

Staff Findings and Recommendations Report Medical Marijuana Act Oversight Committee

151st General Assembly, 2nd session



*Respectfully submitted to the
Joint Legislative Oversight and Sunset Committee
February 2022*

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The Joint Legislative Oversight & Sunset Committee (“JLOSC” or “Committee”) is a bipartisan 10-member legislative body which performs periodic legislative review of boards or commissions. The purpose of the oversight and sunset review is to decide genuine public need and if the entity is effectively performing. The Division of Research is a nonpartisan and confidential reference bureau for the General Assembly and supplies many services including staff support for JLOSC.

Special thanks: We appreciate the aid provided by Medical Marijuana Act Oversight Committee staff in conducting this review.

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ABOUT THIS REPORT

This is a staff findings and recommendations report (“staff report”) drafted by Division of Research staff regarding the sunset and oversight review (“review”) of the Medical Marijuana Act Oversight Committee. This report has staff recommendations for JLOSC review and discussion. Recommendations are not final until discussed and adopted by JLOSC with an affirmative vote by 7 members.

The review’s purpose is to find the public need for the entity and whether the entity is effectively performing to meet the need. The goal of the review is to supply strength and support to entities that are supplying a State recognized need.

JLOSC performs its duties with support provided by the Division of Research’s dedicated and nonpartisan staff in the form of two JLOSC research analysts, a legislative attorney, legislative fellow, and administrative assistant. JLOSC staff completes a performance evaluation of the entity under review and gives a staff report to JLOSC which includes research, analysis, key findings, and recommendations. During the review process, the following is not assumed:

- There is a genuine public need for the entity under review.
- That the entity is satisfactorily and effectively meeting public need.

Rather, the entity under review has the burden of showing, through the statutory criteria for review included in their self-report and analyst requested supplemental documentation, that there is a genuine public need, and that the entity is meeting that need.

JLOSC selected the Medical Marijuana Act Oversight Committee for review on March 25, 2021. During the review process Medical Marijuana Act Oversight Committee support staff supplied information by completing a self-report which had a performance review questionnaire.¹

Division of Research staff compiled the following findings and recommendations after completion of a performance evaluation which included thorough research and analysis outlined in the Objectives, Scope, and Methodology section of this report. Division of Research staff used national auditing and evaluation standards while conducting the performance evaluation. Those standards require that we plan and perform the evaluation to obtain sufficient evidence to supply a reasonable basis for our findings and conclusions based on our evaluation objectives. We believe that the evidence obtained supplies a reasonable basis for our findings and conclusions based on our evaluation objectives. The Objectives, Scope, and Methodology section discusses the fieldwork procedures used while developing the findings and recommendations presented in this report.

The recommendations contained in this report are not final until adopted by JLOSC by affirmative vote of 7 members. Under §10213(a), Title 29, the Committee must first decide whether there is a genuine public need for an entity under review. To meet this requirement, the Committee may select to continue or terminate the entity under review. JLOSC meets publicly to review and

¹ Self-reports available on the Committee’s website, <https://legis.delaware.gov/Committee/Sunset>

discuss its staff's findings and recommendations, and the Committee is free to change, reject, or create brand new recommendations.

The JLOSC statute authorizes the Committee to recommend 1 or more of the following:

- Continuation of the entity as is.
- Termination of the entity.
- Termination of any program within the entity.
- Consolidation, merger, or transfer of the entity or the entity's functions to another entity.
- Termination of the entity unless certain conditions are met or modifications are made, by legislation or otherwise within a specified period.
- Budget appropriation limits for the entity.
- Legislation which the Committee considers necessary to carry out its decision to continue or terminate the entity.

The information contained in this report, along with the previously published self-report², which includes background information from the entity under review, help the Committee in conducting a review of the entity and meeting its statutory requirements under Chapter 102, Title 29. The "Staff Findings" section of this report has information to support the following staff recommendations.

Next Steps

After the release of this report, JLOSC will hold a public hearing in early 2022 for each entity under review to present to the Committee and accept public comment on the scope of the review.³

The Committee will review all information received, including the findings and recommendations presented in this staff report. Recommendations become completed after review, discussion, and an affirmative vote of 7 JLOSC members. Committee members are not bound by recommendations presented by staff and are free to change, reject, or form new recommendations. Once JLOSC adopts recommendations, the review moves to the implementation phase which may include drafting legislation.

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² Self-report available on the Committee's website, <https://legis.delaware.gov/Committee/Sunset>

³ Public meeting notices found on the Committee's website and the State of Delaware's Public Meeting Calendar.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

A performance evaluation conducted as required under JLOSC statute and based on the following criteria⁴:

1. If the agency is a licensing agency, the extent to which the agency has permitted qualified applicants to be licensed.⁵
2. The extent to which the agency has served the public interests.
3. The extent to which the agency has recommended statutory changes, and whether those changes directly benefit the public or whether those changes primarily benefit the agency or other entities and are of only indirect benefit to the public.
4. Review the implementation of recommendations contained in the final reports presented to the General Assembly and the Governor during previous legislative sessions.

Scope

Typically, JLOSC reviews cover a 5-year period. This review covers a 6-year performance period to capture data from the first meeting of the Medical Marijuana Act Oversight Committee. Review scope includes the Medical Marijuana Act Oversight Committee only and does not cover Delaware's medical marijuana program, the Office of Medical Marijuana, Division of Public Health, or Department of Health and Social Services ("DHSS"), or compassion center locations.

JLOSC Statutory Review Criteria #1

If the agency is a licensing agency, the extent to which the agency has allowed qualified applicants to be licensed.

Methodology for JLOSC Statutory Review Criteria #1

The Medical Marijuana Act Oversight Committee is not a licensing agency, statutory criteria #1 is not applicable to this review.

JLOSC Statutory Review Criteria #2

The extent to which the agency has served the public interests.

Methodology for JLOSC Statutory Review Criteria #2

The State of Delaware established the Medical Marijuana Act Oversight Committee in an advisory capacity to evaluate and make recommendations to the Governor, General Assembly, and the Department on the medical marijuana program.⁶

JLOSC Statutory Review Criteria #3

The extent to which the agency has recommended statutory changes, and whether those changes directly benefit the public or primarily benefit the agency or other entities and are of only indirect benefit to the public.

⁴ 29 Del. C. § 10209.

⁵ Agency is a catch-all or blanket term. All 2022 reviews consist of commissions, councils, and committees.

⁶ 16 Del. C. § 4922A.

Methodology for JLOSC Statutory Review Criteria #3

The Medical Marijuana Act Oversight Committee has not recommended statutory changes, statutory criteria #3 is not applicable to this review.

JLOSC Statutory Review Criteria #4

Review the implementation of recommendations contained in the final reports presented to the General Assembly and the Governor during earlier legislative sessions.

Methodology for JLOSC Statutory Review Criteria #4

This is the first JLOSC review of the Medical Marijuana Act Oversight Committee, statutory criteria #4 is not applicable to this review.

Review Fieldwork completed

- Reviewed all information supplied by Medical Marijuana Act Oversight Committee staff.
 - Self-report.
 - Medical Marijuana Act Oversight Committee by-laws.
 - Past 6 years of meeting minutes and agendas.
 - Sample of typical meeting documents prepared by Office of Medical Marijuana support staff.
 - Office of Medical Marijuana Annual Reports.
 - Medical Marijuana Program 2020 Customer Service Survey Results, survey conducted by the Office of Medical Marijuana.
- Reviewed all available public documents such as annual reports, Medical Marijuana Act Oversight Committee’s website, and available news articles.
- Reviewed current statute and regulations.
- Reviewed Medical Marijuana Act Oversight Committee’s overall performance as it relates to current statute and regulations.
- Reviewed Medical Marijuana Act Oversight Committee’s compliance with Freedom of Information Act (“FOIA”).
 - Public meeting calendar: council meeting notices, agendas, minutes.
- Reviewed Medical Marijuana Act Oversight Committee member size, quorum trends, and composition.
 - Membership information received from support staff and Office of Governor.
- Reviewed Medical Marijuana Act Oversight Committee member training opportunities.
- Reviewed summary data from other states which included medical use laws and boards to govern medical use laws.
- Surveyed the public to gather opinions and experiences with Medical Marijuana Act Oversight Committee.
- Held two virtual public input sessions to collect added public comment on review.
- Held virtual meetings with Medical Marijuana Act Oversight Committee staff to discuss review.

