



MEDICAL MARIJUANA TREATMENT CENTER

Evaluator Instructions Manual for *Pigford/BFL* Batching Cycle

OMMU Office of **MEDICAL**
MARIJUANA Use



Florida
HEALTH

SECTION 1: INTRODUCTION

This Evaluator Instructions Manual describes the role of evaluators in the medical marijuana treatment center (MMTC) application process and explains generally how an evaluator should conduct the evaluation and scoring of applications for MMTC licensure in the *Pigford/BFL* batching cycle. Please carefully review all of the following instructions concerning your role and responsibilities as an evaluator. You should direct all questions to the Director of the Office of Medical Marijuana Use (OMMU).

SECTION 2: BACKGROUND

The Department of Health (Department) is required to license MMTCs to ensure reasonable statewide accessibility and availability of medical marijuana for qualified patients in Florida. MMTCs are vertically integrated, meaning each MMTC is required to cultivate, process, transport, and dispense marijuana for medical use and is prohibited from contracting for services directly related to the cultivation, processing, and dispensing of marijuana or marijuana delivery devices.

Section 381.986(8)(b)1.–10., Florida Statutes (F.S.), establishes ten requirements that an applicant for MMTC licensure must demonstrate to be eligible for a license:

- For the five consecutive years before submitting the application, the applicant has been registered to do business in the state;
- Possession of a valid certificate of registration issued by the Department of Agriculture and Consumer Services (DACS) pursuant to section 581.131, F.S.;
- The technical and technological ability to cultivate and produce marijuana, including, but not limited to, low-THC cannabis;
- The ability to secure the premises, resources, and personnel necessary to operate as an MMTC;
- The ability to maintain accountability of all raw materials, finished products, and any byproducts to prevent diversion or unlawful access to or possession of these substances;
- An infrastructure reasonably located to dispense marijuana to registered qualified patients statewide;
- The financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financial statements to the Department;
- That all owners, officers, board members, and managers have passed a background screening;
- The employment of a medical director to supervise the activities of the MMTC; and
- A diversity plan that promotes and ensures the involvement of minority persons and minority business enterprises, as defined in section 288.703, F.S., or veteran business enterprises, as defined in section 295.187, F.S., in ownership, management, and employment.

Once an applicant is licensed by the Department as an MMTC, it must comply with operational requirements imposed by section 381.986(8)(d)–(i), F.S., and Department rules. The Department’s rules governing licensed MMTCs are contained in Chapter 64-4, Florida Administrative Code and in Department emergency rules.

The number of available MMTC licenses is limited by statute. Because the number of available MMTC licenses is limited—and because the number of applicants is expected to exceed the number of available licenses—the selection of an applicant for licensure will be on a competitive basis, designed to identify the applicant that best satisfies the statutory requirements for licensure and that is best prepared to comply with the operational requirements imposed on licensed MMTCs. *See MedPure, LLC v. Department of Health*, 295 So. 3d 318 (Fla. 1st DCA 2020).

The Department is required to issue one of the available MMTC licenses to an applicant that is a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999) (“*Pigford*”) or *In re Black Farmers Litigation*, 856 F. Supp. 2d 1 (D.D.C. 2011) (“*BFL*”). § 381.986(8)(a)2.b., F.S. This is referred to as the “*Pigford/BFL* license.” *See* Emergency Rule 64ER21-16(1)(c). To that end, the Department has established a *Pigford/BFL* batching cycle for *Pigford* members and *BFL* members who seek to apply for the one available *Pigford/BFL* license.

