears to contemplate this scenario when it refers to a requirement that dispensing organizations comply with “other applicable laws” for the duration of the bond’s effective period. We should also keep in mind that cannabis is still illegal under federal law and nothing prevents the federal government from enforcing the laws currently in its books.

The proposed rule should explicitly recognize that the performance bond will not be forfeited if a dispensing organization’s failure to perform results from a change in federal enforcement priorities where the dispensing organization is otherwise compliant with all state law requirements. If this scenario did occur, there would be a \$25 million dollar risk to the bond companies (from the revocation of 5 licenses). This good faith lower cost alternative would help to alleviate some of the risk, thereby reducing bond premiums for applicants and ultimately the cost of low-THC cannabis to qualified patients. This alternative would continue to achieve the objectives of the statute.

Scenario B – Low-THC cannabis proves to be medically unsatisfactory after further study and review, thus diminishing demand to a point that continuing to operate as a dispensing organization is not economically viable for an approved nursery.

Please note that we are firm believers in the potential of low-THC cannabis and would not otherwise be interested in pursuing a license. However, the research and science behind the efficacy of low-THC cannabis as a treatment is not established. If new studies determined definitively that low-THC cannabis was not beneficial to patients, demand could, in that scenario, drop to zero.

Under the current proposed rule, a nursery facing substantially decreased demand for low-THC cannabis would be required to pay a penalty of up to \$5 million to leave the business.

As a good faith lower cost regulatory alternative, the proposed rule should explicitly recognize that the performance bond will not be forfeited if a dispensing organization decides to voluntarily relinquish its license during the effective period where the dispensing organization is otherwise compliant with all state law requirements. This change would reduce the costs to applicants and dispensing organizations while still accomplishing the objectives of the statute.

Other Issues:

Attachment A

The proposed rule's terms regarding performance bonds should also be amended to clarify the "costs and expenses incurred by the Department attributable to retaining a replacement dispensing organization" that will be subject to the bond. The proposed rule states if the winning nursery fails to comply with a requirement at the outset, the next best scoring nursery will be awarded the contract. So, a new bidding process may not be required. If the rules were to specify that the next best scoring nursery will be awarded the contract in the event that a license is revoked, that would minimize taxpayer burden, ensure a quality and timely replacement, and limit the cost to applicants by lowering the cost of the bond. Perhaps this could be the mechanism within the first two years of the license, and then a new bidding process could occur if revocation occurs after that time period.

If a new bidding process is preferred, the Department of Health should be compensated for these costs as well as any third party expenses. If a new bidding process is required, for instance, at the time of renewal, then the proceeds from the bond can be used for these actual expenses.

The bond language in regard to increased costs for patients is also vague, thereby resulting in an increase in the bond premium. If a patient has an alternate source of medicine within 80 miles, is that considered an acceptable new source? It appears that all five of the licenses will be granted to nurseries that demonstrate their ability to supply medicine to patients on a statewide basis. Accordingly, it seems that patients will enjoy healthy competition and a variety of choices for their medical providers, and so the loss of a single provider would be negligible. Could the nursery that has its license revoked mitigate this damage by finding suitable replacement providers of the medicine for its base of patients? This entire provision seems unnecessary. By narrowing down the bond's liability in this instance or removing it in its entirety, a significant cost savings will be realized in the premium and that savings will be passed along to both the nursery owners and ultimately the patients.

Further, the provision that the bond will cover "All costs and expenses incurred by other DISPENSING ORGANIZATIONS attributable to adjusting cultivation, processing or dispensing operations to ensure patient access to low-THC cannabis necessitated by the revocation of PRINCIPAL'S license ..." is also vague and thereby will significantly drive up the cost of the premium. How is this need assessed? What if there is another dispensary within 80 miles? Again, the rule anticipates 5 different providers giving statewide coverage to patients. As well, if a competing nursery decides to step-up production to supply additional product, that nursery will be rewarded with additional sales and profits. It does not seem reasonable that the bond should pay the capital expenses of increasing a for-profit company's production capacity (buying greenhouses and machines) so that this company can then reap ongoing profits from that subsidy. This clause is vague, may not be in line with legislative intent, and certainly drives up the cost of the bond and the burden on the nurseries and cost of medicine to patients. This clause seems unnecessary; please consider removing it in its entirety.