Review Background

This is the first review of the Medical Marijuana Act Oversight Committee by JLOSC. This review began in April of 2021. Support staff completed and returned a self-report in August of 2021. JLOSC staff conducted research and drafted this findings and recommendations report.

Background Research Synopsis

First created in 2011 by the Delaware Medical Marijuana Act (Title 16, Chapter 49A of the Delaware Code), the Medical Marijuana Act Oversight Committee serves to evaluate and advise and make recommendations to the Governor, General Assembly, and DHSS on the implementation of the Medical Marijuana Act.

Statutory clarification to the appointment process occurred in April 2015, member appointments to the Medical Marijuana Act Oversight Committee began in the summer of 2015, with its first meeting held in the fall of that same year. It is composed of 9 members, appointed by the Governor, President Pro Tempore of the Senate, Speaker of the House, and Secretary of DHSS. Members serve at the pleasure of the appointing authority and are not subject to term limits.

Housed within DHSS, the Office of Medical Marijuana supplies support staff to the Medical Marijuana Act Oversight Committee. According to its statute, the Medical Marijuana Act Oversight Committee must hold at least two meetings per year. To meet this statutory obligation, it scheduled meetings annually for February and October; however, in 2015 and 2018, it only held one meeting. Since October of 2015, it held 12 meetings total, only 8 of which had a quorum of its members present.

In 6 years of existence, the Medical Marijuana Act Oversight Committee made only 2 recommendations to the Office of Medical Marijuana for the medical marijuana program, has never taken an official position on marijuana legislation, and did not make recommendations to the Governor or General Assembly. The Medical Marijuana Act Oversight Committee is not involved nor has made decisions on medical marijuana program components such as petitions received by the Office of Medical Marijuana for added debilitating medical conditions or request for proposals for added compassion centers. JLOSC staff reviewed all posted agendas and meeting minutes and saw a pattern that the Medical Marijuana Act Oversight Committee had difficulty finding agenda topics, never recommended legislation for the medical marijuana program, and was rarely able to act on received public comment.

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STAFF FINDINGS

Finding #1

In 6 years of existence, the Medical Marijuana Act Oversight Committee (“Oversight Committee”) only made 2 recommendations to the Office of Medical Marijuana relating to the medical marijuana program and did not make recommendations to the Governor or General Assembly.

The Governor appointed the first members to the Oversight Committee in August of 2015. To summarize its statutory purpose, the Oversight Committee exists to evaluate and make recommendations to the Governor, General Assembly, and the Department on the medical marijuana program.⁷ In full detail, statute outlines the following requirements of the Oversight Committee:

- The Oversight Committee shall meet at least 2 times per year for the purpose of evaluating and making recommendations to the Governor, the General Assembly, and the Department regarding the following:
 - a. The ability of qualifying patients in all areas of the State to obtain timely access to high-quality medical marijuana.
 - b. The effectiveness of the registered compassion centers, individually and together, in serving the needs of qualifying patients, including the provision of educational and support services, the reasonableness of their fees, whether they are generating any complaints or security problems, and the sufficiency of the number operating to serve the registered qualifying patients of Delaware.
 - c. The effectiveness of the registered safety compliance facility or facilities, including whether a sufficient number are operating.
 - d. The sufficiency of the regulatory and security safeguards contained in this chapter and adopted by the Department to ensure that access to and use of marijuana cultivated is provided only to cardholders authorized for such purposes.
 - e. Any recommended additions or revisions to the Department regulations or this chapter, including relating to security, safe handling, labeling, and nomenclature.
 - f. Any research studies regarding health effects of medical marijuana for patients.

In review of materials since its first meeting held on October 27, 2015, JLOSC staff found 2 recommendations the Oversight Committee provided to the Office of Medical Marijuana and did not find recommendations made to the Governor or General Assembly.

- Recommendation 1: In its 2017, 2018, 2019, 2020, and 2021 annual reports, the Office of Medical Marijuana said it issued another request for proposal (“RFP”) for a 2nd compassion center location in New Castle County because of the Oversight Committee’s discussion and recommendation to conduct research and analysis on patient population needs. The compassion center opened in March of 2019 and became the 4th to open in the state.
- Recommendation 2: At its February 12, 2019 meeting, the Oversight Committee recommended an updated fee of \$50.00 instead of the existing \$125.00 application fee for

⁷ Department defined by statute (16 *Del. C.* § 4922A) as the Delaware Department of Health and Social Services.

both new and renewal registrations. Applicants with income at or below 138 percent of the Federal Poverty Level will receive their registration card for \$25.00.⁸

Finding #2

Since October 27, 2015, Oversight Committee agendas and meeting minutes show difficulty finding agenda and policy topics.

Looking at all posted agendas and meeting minutes during the review period, a pattern appeared showing the Oversight Committee had difficulty creating agenda topics.⁹ In minutes from its first meeting, the Oversight Committee discussed its overall goals. After discussion, the Oversight Committee concluded its key roles included evaluating the medical marijuana program, supplying advice to the Office of Medical Marijuana on medical marijuana program implementation, and suggesting any necessary legislative changes to the General Assembly. After receiving medical marijuana program updates from the Office of Medical Marijuana and 35 minutes of public comment, the Oversight Committee Chair requested committee members send agenda topics to support staff after reviewing the minutes, by-laws, and the Oversight Committee's statute.

Each agenda has listed "future agenda topics" as an item for consideration. Members suggested future meeting topics at both meetings held in 2016, 4 topics in February and 2 topics in October. The Oversight Committee last suggested future topics at the October 2017 meeting. Following that, suggestions dropped off, and the Oversight Committee Chair again requested members send topics to committee staff for 2020. There is no evidence that members suggested future topics and meeting attendance declined sharply in 2021 despite the ability to attend virtually. The last 2 meetings held virtually in 2021 did not have a quorum of members present with 4 of the 9 members attending on February 9, 2021 and only 1 member at the October 12, 2021 meeting.

Finding #3

Oversight Committee meetings center on updates provided by the Office of Medical Marijuana, with decreasing discussion and attendance from Oversight Committee members. A quorum of members did not attend meetings held in 2018, 2020, or 2021. The Oversight Committee did not meet its statutory obligation to hold 2 meetings in 2015 and 2018.

Delaware law created the Oversight Committee in May 2011 assigning appointment authority to the legislature; however, the legislature did not make appointments.¹⁰ Clarification to the appointment process occurred in April 2015 transferring most member appointments to the Governor.¹¹ The Oversight Committee finally formed in August 2015, first met on October 27, 2015, and decided on a February and October meeting schedule.¹² By statute, the Oversight Committee must meet at least 2 times per year with no restriction on holding more meetings.¹³ The Oversight Committee only held 1 of the 2 needed meetings in 2015 and 2018. In 2018, the Oversight Committee rescheduled its October 9, 2018 meeting for December 6, 2018, which was ultimately canceled.

⁸ Statute or regulation does not require the Oversight Committee to approve or review application fee changes. The Oversight Committee asked the Office of Medical Marijuana to investigate restructuring the medical marijuana card application fees for fiscal year 2020 to be more in line with medical marijuana programs in surrounding states. The Office of Medical Marijuana presented 2 different fee scenarios and the Oversight Committee discussed and recommended a third, which all parties agreed to.

⁹ Review period October 2015 – November 2021.

¹⁰ 146th General Assembly, Senate Bill 17.

¹¹ 148th General Assembly, Senate Bill 7.

¹² At its first meeting 35 members of the public attended, offering about 35 minutes of public comment.

¹³ 16 *Del. C.* § 4922A.

Since August 2015, the Oversight Committee has scheduled 14 meetings, cancelled 2, and held 12. Only 8 of the 12 (67%) meetings had a quorum of its members present. The chart below outlines all 14 scheduled meetings. Columns highlighted in yellow show meetings without quorum and columns highlighted in orange show cancelled meetings. Quorum issues began with the February 13, 2018 meeting. Only 1 of 2 meetings held in 2020 had quorum with no quorum for the 2 meetings held in 2021.

Medical Marijuana Oversight Committee Quorum Trends

Meeting Schedule Date	Meeting Held?	# of members present	Quorum?
10/27/2015	Yes	8 of 9	Yes
2/29/2016	Yes	6 of 9	Yes
10/11/2016	Yes	7 of 9	Yes
2/7/2017	Yes	5 of 9	Yes
10/10/2017	Yes	8 of 9	Yes
2/13/2018	Yes	4 of 9	No
10/9/2018	No, cancelled	none	n/a
12/6/2018	No, cancelled	none	n/a
2/12/2019	Yes	5 of 9	Yes
10/8/2019	Yes	7 of 9	Yes
2/11/2020	Yes	4 of 9	No
10/13/2020	Yes	5 of 9	Yes
2/9/2021	Yes	4 of 9	No
10/12/2021	Yes	1 of 9	No

Yellow highlight: Meetings without quorum.