The Department’s MMTC application process for the *Pigford/BFL* license is outlined in the Department’s License Application Instructions, Requirements, and Forms for *Pigford/BFL* Applicants (Application Instructions). The Department’s Application Instructions are specifically designed to solicit information from applicants to allow them to demonstrate that they meet the licensure requirements stated in section 381.986(8)(b)1. and 3. – 10., F.S., and that they are positioned to satisfy the operational requirements stated in section 381.986(8)(d) – (i), F.S., and Department rules upon licensure. Because each applicant may have a different or unique approach to satisfying licensure requirements (for example, the technical and technological ability to cultivate marijuana), the Department’s Application Instructions allow for flexibility in an applicant’s approach and description of those approaches. The Application Instructions are intended to allow the Department to determine which applicant, as compared to the other applicants, best satisfies the licensure requirements of section 381.986(8)(b)1. and 3.–10., F.S., and is best prepared to comply with the operational requirements imposed on licensed MMTCs in section 381.986(8)(e)–(i), F.S., and Department rules. This is accomplished through evaluators who will undertake a comparative, qualitative assessment of the competing applications for licensure and assign scores pursuant to the Scoring Rubrics and Evaluator Score Ranges described in Section 5.2 of the Application Instructions.

SECTION 3: ROLE OF EVALUATORS

The Department’s application process is divided into three phases: Phase One Review, Phase Two Review, and Phase Three Review. The Department will complete Phase One Review of the MMTC application process. Evaluators are not responsible for the Department’s Phase One

Review of applications. The MMTC applications will be provided to you after the Department's completion of Phase One Review.

Your role is limited to comparatively evaluating and scoring your assigned section of the MMTC applications, as explained in Section 5 below. After you complete your evaluation and scoring of the applications, the Department will complete Phase Three Review of the application process. Evaluators are not responsible for the Department's Phase Three Review of applications.

SECTION 4: EVALUATOR MATERIALS

You will be provided the following materials:

1. Cover letter;
2. Section 381.986, F.S.;
3. Section 381.988, F.S.;
4. Emergency Rule 64ER21-16, Application for MMTC Licensure and Incorporated Form DH8035-OMMU-10/2021 "Medical Marijuana Treatment Center License Application Instructions, Requirements, and Forms for *Pigford/BFL* Applicants;"
5. Chapter 64-4, Florida Administrative Code and all Department emergency rules governing MMTCs and certified marijuana treatment laboratories;
6. Chapter 500, F.S., and Chapter 5K-11, F.A.C.;
7. Section 288.703, F.S.;
8. Section 295.187, F.S.; and
9. Scorecards for your assigned section of the application.

You are expected to review these materials carefully **before** you begin scoring MMTC applications. These materials include, among other things, the statutory and rule based operational requirements for MMTCs.

SECTION 5: EVALUATION PROCESS AND GUIDELINES

At the outset of the evaluation process, you will receive an electronic file that contains the MMTC applications. You will be assigned a specific section of the MMTC application to score. The cover letter referenced in Section 4 above will advise you of the specific section that you are responsible for scoring. Each application will be saved as a separate PDF file. Files will be named using the following format: "Applicant Name."

You will be given 75 calendar days to complete your evaluation and scoring. All application scorecards must be completed and returned to the Department by 5:00 p.m. on the 75th day after your receipt of the MMTC applications. Additional time may be approved by the OMMU Director upon request.

You should carefully read your assigned section for each MMTC application **before** attempting to assign scores to any one application. Evaluators are free to review the entirety of each MMTC application. However, if an application subsection includes pages in excess of the page limit, do not evaluate or consider the excess pages during your review. Each evaluator will score only one specific section as follows:

1. One evaluator for Section 4.4 (Plan for the Cultivation of Marijuana and Supporting Infrastructure) of the applications.
2. One evaluator for Section 4.5 (Plan for Processing Marijuana and Supporting Infrastructure) of the applications.
3. One evaluator for Section 4.6 (Plan for Dispensing Marijuana and Supporting Infrastructure) of the applications.
4. One evaluator for Section 4.7 (Plan for Security and Accountability) of the applications.
5. One evaluator for Section 4.8 (Ability to Execute Proposed Plans) of the applications. Prior to assigning scores to Section 4.8, this evaluator must review (but not score) Sections 4.4, 4.5, 4.6, and 4.7 of the MMTC application.
6. One evaluator for Section 4.9 (Medical Director) of the applications.
7. One evaluator for Section 4.10 (Personnel and Staffing) of the applications. Prior to assigning scores to Section 4.10, this evaluator must review (but not score) Sections 4.4, 4.5, 4.6, and 4.7 of the MMTC application.
8. One evaluator for Section 4.11 (Diversity Plan) of the applications.
9. One evaluator for Section 4.12 (Certified Financial Documents and Available Funding) of the applications. Prior to assigning scores to Section 4.12, this evaluator must review (but not score) Sections 4.4, 4.5, 4.6, 4.7, and 4.8 of the MMTC application.