Attachment A

And the clause that the bond will cover “All damages resulting from PRINCIPAL’S failure to comply with the requirements of Florida Law ...” again appears to be vague and will unnecessarily drive up expenses. Please consider narrowing this to specific requirements and to specific damages (or removing it in its entirety).

Also, it seems unreasonable to ask a bond company to agree to provide the same coverage even if the laws or rules change that govern the coverage and that could change the provisions that lead to revocation of a license:

"The SURETY hereby waives notice of and agrees that any changes in applicable Florida law and compliance or noncompliance with any formalities required thereby or the changes made thereto do not affect SURETY's obligation under this BOND."

The exposure to this unknown set of risks will necessarily drive up the cost of the bond.

We suggest adopting these good faith proposals for lower cost regulatory alternatives and reducing the liability of the surety to only ACTUAL costs incurred to:

- a) destroy remaining product, and to
- b) select a new dispensing organization

This would significantly reduce the bond premium while accomplishing the objectives of the statute. If these alternatives are not adopted, even a nursery with adequate collateral for the bond would be required to pay premiums of at least \$150,000 per year based on estimates from several bonding agents. The total adverse impact of this provision alone would be at least \$1.5 million (\$150,000 x 2 years x 5 dispensing organizations). Alternatively, dispensing organizations would face the opportunity cost, in real dollars, of tying up \$5 million in working capital during this time period (or if collateral is not available, the cost of having to borrow money to meet the collateral needs). These unnecessary regulatory costs would be avoided, while still accomplishing the objectives of the statute, if the Department adopts the good faith lower cost alternatives to the performance bond terms discussed above.

Application Fee

The Compassionate Medical Cannabis Act of 2014 requires the Department to impose an application fee to cover the costs of administering the law and the associated rules. Rather than imposing an arbitrary and potentially excessive amount for this fee, the Department should consider the following good faith lower cost regulatory alternative:

- 1) Estimating the costs of administering the statute; then
- 2) Accepting applications; then
- 3) Dividing the cost of administering the statute by the actual number of applications; then

Attachment A

4) Requiring all remaining applicants to pay their pro-rata share.

Should any applicants drop out after the fee is announced, then their pro-rata fees should be assessed against the remaining applicants so that the state is “made whole” for its estimated expenses. This can be repeated until the remaining applicants all submit an application fee that, cumulatively, covers the estimated costs of administering the statute.

The proposed rule’s requirement that each applicant submit a non-refundable fee of \$60,063 imposes unnecessary expense on the applicant. Under a conceivable scenario in which 50 nurseries apply, the application fees would total more than \$3,000,000—an amount that would greatly exceed the Department’s administrative costs (in contravention of the statutory requirement) and would raise additional procedural obstacles to implementation under Florida Statute 120.541(3). Because the Department cannot reasonably predict, in advance, how many nurseries will apply, it should adopt the good faith lower cost regulatory alternative proposed above. This alternative will achieve the objectives of the statute by allowing the Department to accurately cover its administrative expenses as required by law while also guaranteeing that applicants are not required to pay a higher application fee than necessary to cover the Department’s expenses.

Pursuant to Florida Statute 120.541, we respectfully submit these good faith lower cost regulatory alternatives for your consideration as we all work together to create a fair and cost effective system to provide the highest quality low-THC cannabis at the lowest expense to qualified patients in need in Florida.

Thank you again for your efforts with the Compassionate Medical Cannabis Act of 2014.

Sincerely,

Kostas Stoilas
Green Therapeutics

CC:
Baharea Larsen
Kris Kraft
Manuel Echegaray