Orange highlight: Cancelled meetings.

Oversight Committee meetings center on updates provided by the Office of Medical Marijuana. Discussion from members, member attendance, and total meeting time decreased over the past several years. The Office of Medical Marijuana spends a significant amount of time preparing medical marijuana program update materials for meetings. As required by statute, the Office of Medical Marijuana also prepares an annual report for the Governor and the General Assembly highlighting 7 different medical marijuana program areas.¹⁴ These annual reports are accessible through the website supported by the Office of Medical Marijuana. Additionally, in lieu of Oversight Committee meetings, the public could receive more frequent updates from the Office of Medical Marijuana through other methods such as a newsletter. The Office of Medical Marijuana keeps an extensive email list of active cardholders and members of the public. This could be used in continued efforts to communicate medical marijuana program updates and general education.

Finding #4

Oversight Committee discussed legislation but never adopted an official position nor made legislative recommendations to the Governor, General Assembly, or Office of Medical Marijuana.

In addition to updates from the Office of Medical Marijuana, each meeting includes updates on legislation affecting the medical marijuana program. Meeting minutes do not show the Oversight Committee adopting an official position on any legislation discussed or recommending areas for legislative changes to the medical marijuana program. Since the first meeting on October 27, 2015, legislative task forces have met independently of the Oversight Committee to discuss marijuana policy. Members of the Oversight Committee often served on these legislative task forces;

¹⁴ 16 Del. C. § 4922A.

however, limited interaction occurred between the task forces and the Oversight Committee. In October 2015, the Oversight Committee referred 1 public comment about product purity to a legislative task force.

Finding #5

Oversight Committee receives public comment but is rarely in a position to act.

As previously mentioned, the Oversight Committee referred 1 public comment about product purity to a legislative task force in October 2015. The Oversight Committee receives significant public comment on policy areas that it cannot act on without legislation. Additionally, the Oversight Committee has no authority over compassion centers, a popular topic during public comment periods, and many advocacy groups currently lobby on these topics. Below are highlights and relevant updates:

- Home grow.
- Legalization.
- Cost of medical marijuana products.
- Product quality/purity.
 - Oversight Committee referred 1 public comment from October 2015 meeting to a legislative task force for review.
- Supply and variety of medical marijuana products.
- More qualifying conditions.
 - Public can petition the Department to add a qualifying medical condition.
- Card renewals.
- Product packaging.
 - Oversight Committee discussed and reviewed information on topic from the Office of Medical Marijuana in 2016. Satisfied with the information and explanation, the Oversight Committee did not discuss further.
- Number of compassion centers and their locations.
 - Oversight Committee did recommend research into public need, which resulted in another compassion center opening in New Castle County.
- Education, informing card holders of medical marijuana program changes.
 - Office of Medical Marijuana posts updates on its website and implemented a mailing list, without Oversight Committee input or suggestion.
- Application fees.
 - Worked with the Office of Medical Marijuana to lower fees in 2019.
- Meeting twice per year is not sufficient.
 - The Office of Medical Marijuana discussed this topic with the Oversight Committee in October 2019. The Oversight Committee did not adopt changes to the meeting schedule.

Due to the lively nature of public comment, the Oversight Committee issued guidance after its first meeting to help make the comment period more productive. The following guidance to members of the public is from the October 10, 2017 meeting:

- Offer suggestions for how to address the concern being sharing.
- Put comments in the form of a statement rather than a question. Time does not allow for open dialog during the meeting, but the Oversight Committee is open to comments and suggestions.
- Please keep comments to under 2 minutes.

The chart below traces the popularity of public comment topics while showing the fluctuation of comments received. The Oversight Committee began holding virtual meetings on October 13, 2020, and JLOSC staff saw a small, brief increase in public comments at the February 2021 meeting.

Medical Marijuana Oversight Committee Meeting Public Comments

Meeting Schedule Date	Number of Public Attending	Number of Public Comments	Number of Written Comments	Number of Mentions of Main Topic Trends
10/27/2015	35	9	0	3 home grow, 2 amount of centers, 1 meeting twice not enough, 1 cost & quality
2/29/2016	50	13	0	3 home grow, 3 cost, 3 conditions, 1 education, 1 supply options
10/11/2016	unknown	12	0	2 more conditions, 1 card renewal for chronic conditions, 1 cost and supply, 1 homegrown and legalization, 1 quality
2/7/2017	unknown	6	0	2 cost, 1 supply, 1 home grow, 1 testing, 1 more conditions
10/10/2017	unknown	5	0	1 meeting twice not enough, 1 home grow & supply, 1 more conditions (opioid)
2/13/2018	unknown	7	0	4 more conditions (anxiety, pediatric use, autism), 1 waive app fee for vets
2/12/2019	unknown	3	0	2 more conditions (opioid), 1 cost, 1 home grow
10/8/2019	unknown	4	0	2 requesting updates be sent to card holders regarding program, 1 supply, 1 more conditions (opioid)
2/11/2020	unknown	4	5	5 home grow, 2 legalize, 2 supply/consistency
10/13/2020	unknown	1	0	1 home grow
2/9/2021	unknown	7	0	6 home grow
10/12/2021	13	1	0	1 quorum issues/cost/supply

* Office of Medical Marijuana’s 2017 annual report supplied number of public attendees at the first 2 meetings. Last meeting held JLOSC staff counted attendees at the virtual meeting.

Finding #6

Limited mention of the Oversight Committee in the Office of Medical Marijuana annual report. For many years, the same information was repeated.

Unlike the Office of Medical Marijuana, the Oversight Committee does not have an annual report requirement in its statute.¹⁵ The Office of Medical Marijuana makes annual reports accessible through its website dating back to its first in 2013.¹⁶ During the review period, these annual reports average 19 pages in length and have limited detail surrounding the Oversight Committee.

¹⁵ 16 Del. C. § 4922A.

¹⁶ Office of Medical Marijuana annual reports available online: <https://dhss.delaware.gov/dhss/dph/hsp/medmarhome.html>

Reporting on the Oversight Committee in its annual report is not 1 of the 7 required criteria; however, the Office of Medical Marijuana chose to include available updates from the Oversight Committee. In comparison to Oversight Committee meeting minutes, there was a lack of detailed information to report, and, in the absence of updates from the Oversight Committee, the Office of Medical Marijuana repeated the same highlights each year.

- Annual reports 2017, 2018, 2019, 2020, and 2021: All 5 annual reports include the same update on the additional contract in New Castle County offered to the Compassionate Care Research Institute to make more product available. The Office of Medical Marijuana offered this contract following the advice of the Oversight Committee to research the demand of patients.
- Annual reports 2019 and 2020: Both annual reports explained that advice from the Oversight Committee created a new application fee structure. The application fee was reduced to \$50 for both new and renewal registrations and \$25 for applicants with income at or below 138 percent of the Federal Poverty Level.

Finding #7

The Oversight Committee does not approve more debilitating medical conditions.

Petitions for new qualifying medical conditions do not go before the Oversight Committee. The medical marijuana program's website has information under a heading, "How to Petition the Committee to Add a Qualifying Medical Condition." JLOSC staff find this language could cause confusion as the Department conducts the review without the Oversight Committee involved in the process. JLOSC staff recommend removing the word "committee" from these instructions. Delaware Administrative Code and statute cover petitions, and neither mention the involvement of the Oversight Committee in the process.¹⁷ Additionally, approval and denial documents from past petitions do not include the Oversight Committee in decisions.¹⁸

Finding #8

The Oversight Committee is not involved in the request for proposal process for the medical marijuana program.

Oversight Committee meeting minutes have updates from the Office of Medical Marijuana on the ongoing request for proposal ("RFP") processes on various medical marijuana program elements such as compassion centers. Oversight Committee members do not take part in the RFP process, nor did Oversight Committee meeting minutes discuss any member participation. Statute and regulations for this topic do not include the involvement of the Oversight Committee.

Finding #9

The Oversight Committee only appears in limited sections of statute and regulations. JLOSC staff did not find information on the committee presenting recommendations to update policies surrounding oil formulation, definitions for CBD-rich strains, or product formulation.

Under statute and regulations, the committee appears in the following definitions to supply recommendations to the Department for the approval of any changes in medical marijuana oil

¹⁷ 16 Del. C. § 4922A and Delaware Administrative Code 4470.