You must undertake a comparative, qualitative review of each application for licensure. You must score an application section by comparing the relative quality of the application section to the same section in all other applications. The Scoring Rubrics and Evaluator Score Ranges that must be used are contained in Section 5 of the Application Instructions. As stated in the Application Instructions, you must first determine within which qualitative category a particular application response falls (e.g., category A, B, C, D, or F). Please carefully review the categories, which range from best to worst qualitatively. Category F has been established for those applicants who have completely failed to meet a particular threshold. As noted in Section 6 of the Application Instructions, applicants who receive a score of zero (category F) for certain subsections are ineligible for licensure because they will have failed to demonstrate compliance

with a particular licensure requirement(s) in section 381.986(8)(b), F.S. All other categories (A through D) have been established for applicants exceeding the category F threshold. Categories A through D denote relative merit as between the competing applicants for licensure.

After determining within which category an application response falls, you must then assign a score within the applicable Evaluator Score Range based on your individual assessment of the comparative merit of the application response. You are expected to apply your knowledge and expertise when evaluating the application responses and applying Scoring Rubrics and Evaluator Score Ranges. An application response that demonstrates the applicant's understanding of, and ability to meet or exceed, licensure requirements and the operational requirements imposed on MMTCs should be viewed by you as superior to an application response that does not make such a showing. Questions concerning Scoring Rubrics, Evaluator Score Ranges, or any other aspect of the evaluation process must be directed to the Director of OMMU.

At the outset of the evaluation process, you will be advised of similar application responses. You should consider the similarity of responses when assigning scores. Additionally, you will receive from the Department application scorecards (in hard copy) for your assigned application section only. The scorecards are included at the end of this Evaluator Instructions Manual. You must complete a scorecard for each application. In assigning scores, you must abide by the following guidelines:

1. Scores must be assigned in accordance with the Scoring Rubrics and Evaluator Score Ranges described in Section 5 of the MMTC Application Instructions.
2. You must complete your evaluation independently of all other evaluators. No collaboration among evaluators is permitted. Scoring must reflect your independent judgment and evaluation of the application section assigned to you.
3. Do not conduct independent research about the individual MMTC applicants. Scores should be assigned based solely on your assessment of the information supplied by the applicants. However, you are expected to use your expertise, industry knowledge, and materials supplied by the Department in qualitatively assessing the applications.
4. If a particular subsection of an application does not contain *any* information, you must assign a score of zero for that particular subsection.
5. For the evaluator assigned to score Subsection 4.12.1: If Subsection 4.12.1 does not contain certified financial statements that meet the requirements of Subsection 4.12.1, you must assign a score of zero for that subsection.
6. You may document any strengths or weaknesses found in an application. In fact, you are encouraged to take notes concerning an application if you believe the notes will help you answer questions regarding your assigned scores in the future. All notes associated with

the evaluation will become public record and must be provided to the Department upon completion of the evaluation process.