¹⁸ Decisions available at: <https://dhss.delaware.gov/dhss/dph/hsp/medmarocpet.html>

formulation and to define cannabidiol-rich medical marijuana or CBD-rich strains or product formulization.¹⁹

- Statute definitions:
 - (1) “Cannabidiol-rich medical marijuana” or “CBD-rich” means a marijuana strain or product formulization that has elevated levels of cannabidiol (“CBD”) and contains the profile of CBD and tetrahydrocannabinol (“THC”) concentrations approved by the Department, based upon the recommendation of the Medical Marijuana Act Oversight Committee.
 - (12) c. Any change in the [medical marijuana] oil formulization which is made by the Department based upon the recommendation of the Medical Marijuana Act Oversight Committee.

- Regulation definitions:
 - "Cannabidiol-Rich medical marijuana" or "CBD-Rich" means a marijuana strain or product formulization that has elevated levels of cannabidiol ("CBD") and contains the profile of CBD and tetrahydrocannabinol ("THC") concentrations approved by the Department, based upon the recommendation of the Medical Marijuana Act Oversight Committee.
 - “Medical Marijuana Act Oversight Committee” means the committee established to evaluate and make recommendations regarding the implementation of 16 Del. C. Ch. 49A.
 - Any change in the [pediatric medical marijuana] oil formulization which is made by the Department based upon the recommendation of the Medical Marijuana Act Oversight Committee.

Because the Oversight Committee started meeting after the first compassion center opened on June 26, 2015, these formulations and definitions were already established. In review of meeting minutes and agendas since then, there is no information found on the Oversight Committee making recommendations to change oil formulization or definitions for CBD-rich strains or product formulization.

Additionally, the Department and Office of Medical Marijuana should make necessary changes to these formulations and definitions based on the internal research conducted as the Oversight Committee does not conduct its own research.

Finding #10

This review observed FOIA compliance issues with meeting minutes. Virtual meetings have not increased meeting attendance by Oversight Committee members or the public.

The Oversight Committee is a public body as defined by the Freedom of Information Act (“FOIA”).²⁰ During the course of this review JLOSC staff reviewed the past 6 years of held meetings and checked for FOIA compliance on meeting notice, agendas, and minutes. Using FOIA open meeting requirements the *FOIA Scorecard* below notes the following FOIA compliance items²¹:

¹⁹ 16 Del. C. § 4922A and Delaware Administrative Code 4470.

²⁰ 29 Del. C. § 10002.

²¹ 29 Del. C. § 10004.

- Every meeting must be open to the public, except for valid exception under FOIA.
 - Executive session closed to the public for FOIA named purposes.
- Public notice of regular meetings posted at least 7 days in advance of the meeting.
 - Includes agenda if determined.
 - Posted within 6 hours in advance of the meeting with reason for posting delay included.
 - Posted in public location accessible to the public, including electronic posting on designated State of Delaware website.²²
 - Includes date, time, and place of meeting.
 - Indicates intent to hold executive session (if applicable).
- Agenda is subject to change, changes may include:
 - Added items, including executive session.
 - Deletion of items, including executive session.
- Minutes recorded and made available for public inspection and copying as a public record. Minutes must include the following:
 - Record of members present.
 - Record by individual members of each vote taken and action agreed on.
- Final minutes posted within 5 working days of final approval.
 - Draft minutes posted within 20 working days of meeting conclusion for public bodies who meet 4 or fewer times per year.

FOIA Scorecard for October 2015 – October 2021	
Total Meetings Held and Open to Public	12
Properly Noticed Meetings	11
Properly Posted Agendas	12
Properly Posted Meeting Minutes (draft)	7
Properly Posted Meeting Minutes (final)	5
Missing Agendas	0
Missing Draft Minutes	5
Missing Final Minutes	2
Minutes Contain Required FOIA Information	0
Agendas Contain Required FOIA Information	12
Number of Executive Sessions Held	0

JLOSC staff reviewed Delaware’s Public Meeting Calendar for all meetings held by the Oversight Committee during a 6-year review period (October 2015 – November 2021). The Public Meeting Calendar keeps a record of all administrative actions for a meeting date including announcement creation date and posting dates for agendas and minutes. During the review period, the Oversight Committee properly noticed 11 out of 12 public meetings held, 1 meeting announcements did not

²² Designated website is the Public Meeting Calendar: <https://publicmeetings.delaware.gov>

supply 7 days' notice. All meeting announcements included properly posted agendas, which met FOIA requirements, and no executive sessions held.

FOIA requires draft minutes posted within 20 working days after the meeting for public bodies who meet less than 4 times per year. The Oversight Committee falls into this category as it only meets twice per year. Seven meeting announcements included draft minutes with 5 sets missing. Five meeting announcements included properly posted final meeting minutes, 2 sets were posted late, and 2 sets were missing. JLOSC staff did not include the final minutes of the last 3 meetings in this count as the Oversight Committee lacked a quorum and the February 2022 meeting has not occurred. All posted minutes (final and draft) are missing record of motions made, a requirement of FOIA.

The Oversight Committee has held 3 virtual meetings, starting on October 13, 2020. In other reviews JLOSC staff conducted during this same period, virtual meetings increased access and saw an increase in member attendance and public participation. However, this was not true with the Oversight Committee as its last 2 virtual meetings did not have a quorum of its members present. Additionally, public comment was down in virtual meetings of the Oversight Committee, as the October 23, 2020 and October 12, 2021 had only 1 attendee offer public comment.

The only notable FOIA compliance issues seen during the review period dealt with the posting of minutes. JLOSC analysts do not anticipate FOIA compliance issues to be an ongoing concern and feel this review will supply the necessary reminders for ongoing compliance.

Finding #11

The average attendance rate by Oversight Committee members dropped to 52% during the 2019-2021 meeting years (virtual meetings started in October 2020). Currently, there are 3 vacancies.

According to statute, the committee consists of the following 9 members²³:

- 1 member, appointed by the President Pro Tempore of the Senate.
- 1 member, appointed by the Speaker of the House.
- Secretary of the Department of Health and Social Services, or a designee appointed by the Secretary.
- 2 medical professionals, each licensed in Delaware, with experience in medical marijuana issues, appointed by the Governor.
- 1 member with experience in policy development or implementation in the field of medical marijuana, appointed by the Governor.
- 3 members who hold valid registry identification cards as a qualifying patient or caregiver, appointed by the Governor.

Initial appointments came in August 2015 and the Oversight Committee held its first meeting on October 27, 2015. Oversight Committee membership changed between October 10, 2017 and February 12, 2019, when 4 members rotated off the Oversight Committee. The following 2 charts outline meeting attendance for these 2 distinct time periods: 2015-2018 and 2019-2021. JLOSC staff saw a decline in member meeting attendance.

²³ 16 Del. C. § 4922A.

Medical Marijuana Oversight Committee Meeting Attendance 2015-2018

Member Type	Appointment Type	DEC 2018	OCT 2018	FEB 2018	OCT 2017	FEB 2017	Oct 2016	Feb 2016	Oct 2015	Total Absences	Notes:	attendance % (6 meetings)*
Sen. Margaret Rose Henry, chair	State Senator	C	C					X		1		83%
Drewry Fennell, co-chair	Deputy Chief of Staff	C	C	NA	X	X	X			3	left by Feb 2018 meeting	40%
Rep. Stephanie Bolden	State Representative	C	C	X			X	X	X	4		33%
Dr. Karyl Rattay	Director, DPH	C	C			X				1		83%
Pearl Golden	Caregiver Cardholder (SC)	C	C			X				1		83%
Thomas Shabazz	Patient Cardholder (KC)	C	C	X						1		83%
Dr. Samuel Stubblefield	Physician - Pediatrician	C	C							0		100%
Elizabeth Cusack	Patient Cardholder (NCC)	C	C	X						1		83%
Dr. Jason Silversteen	Physician - Neurologist	C	C	X		X		X		3		50%
C = Cancelled meeting												average = 71%
X shows member was absent.												
NA shows member was not a member of the board, see the notes column for more info.												

*Ms. Fennell attendance percentage calculated based on 5 meetings.

Medical Marijuana Oversight Committee Meeting Attendance 2019-2021

Member Name	Appointment Type	OCT 2021	FEB 2021	OCT 2020	FEB 2020	OCT 2019	FEB 2019	Total Absences	Notes:	attendance % (6 meetings)*
Dr. Jason Silversteen, chair	Physician - Neurologist	X					X	2		67%
Sen. Elizabeth Lockman, co-chair	State Senator	X						1		83%
Rep. Stephanie Bolden	State Representative	X	X	X	X	X	X	6		0%
Dr. Karyl Rattay	Director, DPH	X	X		X			3		50%
Susan Kelly	Caregiver Cardholder (SC)							0		100%
Thomas Shabazz	Patient Cardholder (KC)	X	X	X	X			4		33%
Joe Bryant	Health Care Policy Advisor	X			X	X	X	4		33%
Dr. Samuel Stubblefield	Physician - Pediatrician	NA	NA	NA				0	deceased 7/28/2020	100%
Jan Roberts-Rudzinski	Patient Cardholder (NCC)	NA	NA	NA	X	X	X	3	left board by Oct 2020	0%
X shows member was absent.										average = 52%
NA shows member was not a member of the board, see the notes column for additional info.										

*Dr. Stubblefield and Ms. Roberts-Rudzinski attendance percentages calculated based on 3 meetings.

From the Oversight Committee’s first meeting on October 27, 2015 through February 13, 2018, members attended an average of 71% of meetings held. This average dropped to 52% during the meeting span of February 12, 2019 through October 12, 2021, with only 1 member attending the October 12, 2021 virtual meeting. The Oversight Committee held 3 virtual meetings with only 1 meeting quorum requirements.

Since the February 11, 2020 meeting, 2 vacancies have occurred. In December of 2021, JLOSC staff received updated information from the Office of Medical Marijuana that Joe Bryant, a health care policy advisor, resigned leaving a third vacancy. Another update included a transition for the Secretary of DHSS designee. Dr. Karyl Rattay, Department of Public Health director, served as the designee since the first meeting; however, her new responsibilities following the onset of the Covid-19 pandemic made serving on the committee difficult. DHSS Secretary Molly Magarik designated Dr. Josh Rosen to serve in that role on the committee. The following chart shows committee membership as of December 15, 2021.

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Medical Marijuana Oversight Committee Members as of December 15, 2021

Member Name	Appointment Type	Appointment Authority	Appointment Date or Year
Dr. Jason Silversteen, chair	Physician - Neurologist	Governor	8/11/2015
Sen. Elizabeth Lockman, co-chair	State Senator	President Pro Tempore of the Senate	2018
Rep. Stephanie Bolden	State Representative	Speaker of the House	2015
Dr. Josh Rosen	DPH Physician	Secretary of the Department	Dec. 2021
Susan Kelly	Caregiver Cardholder (SC)	Governor	12/14/2018
Thomas Shabazz	Patient Cardholder (KC)	Governor	8/11/2015
vacant as of December 2021	experience in policy development or implementation in the field of medical marijuana	Governor	n/a
vacant as of July 2020	DE licensed medical professional experience in medical marijuana issues	Governor	n/a
vacant as of October 2020	qualifying patient or designated caregiver cardholder	Governor	n/a

Finding #12

Committee by-laws set up an Executive Committee; however, records have not been found of an Executive Committee holding meetings or conducting business. By-laws grant duties to the Executive Committee that would require legislative action.

The Committee issued by-laws on October 12, 2015 and made 1 revision on October 27, 2015. Article VII of its by-laws include information on creating sub-committees; however, no records exist of the Committee creating a sub-committee.

Article VII also outlines an Executive Committee to consist of Oversight Committee officers (with the Chair presiding) to supervise affairs between meetings, and act on behalf of the Oversight Committee if immediate action is needed or an emergency surfaced. The by-laws include the following added duties for the Executive Committee:

- May recommend to the Oversight Committee additions and deletions to the Roster, and monitor member performance and attendance at meetings.
- Shall oversee expenditures and funds and make recommendations to the Oversight Committee for changes.
- May recommend to the Oversight Committee changes for policies and procedures.
- Must approve all major changes to the projected or approved annual budget.

The Executive Committee never held a meeting or reported to the Oversight Committee; therefore, it is unlikely action was taken on any of these duties. It is unclear why the Oversight Committee's by-laws structured its Executive Committee in this fashion. Because the Oversight Committee does not have a budget, it is uncertain what expenditures and funds the Executive Committee would oversee. Additionally, the by-laws do not discuss other budget information, so it is unclear if there were plans for the Oversight Committee to eventually have a budget or additional statutory authority, both of which would require legislative action. Since the Executive Committee never conducted business, JLOSC staff concludes this to be a non-issue, currently. However, it is an area to address should an Executive Committee form in the future.

Finding #13

Public outreach survey received mixed feedback on the medical marijuana program and compassion centers instead of the Oversight Committee, which is the scope of this review.

JLOSC staff conducted a public outreach survey from August 9 – September 30, 2021 and received 610 responses for the Oversight Committee. However, based on the comments, it became clear respondents were completing the survey based on their opinions of the medical marijuana program and compassion centers, not the Oversight Committee as instructed.

In addition to multiple choice questions, the survey supplied an opportunity for the public to supply written comments to JLOSC staff. The survey received 201 written comments, with an almost even mix of positive and negative comments regarding the medical marijuana program and compassion centers. Comments mentioning the Oversight Committee were uncommon. The survey also received 36 written comments with blanket statements such as:

- Do not know enough to comment.
- Medical marijuana has changed the lives of many.
- Have issues with prescription pain killers and this is the only thing that helps.
- It's a plant, not a crime.
- Time to legalize recreationally.
- Need individual grow permits.
- Green Docs is misleading.

JLOSC staff considered these blanket statements to be neutral and did not include them in the positive and negative comment totals. The survey received 78 positive comments, which focused on the medical marijuana program and compassion centers. A small number of comments voiced support for the Oversight Committee. The following is a summary of positive comment highlights:

- Medical marijuana program well structured.
- Process for obtaining card appropriate, user friendly.
- Friendly and helpful staff, pleasant experience.
- Grateful for the medical marijuana program, have received help from the program.
- Overall doing an excellent job.
- I hope the committee stays active.

The survey received 87 negative comments. Many respondents were not aware of the Oversight Committee, but those who were stated displeasure with its performance. Written comments included popular topic areas received in the public comment periods at Oversight Committee meetings. The following is a summary of negative comment highlights:

- Cardholders not aware of oversight committee, would like to see advertising of committee meetings sent to cardholders.
- Poor attendance by some committee members, constant quorum issues, not enough patient representatives.
- Oversight board only meets twice a year, not affective [sic], no true oversight.
- Oversight board is for show, does not accomplish much.
- Oversight board should be doing more to identify best practices, medical marijuana program design, product availability, and study similar medical marijuana programs in other states.

- More research into effective, county-based medical marijuana systems and would like to see a better relationship formed with Substance Abuse & Mental Health Services Administration (“SAMHSA”) and Office of National Drug Control Policy (“ONDCP”).
- Demand for more disclosure of product information on packaging, such as terpene profile.
- Concerns over quality, product availability, menu instability, and cost.
- Not enough compassion centers, specifically Kent and Sussex counties.
- Compassion centers run self-monitored, no oversight, patients have nowhere to go with issues.
- Doctors charge high fees to complete paperwork, renewing cards should be easier, renewal shouldn’t have to occur annually, chronic conditions should not have to recertify every year.

Considering the vast number of comments received outside the scope of this review such as the medical marijuana program and its compassion centers, JLOSC staff supplied the public an opportunity for additional comments and held 2 virtual public comment sessions in October 2021.²⁴

On October 26, 2021, JLOSC staff held its first Division of Research Public Input Session and received a comment on supply of edible products and a request to continue the education on medical marijuana. Another comment questioned the medical license renewal process, cost of product, and requested 1 of the fees be eliminated.

On October 27, 2021 the 2nd session was held, and 1 comment was received on the medical marijuana program stating that finding a doctor to certify is difficult and insurance doesn’t cover the medical marijuana program. Additionally, annual medical card renewals are burdensome on patients with chronic conditions and a lifetime card for these patients should be issued or at least valid for more than 1 year.

Finding #14

The Office of Medical Marijuana conducted a customer survey in 2020 and received positive feedback. Compassion centers are monitored by Office of Medical Marijuana investigative staff, not the Oversight Committee. Without additional legislative action or a strategic plan, the Oversight Committee is not meeting a public need.

As said in the objective, scope, and methodology section of this report, the scope of this review was not on the Office of Medical Marijuana, but on the Oversight Committee. Through researching the Oversight Committee, JLOSC staff found the Office of Medical Marijuana conducting its own outreach and medical marijuana program monitoring.