7. You may print hardcopies of the electronic files you receive from the Department. If you choose to do so, the hardcopies must remain confidential throughout the duration of your evaluation process and must be turned in to the Department when you submit your scorecards to the Department. If you make any notes, regardless of medium, the notes will become public record and must be provided to the Department upon completion of the evaluation process.
8. MMTC applicants are required to abide by the page limits specified in the MMTC Application Instructions. If an application subsection includes pages in excess of the page limit, do not review or consider the excess pages during your evaluation.
9. In certain subsections of the application, MMTC applicants have been asked to supply addenda in addition to a narrative response. If an application subsection includes excess documents other than the requested addenda, do not review or consider the excess documents during your evaluation.
10. Questions related to the evaluations of the MMTC applications must be directed to the Director of OMMU.
11. After you complete your evaluation and assign scores, sign and date each scorecard. Return the completed scorecards and supporting notes (if any) to the Department by hand delivery or email (with receipt confirmed) to the Director of OMMU.
12. Should the Department have questions regarding your evaluations, you may be contacted by the Department. Please do not discuss your scoring with anyone other than the Director of OMMU.

SECTION 6: CONFLICT OF INTEREST CERTIFICATION

The Department will provide each evaluator with a list of the MMTC applicant names and, for each MMTC applicant, a listing of the applicant's owners and managers, as identified by the applicant in the application. **Prior to beginning evaluations**, you must certify that you have no conflict of interest. If you become aware of a conflict of interest at any time during the evaluation process, immediately notify the Director of OMMU. The Conflict of Interest Certification form is found at the end of these instructions.

A conflict of interest means a situation in which regard for a private interest tends to lead to disregard of a public duty or interest—here, your independent assessment of the qualitative merit of the MMTC applications.

SECTION 7: OUTSIDE INFLUENCE

If you believe any attempt has been made to unduly influence you or another evaluator, you must immediately report the incident to the Director of OMMU. Evaluators should work carefully to ensure a fair and open competitive application process. No attempt by Department personnel or others, including other evaluators, to unduly influence an evaluator's score will be tolerated.

EVALUATOR STATEMENT OF NO CONFLICT

By signing this form, I _____, confirm that I am independent of, and have no conflict of interest of any kind, either directly or indirectly, with any applicant for MMTC licensure or any persons identified in the list provided to me by the Department of Health, Office of Medical Marijuana Use.

Evaluator Signature: _____ Date: _____

Applicant Name: _____

Scorecard for Medical Marijuana Treatment Center Selection	
SECTION 4.4 – Plan for Cultivating Marijuana and Supporting Infrastructure	POINTS AWARDED
<p>Subsection 4.4.1 – Cultivation Plan: Describe your plan for cultivating marijuana in accordance with the requirements of section 381.986(8), F.S.</p>	<p>__ out of 80 points</p>
<p>Subsection 4.4.2 – Cultivation Infrastructure: Describe the areas and infrastructure proposed for the cultivation of marijuana and explain how that infrastructure will be sufficient to execute your cultivation plan.</p>	<p>__ out of 60 points</p>
<p>Subsection 4.4.3 – Ability to Secure Cultivation Infrastructure: With respect to the cultivation infrastructure described in response to Subsection 4.4.2, identify the cultivation infrastructure you have already secured and the cultivation infrastructure you intend to secure upon licensure.</p>	<p>__ out of 60 points</p>

Evaluator: _____
 PRINT NAME

 SIGNATURE

 DATE

Applicant Name: _____

Scorecard for Medical Marijuana Treatment Center Selection	
SECTION 4.5 – Plan for Processing Marijuana and Supporting Infrastructure	POINTS AWARDED
<p>Subsection 4.5.1 – Processing Plan: Describe your plan for processing marijuana in accordance with the requirements of section 381.986(8), F.S. and Department rules.</p>	<p>__ out of 80 points</p>
<p>Subsection 4.5.2 – Processing Infrastructure: Describe the areas and infrastructure proposed for the processing of marijuana and explain how that infrastructure will be sufficient to execute your processing plan.</p>	<p>__ out of 60 points</p>
<p>Subsection 4.5.3 – Ability to Secure Processing Infrastructure: With respect to the processing infrastructure described in response to Subsection 4.5.2, identify the processing infrastructure you have already secured and the processing infrastructure you intend to secure upon licensure.</p>	<p>__ out of 60 points</p>