At the Oversight Committee’s October 13, 2020 meeting, the Office of Medical Marijuana went over customer service survey results. Office of Medical Marijuana staff conducted the survey independently, without a recommendation from the Oversight Committee. The survey collected 1,134 responses and received positive feedback on the medical marijuana program and Office of Medical Marijuana. On the topic of overall satisfaction with the medical marijuana program, 83% showed satisfaction, with only 17% disappointed. Not all respondents experienced contact with the Office of Medical Marijuana, but of those who interacted, 88% selected that staff was helpful in answering questions, with only 3% indicating any trouble. Oversight Committee meeting minutes in 2015 and 2016 showed the public had difficulty with applications and experienced long wait times for their cards. As the Office of Medical Marijuana made improvements and the medical

²⁴ Both sessions recorded and archived on the General Assembly YouTube [page](#).

marijuana program advanced, these comments and discussions ended. To show further progress in this area, the October 2020 survey indicated 81% of respondents received their medical marijuana program cards quickly after applying. When asked about difficulty with the application process, only 9% of respondents reported difficulty in applying for their card.

Oversight Committee meeting minutes explain that the medical marijuana program has investigative staff that work to receive and investigate public complaints of compassion centers. Existing regulations cover the complaint process as well as and the medical marijuana program itself. Additionally, the Office of Medical Marijuana website includes a complaint form link in the frequently asked question section; however, it could be more prominently displayed. Additionally, converting the form to a fillable PDF would be helpful and more easily accessible.

Through researching the Oversight Committee, JLOSC staff concluded that the Office of Medical Marijuana is fully supporting the Oversight Committee and receives little feedback or recommendations in return. JLOSC staff considered scenarios of reformatting the Oversight Committee into an entity more advisory in nature. However, based on the evidence collected and the operations of the Office of Medical Marijuana, a restructured body would not result in a positive use of time and resources as JLOSC staff found little evidence showing the Oversight Committee made an observable impact on the Office of Medical Marijuana or medical marijuana program.

Additionally, JLOSC staff looked at the 37 other states and the District of Columbia that have a medical marijuana program. Fourteen states and the District of Columbia run their medical marijuana programs without the help of a board. Notably, Arizona created a council in 2019 for the sole purpose of investigating product testing and then dissolved after holding 7 meetings and releasing a final report of findings. In contrast, New York ran its medical program for 7 years without a board. It recently created a Cannabis Control Board to make decisions on the state's newly created adult recreational program and will supply some added support to the already established medical program. Delaware could benefit from the support of a board if it enacted an adult recreation program or provided a specific policy task to conduct research on, like in the Arizona example.

With the lack of support provided to the Office of Medical Marijuana and in absence of a specific policy task or legislative action for the existing Oversight Committee to consider, the Office of Medical Marijuana could continue to function without the Oversight Committee. It could be beneficial to allocate the staffing resources dedicated to the Oversight Committee to increase outreach initiatives, engage more often with card holders, distribute information, and respond to feedback. Based on research conducted JLOSC staff does not find the Oversight Committee meeting a public need.

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STAFF RECOMMENDATIONS

Recommendation #1, Option 2 – Sunset the Medical Marijuana Act Oversight Committee

Review and analysis by JLOSC staff concludes the Office of Medical Marijuana oversees a functioning medical marijuana program without support from the Medical Marijuana Act Oversight Committee. Since October 27, 2015, the Medical Marijuana Act Oversight Committee has only made 2 recommendations to the Office of Medical Marijuana relating to the medical marijuana program and has not made recommendations to the Governor or General Assembly. Without additional legislative action or a strategic plan, the Medical Marijuana Act Oversight Committee is not meeting a public need.

JLOSC staff recommends **Option 2: Sunset the Medical Marijuana Act Oversight Committee with JLOSC sponsoring legislation to implement this recommendation.**

Continue or Terminate (standard JLOSC recommendation):

Option 1: The Medical Marijuana Act Oversight Committee shall continue, subject to any further recommendations that JLOSC adopts.

- OR -

Option 2: The Medical Marijuana Act Oversight Committee is terminated, and JLOSC will sponsor legislation to implement this recommendation.

Recommendation #2 – Release from Review.

Release the Medical Marijuana Act Oversight Committee from review upon enactment of sunset legislation.

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February 15, 2022

Joint Legislative Oversight & Sunset Committee
Legislative Council, Division of Research
411 Legislative Avenue
Dover, DE 19901

Dear JLOSC members and Division of Research staff,

The Office of Medical Marijuana (OMM) sincerely thanks the staff of the Division of Research and the Joint Legislative Oversight & Sunset Committee members for their findings and recommendations. We also thank you for the opportunity to address the function and challenges of the Medical Marijuana Act Oversight Committee.

OMM is committed to protecting Delawareans through proactive monitoring and enforcement of the Delaware Medical Marijuana Act and accompanying regulations. We welcome and value your input and determined that findings contained in this Report are accurate portrayals of current processes, structure, and responsibilities as they relate to both the Oversight Committee and OMM.

The Oversight Committee and the Medical Marijuana Program were established through the Delaware Medical Marijuana Act in 2011. Due to uncertainty related to federal enforcement of marijuana prohibitions during this period, the first compassion center did not open until June 2015. This correlates with the timing of the Oversight Committee appointment authority being transferred from the legislature to the Governor, as described by Finding #3. Given a statutory requirement to promulgate regulations in 2012, the Medical Marijuana Act regulations were already finalized when the Oversight Committee was fully appointed in August 2015. Therefore, the Oversight Committee was unable to participate in discussions related to the original regulatory framework, and the JLOSC Report has accurately captured how the development of the Oversight Committee has led to the challenges it currently experiences.

As detailed in Findings #2, 3, and 11, the Oversight Committee has had difficulty identifying actionable items of discussion and has had a gradual decline of committee member attendance and engagement as the Medical Marijuana Program has become more firmly established, leading to quorum issues. Typically, the public comment portion of the Oversight Committee meetings has considerable participation, but as noted in Finding #5, there is a discrepancy between the public perception and the actual scope of the Oversight Committee's authority.

While the Oversight Committee has the statutory authority to advise OMM on “the sufficiency of the number [of compassion centers] operating” (16 *Del.C.* §4922A[b]), OMM has largely been responsible for researching best safety practices and, per statute, is exclusively responsible for enforcement of the regulations. Despite exponential growth in the medical marijuana industry, OMM has remained committed to processing new and renewal applications and considering patient needs when opening new compassion centers. There are currently four growers that serve Delaware patients through seven retail locations with two additional vendors working to establish new grow locations. In November 2022 there will be 12 retail locations throughout Delaware including five in New Castle County, three in Kent County, and four in Sussex County. In 2019 total sales were \$19 million, 2020 total sales were \$27.7 million and in 2021 total sales exceeded \$41.2 million. During the COVID-19 pandemic alone the patient population grew 38% from 8,936 in February 2020 to nearly 14,500 patients in February 2022.

OMM acknowledges that the JLOSC Report recommends sunseting the Oversight Committee. Based on the findings contained in the Report and the experiences of the committee members, OMM staff, and patients, OMM does not dispute that the Oversight Committee has outlived its original intent in helping to establish the Medical Marijuana Program.

However, what has become clear as a result of robust public comment during Oversight Committee meetings is the interest of patients, advocates, and compassion centers in continuing to engage with OMM on issues related to the Medical Marijuana Program. In the absence of the Oversight Committee, OMM will identify other forums in which stakeholders can engage with OMM. In May 2020, OMM proactively initiated a patient satisfaction survey (Finding #14) in response to concerns of compassion center capacity and product shortages during the pandemic and to ensure OMM had a holistic view of the challenges patients saw with the program. This type of feedback is critical to effectively addressing patient needs, and surveys would be part of a larger engagement strategy if JLOSC votes to sunset the Oversight Committee. Other outreach could include more regular communication with cardholders about available services through newsletters or virtual office hours, and establishing informal workgroups of patients, medical providers, compassion center leadership, and OMM to ensure open communication about the Medical Marijuana Program and patient needs.

In addition, OMM submitted website updates addressing the actionable items identified by JLOSC staff in the Report, including removing the word “Committee” from the petition page on the OMM website for clarity (Finding #7) and making the complaint form more prominent on the website and the process more easily understandable (Finding #14). OMM will also ensure FOIA compliance regarding meeting minutes (Finding #10).

OMM is dedicated to ensuring access to safe and quality medical marijuana to patients with qualifying medical conditions and we remain committed to achieving that mission as we continue to work with patients, certifying providers, compassion centers, and advocates. OMM is

grateful for the collaborative assessment, detailed review process, time, effort, and diligence that went into developing this report and recommendations. We take the insights, recommendations, and findings seriously and will work to enable the Medical Marijuana Program to function in the best possible manner. We look forward to presenting and further discussing ways to enhance the access of safe medical marijuana for patients within our state.

Respectfully submitted,

Signature:  _____ Date: February 15, 2022

Paul Hyland
Director, Office of Medical Marijuana
Delaware Division of Public Health

Cc: Molly K. Magarik, Cabinet Secretary DHSS
Kiki Evinger, Chief Policy Advisor, Office of the Secretary, DHSS
Dr. Karyl T. Rattay, Director, Division of Public Health, DHSS
Crystal Mintzer Webb, Deputy Director, Division of Public Health, DHSS
Alanna Mozeik, Policy Lead, Division of Public Health, DHSS
Dr. Jason Silversteen, Chair, Medical Marijuana Act Oversight Committee

Appendix A: Medical Marijuana Act Oversight Committee Bylaws

BY-LAWS OF

THE DELAWARE MEDICAL MARIJUANA ACT OVERSIGHT COMMITTEE

ARTICLE I. NAME AND LOCATION.

Section 1. Name – The name shall be the Medical Marijuana Act Oversight Committee, hereinafter referred to as “the Oversight Committee”.

Section 2. Location – The place of normal business of the Oversight Committee shall be within the state of Delaware.

ARTICLE II. PURPOSE, DUTIES AND RESPONSIBILITIES.

Section 1. Purpose – The purpose of the Oversight Committee, as established in 16 Delaware Code, Ch. 49A, is to evaluate and make recommendations regarding the implementation of this chapter.

Section 2. Duties and Responsibilities – The duty and responsibility of the Oversight Committee, as set forth in 16 Delaware Code, Section 4922A is to meet at least two times per year for the purpose of evaluating and making recommendations to the Governor, the General Assembly, and the Department of Health and Social Services (DHSS) regarding:

a. the ability of qualifying patients in all areas of the state to obtain timely access to high-quality medical marijuana;

b. the effectiveness of the registered compassion center(s), individually and

Issued Date: October 12, 2015

Revised Date: October 27, 2015

20 together, in serving the needs of qualifying patients, including the provision of
21 educational and support services, the reasonableness of their fees, whether
22 they are generating any complaints or security problems, and the sufficiency

- 23 of the number operating to serve the registered qualifying patients of
24 Delaware;
- 25 c. the effectiveness of the registered safety compliance facility or facilities,
26 including whether a sufficient number are operating;
- 27 d. the sufficiency of the regulatory and security safeguards contained in 16 Del.
28 C. Ch. 49A and 16 DE Admin. C. 4470 adopted by DHSS to ensure that
29 access to and use of marijuana cultivated is provided only to cardholders
30 authorized for such purposes;
- 31 e. any recommended additions or revisions to 16 Del. C. Ch. 49A and 16 DE
32 Admin. C. 4470, including but not limited to, additions or revisions relating to
33 security, safe handling, labeling, and nomenclature of medical marijuana; and
- 34 f. any research studies involving health effects of medical marijuana for
35 patients.

36 ARTICLE III. MEMBERS AND COMPENSATION.

37 Section 1. Members – The Oversight Committee shall consist of nine members, as
38 follows, who possess the qualifications and are appointed in accordance with 29 Del. C. §
39 4922A:

- 40 a. one member, appointed by the President Pro Tempore of the Senate;
- 41 b. one member, appointed by the Speaker of the House;
- 42 c. the Secretary of DHSS, or a designee appointed by the Secretary;
- 43 d. two medical professionals, each licensed in Delaware, with experience in
44 medical marijuana issues, appointed by the Governor;

- 45 e. one member with experience in policy development or implementation in the
46 field of medical marijuana, appointed by the Governor; and
47 f. three members who each shall be a cardholder, as defined in 16 Del. C.
48 §4902A , appointed by the Governor.

49 Section 2. Compensation – No member of the Oversight Committee shall receive any
50 salary, compensation, or emolument for his or her services on behalf of the Oversight
51 Committee.

52 Section 3. Removal of Member from Committee – The members of the Oversight
53 Committee shall serve at the pleasure of the appointing authority.

54 Section 4. Resignation – A member of the Oversight Committee may resign by
55 submitting either verbal or written notice of resignation to the Chair or Appointing
56 Authority. If a member misses two consecutive meetings without just cause, that
57 member shall be presumed to have resigned. In order to have just cause considered the
58 member:

- 59 i. must contact the Chair or Vice Chair prior to the day of the second
60 scheduled meeting which will be missed;
61 ii. must inform the Chair or Vice Chair they are unable to attend the second
62 scheduled meeting; and
63 iii. must request to be excused

64

65 ARTICLE IV. ADMINISTRATOR OF THE OFFICE OF MEDICAL
66 MARIJUANA.

67 The Administrator of the Office of Medical Marijuana shall have the following duties and
68 responsibilities as it pertains to the Oversight Committee:

- 69 (1) issue meeting notices and agendas;
- 70 (2) direct minutes of all meetings of the Oversight Committee, ensure those
71 minutes are maintained as a history of the meetings of the Oversight
72 Committee, and distribute the minutes to members of the Oversight
73 Committee prior to the next meeting;
- 74 (3) assist the Chairperson in the preparation of the agenda for meetings;
- 75 (4) keep a current roster of members of the Oversight Committee and any other
76 records related to the history or duties of the Oversight Committee;
- 77 (5) report on medical marijuana program activities and answer questions;
- 78 (6) conduct the general correspondence of the Oversight Committee;
- 79 (7) prepare position papers, regulatory amendment documents, or other official
80 documents generated by the Oversight Committee; and
- 81 (8) perform any other duties delegated by the Secretary of DHSS.

82 ARTICLE V. OFFICERS.

83 Section 1. Chair and Vice-Chair – The officers of the Oversight Committee shall be a
84 Chair and a Vice-Chair.

85 Section 2. Duties and Responsibilities – The duties and responsibilities of the Chair
86 and Vice-Chair shall be as follows:

- 87 (1) Chair – The Chair shall preside at all meetings of the Oversight Committee,
88 except the Chair may designate another member to preside at a particular

89 meeting or at a certain part of a meeting. The Chair may lead periodic review
90 of the Oversight Committee by-laws. The Chair shall perform such other
91 duties as the Oversight Committee, from time to time, shall designate.

92 (2) Vice-Chair – In the absence of the Chair, the Vice-Chair shall have all of the
93 duties and responsibilities of the Chair. The Vice-Chair shall perform such
94 other duties as the Oversight Committee, from time to time, shall designate.

95 Section 3. Term – The term of office of the Chair and Vice-Chair shall be two years
96 and shall begin at the close of the Oversight Committee meeting at which they are
97 elected.

98 Section 4. The Oversight Committee shall hold election of Officers – the Chair and
99 Vice-Chair – on a semi-annual basis with elections occurring at either the meeting
100 preceding the end of an officer’s term if within 90 days of the term completion, or the
101 first meeting after a two-year term has elapsed.

102 Section 5. Vacancies – A vacancy in the office of Chair shall be filled by the
103 advancement of the Vice-Chair, until the Oversight Committee can convene to elect a
104 new Chair. A vacancy in the office of the Vice-Chair shall be filled temporarily by a
105 selection of the Chair, until the Oversight Committee can convene to elect a new Vice-
106 Chair.

107 Section 6. Removal from Office – The Chair or Vice-Chair may be removed from

108 office for cause by a two-thirds vote of the members present at any meeting of the
109 Oversight Committee, after notice of the meeting and agenda has been distributed to the
110 membership.

111 ARTICLE VI. MEETINGS.

112 Section 1. Regular Meetings – The Oversight Committee shall hold two regular
113 meetings each calendar year and will hold its election of officers at the last meeting of the
114 year.

115 Section 2. Special Meetings – The Oversight Committee may, upon written request
116 of a majority of the members, upon the request of the Chair or at the request of the
117 Department Secretary or designee shall call special meetings at such times and places as
118 may be determined.

119 Section 3. Notice – Notices of meetings of the Oversight Committee shall be
120 distributed to the membership prior to the meeting and shall be posted to the State Public
121 Meetings webpage at least ten days prior to the meeting date. In addition, in response to
122 29 Del. C. § 10004(e)(2), the Oversight Committee shall pre-announce or pre-publish the
123 agenda for all Executive Sessions; however, such agenda shall be subject to include
124 additional items which arise at the time of the Oversight Committee’s regular meeting.