Evaluator: _____
 PRINT NAME

 SIGNATURE

 DATE

Applicant Name: _____

Scorecard for Medical Marijuana Treatment Center Selection	
SECTION 4.6 – Plan for Dispensing Marijuana and Supporting Infrastructure	POINTS AWARDED
<p>Subsection 4.6.1 – Dispensing Plan: Describe your plan for dispensing marijuana in accordance with the requirements of section 381.986(8), F.S., and Department rules.</p>	<p>__ out of 80 points</p>
<p>Subsection 4.6.2 – Dispensing Infrastructure: Describe the areas and infrastructure proposed for dispensing marijuana and explain how that infrastructure will be sufficient to execute your dispensing plan.</p>	<p>__ out of 60 points</p>
<p>Subsection 4.6.3 – Ability to Secure Dispensing Infrastructure: With respect to the dispensing infrastructure described in response to Subsection 4.6.2, identify the dispensing infrastructure you have already secured and the dispensing infrastructure you intend to secure upon licensure.</p>	<p>__ out of 60 points</p>

Evaluator: _____
 PRINT NAME

 SIGNATURE

 DATE

Applicant Name: _____

Scorecard for Medical Marijuana Treatment Center Selection	
SECTION 4.7– Plan for Security and Accountability	POINTS AWARDED
Subsection 4.7.1 – Premises Security: Describe your plan to ensure the safety and security of the premises where the cultivation, processing, storing, or dispensing of marijuana will occur.	__ out of 40 points
Subsection 4.7.2 – IT Security: Describe your plan for securing your information technology system and infrastructure, including how you intend to secure the physical infrastructure and how you intend to secure and protect the system from outside intrusion and hacking.	__ out of 40 points
Subsection 4.7.3 – Diversion, Unlawful Access, and Transportation: Describe your plan to prevent the diversion of, and unlawful access to, marijuana (both internally and externally) and to ensure the safe and secure transport of marijuana during all phases of the MMTC business.	__ out of 40 points
Subsection 4.7.4 – Personnel Screening and Training: Describe your plan to background screen all owners, managers, and employees and to provide safety and security training to such persons.	__ out of 40 points
Subsection 4.7.5 – Recalls: Describe your plan for the recall of any marijuana or Usable Product that is, or may be, unsafe for human consumption (as evidenced by testing results, patient reactions, or otherwise); fails to meet the potency requirements of section 381.986(8)(e)8., F.S.; or for which the labeling of tetrahydrocannabinol and cannabidiol concentration is inaccurate.	__ out of 40 points

Evaluator: _____

PRINT NAME

SIGNATURE

DATE

Rule 64ER21-16

Effective: 10/2021

DH8036-OMMU-10/2021

Applicant Name: _____

Scorecard for Medical Marijuana Treatment Center Selection	
SECTION 4.8 – Ability to Execute Proposed Plans	POINTS AWARDED
<p>Subsection 4.8.1 – Experience in the Marijuana Industry: Describe your experience, or that of your personnel, (whether in Florida or another jurisdiction) cultivating, processing, dispensing, or securing marijuana.</p>	__ out of 60 points
<p>Subsection 4.8.2 – Other Relevant Experience: Describe your experience (regardless of industry or type), or that of your personnel, which demonstrates your ability to implement the plans described in response to Subsections 4.4.1, 4.5.1, 4.6.1, and 4.7.1.</p>	__ out of 60 points
<p>Subsection 4.8.3 – Business Plan: Describe your business plan, including each of the specific steps you intend to take to implement your proposed MMTC business upon licensure by the Department.</p>	__ out of 60 points
<p>Subsection 4.8.4 – Prior Enforcement Action: Disclose and describe prior enforcement action taken against the applicant, or the applicant’s owners and managers, relating to: (i) a dispensing organization or MMTC license in Florida, (ii) a marijuana license in another jurisdiction, and (iii) any other business or operational license in Florida or another jurisdiction within the past ten years.</p>	__ out of 20 points

Evaluator: _____

PRINT NAME

SIGNATURE

DATE

Applicant Name: _____

Scorecard for Medical Marijuana Treatment Center Selection	
SECTION 4.9 – Medical Director	POINTS AWARDED
<p>Subsection 4.9.1 – Experience in the Marijuana Industry: Describe your medical director’s experience, if any, related to patient use of medical marijuana, including any prior employment by an entity authorized to cultivate, process, or dispense marijuana in Florida or another jurisdiction.</p>	__ out of 80 points
<p>Subsection 4.9.2 – Other Relevant Experience: Describe any other relevant experience that you believe demonstrates your medical director’s ability to adequately supervise the activities of the MMTC.</p>	__ out of 40 points
<p>Subsection 4.9.3 – Oversight: Describe the scope of the medical director’s responsibilities, supervision, and oversight over the activities of the licensed MMTC. In addition, describe your plans to ensure the MMTC has a medical director without lapse (i.e., if your medical director unexpectedly resigns).</p>	__ out of 60 points
<p>Subsection 4.9.4 – Managing Conflicts of Interests: Describe your plan for ensuring that your medical director does not engage in behavior that creates, or may create, a conflict of interest with ordering physicians, including, but not limited to, kickbacks.</p>	__ out of 20 points

Evaluator: _____
 PRINT NAME

 SIGNATURE

 DATE

Applicant Name: _____

Scorecard for Medical Marijuana Treatment Center Selection	
SECTION 4.10 – Personnel	POINTS AWARDED
Subsection 4.10.1 – Personnel Qualifications: Describe the organizational structure of your proposed MMTC, identify the persons you deem as necessary to the implementation of your cultivation, processing, dispensing, and security and accountability plans; and describe the qualifications of those persons.	__ out of 100 points
Subsection 4.10.2 – Drug-Free Workplace: Describe your plans to implement and maintain an alcohol- and drug-free workplace	__ out of 40 points
Subsection 4.10.3 – Personnel Training: Describe your plan to train employees concerning compliance with section 381.986, F.S. and Department rules.	__ out of 60 points

Evaluator: _____
PRINT NAME

SIGNATURE

DATE

Applicant Name: _____

Scorecard for Medical Marijuana Treatment Center Selection	
SECTION 4.11 – Diversity Plan	POINTS AWARDED
Subsection 4.11.1 – Diversity Plan: Describe your plan to promote and ensure the involvement of minority persons and minority business enterprises, as defined in section 288.703, F.S., and veteran business enterprises, as defined in section 295.187, F.S., in ownership, management, employment, and contracting.	__ out of 100 points
Subsection 4.11.2 – Implementation of Diversity Plan: Describe how you intend to implement your proposed diversity plan and identify the steps you have taken, if any, to implement the plan.	__ out of 100 points

Evaluator: _____

PRINT NAME

SIGNATURE

DATE

Applicant Name: _____

Scorecard for Medical Marijuana Treatment Center Selection	
SECTION 4.12 – Certified Financial Documents and Available Funding	POINTS AWARDED
<p>Subsection 4.12.1 – Certified Financial Statements: Provide annual certified financial statements for the applicant’s most recent fiscal year. Certified financial statements must be prepared in accordance with U.S. Generally Accepted Accounting Principles (GAAP) and audited in accordance with U.S. Generally Accepted Auditing Standards (GAAS) by a Certified Public Accountant, licensed pursuant to chapter 473, F.S. or licensed by another state.</p>	<p>__ out of 100 points</p>
<p>Subsection 4.12.2 – Available Funding: Describe how you will obtain the funding needed to implement the cultivation, processing, dispensing, and security and accountability plans you described in response to Subsections 4.4.1, 4.5.1, 4.6.1, and 4.7.1.</p>	<p>__ out of 60 points</p>
<p>Subsection 4.12.3 – Projected Budget: Describe your projected financial budget for the first two years after licensure, including how the projected budget is consistent with your plans described in Subsections 4.4.1, 4.5.1, 4.6.1, and 4.7.1.</p>	<p>__ out of 40 points</p>

Evaluator: _____
 PRINT NAME

 SIGNATURE

 DATE