125 Section 4. Quorum – A quorum shall consist of 51% of the membership of the

126 Oversight Committee. If at any meeting there is less than a quorum present, official
127 business cannot be performed.

128 Section 5. Voting – Each member of the Oversight Committee shall have one vote on
129 matters brought before the Oversight Committee except when the member has a conflict
130 of interest. The disqualification of a member from voting shall not affect the quorum.

131 All matters shall be decided by a majority of the members present and voting.

132 Section 6. Conflict of Interest – Members of the Oversight Committee shall comply
133 with the State Employees', Officers' and Officials' Code of Conduct – 29 Del. C. Ch. 58.
134 A member may not participate in the review or disposition of any matter in which the
135 member has a conflict of interest except to respond to questions from another member or
136 any other person with official responsibility with respect to that matter. A member shall
137 declare the conflict of interest at the earliest practicable time after learning of such
138 conflict.

139 Section 7. Parliamentary procedure – Parliamentary procedures at all meetings of the
140 Oversight Committee shall be in accordance with the current version of Robert’s Rules of
141 Order Newly Revised.

142 ARTICLE VII. COMMITTEES.

143 Section 1 Executive Committee:

- 144 A. The Executive Committee shall be a continuing Committee and:
- 145 a. shall consist of all Oversight Committee officers;
 - 146 b. shall have general supervision of the affairs of the Oversight Committee

147 between meetings;

148 c. may, as emergencies arise and immediate action is required, act on behalf of
149 the Oversight Committee, and shall report any such interim actions at the next
150 scheduled Oversight Committee meeting, such action may be ratified by the full
151 Committee;

152 d. shall be subject to the orders of the Oversight Committee and none of its
153 acts shall conflict with action taken by the Oversight Committee;

- 154 e. may recommend to the Oversight Committee additions and deletions to the
155 Roster, and monitor member performance and attendance at meetings;
- 156 f. shall oversee expenditures and funds, and make recommendations to the
157 Oversight Committee for changes;
- 158 g. may recommend to the Oversight Committee changes for policies and
159 procedures;
- 160 h. must approve all major changes to the projected or approved annual budget.
- 161 B. The Oversight Committee Chair shall preside over the Executive Committee
- 162 Section 2 Sub-Committees:
- 163 A. The Oversight Committee or the Executive Committee may establish sub-
164 committees as necessary to carry out business, responsibilities or assigned projects.
- 165 B. The Oversight Committee or Executive Committee shall review and decide when a
166 sub-committee is essential and vote to establish such sub-committee.
- 167 C. The Oversight Committee Chair shall designate a Committee member to Chair the
168 assigned sub-committee.

- 169 D. The sub-committee Chair shall:
- 170 a. assign all sub-committee meeting dates;
- 171 b. ensure the meeting agendas and minutes are posted pursuant to statutory
- 172 requirements;
- 173 c. ensure all sub-committee progress is presented to the Oversight Committee
- 174 members, at each scheduled Oversight Committee meeting through the duration
- 175 of a project

- 176 E. Non Oversight Committee members may participate in sub-committee meetings
177 and work.
- 178 a. The sub-committee members may reach out for assistance as needed to
179 accomplish the assigned project.
- 180 b. Sub-committee members selected from the community at large will serve on
181 a voluntary basis and will not have voting privileges on matters before the
182 Oversight Committee.
- 183 c. Upon selection of a sub-committee member who is not a member of the
184 Oversight Committee, the Chairperson shall notify the Secretary of DHSS or the
185 Secretary's designated representative.
- 186 d. The Oversight Committee Chair shall be an ex-officio member of all sub-
187 committee and shall be responsible for their task completions.
- 188 i. Sub-committee chairpersons shall be appointed by the Chair of the
189 Oversight Committee, and the tasks and products of any such committee
190 shall be defined by the Chair of the Oversight Committee with specific

191 dates established for reports to the full Oversight Committee membership.

192 F. All established sub-committee members shall be responsible for accomplishing
193 assigned projects in a timely manner.

194 G. Sub-committee critical decisions should be addressed at scheduled Oversight
195 Committee meetings for a vote, prior to the sub-committee taking action. If the sub-
196 committee is working with a deadline and needs sudden action, and there is not a
197 scheduled Oversight Committee meeting to address the need in a timely manner, the

198 Chair of the sub-committee shall address the Executive Committee for a decision.

199 ARTICLE VIII. AMENDMENT OF BYLAWS.

200 These bylaws may be altered, amended, or repealed, and new bylaws may be adopted by
201 a majority (quorum) of the Oversight Committee members present at any regular or
202 special meeting, provided that no such action in any way conflicts with the statutory
203 obligations of the Oversight Committee, as stated in 16 Del. C. Ch. 49A and provided
204 that written notice shall have been sent to each member. Such notice shall describe, at
205 least in general terms, the alterations, amendments, or changes that are proposed to be
206 made to the Bylaws. Whenever these Bylaws, or a provision of these Bylaws, is found to
207 conflict with Delaware law, such provision shall be deemed invalid without affecting the
208 remainder of the Bylaws.

§ 4922A. Oversight Committee; annual report by Department.

(a) The Medical Marijuana Act Oversight Committee is established to evaluate and make recommendations regarding the implementation of this chapter.

(1) The Oversight Committee shall consist of 9 members who possess the qualifications and are appointed as follows:

a. One member, appointed by the President Pro Tempore of the Senate.

b. One member, appointed by the Speaker of the House.

c. The Secretary of the Department, or a designee appointed by the Secretary.

d. Two medical professionals, each licensed in Delaware, with experience in medical marijuana issues, appointed by the Governor.

e. One member with experience in policy development or implementation in the field of medical marijuana, appointed by the Governor.

f. Three members who each shall be a cardholder, as defined in § 4902A of this title, appointed by the Governor.

(2) The members of the Oversight Committee shall serve at the pleasure of the appointing authority.

(3) A quorum shall consist of 51% of the membership of the Oversight Committee.

(4) The Oversight Committee shall select a Chair and Vice Chair from among its members.

(5) Staff support for the Oversight Committee shall be provided by the Department.

(6) The Oversight Committee shall meet at least 2 times per year for the purpose of evaluating and making recommendations to the Governor, the General Assembly, and the Department regarding the following:

a. The ability of qualifying patients in all areas of the State to obtain timely access to high-quality medical marijuana.

b. The effectiveness of the registered compassion centers, individually and together, in serving the needs of qualifying patients, including the provision of educational and support services, the reasonableness of their fees, whether they are generating any complaints or security problems, and the sufficiency of the number operating to serve the registered qualifying patients of Delaware.

c. The effectiveness of the registered safety compliance facility or facilities, including whether a sufficient number are operating.

d. The sufficiency of the regulatory and security safeguards contained in this chapter and adopted by the Department to ensure that access to and use of marijuana cultivated is provided only to cardholders authorized for such purposes.

e. Any recommended additions or revisions to the Department regulations or this chapter, including relating to security, safe handling, labeling, and nomenclature.

f. Any research studies regarding health effects of medical marijuana for patients.

(b) The Department shall submit to the Governor and the General Assembly an annual report that does not disclose any identifying information about cardholders, registered compassion centers, or health-care practitioners, but does contain, at a minimum, all of the following information:

(1) The number of applications and renewals filed for registry identification cards.

(2) The number of qualifying patients and designated caregivers approved in each county.

(3) The nature of the debilitating medical conditions of the qualifying patients.

(4) The number of registry identification cards revoked for misconduct.

(5) The number of health-care practitioners providing written certifications for qualifying patients.

(6) The number of registered compassion centers.

(7) Specific accounting of fees and costs.

(78 Del. Laws, c. 23, § 1; 80 Del. Laws, c. 11, § 1; 83 Del. Laws, c. 48, § 12.)

**TITLE 16 HEALTH AND SAFETY
 DELAWARE ADMINISTRATIVE CODE**

**DEPARTMENT OF HEALTH AND SOCIAL SERVICES
 DIVISION OF PUBLIC HEALTH
 4400 Health Systems Protection**

4470 State of Delaware Medical Marijuana Code

Preamble

The Secretary of Delaware Health and Social Services adopts these regulations in response to the authority vested in the Secretary by 16 **Del.C.** Ch. 49A, The Delaware Medical Marijuana Act. These regulations establish the standards for the procedures for issuing a certificate of registration to qualified patients and designated caregivers. These regulations provide a system of permitting and inspection, as well as governing confidentiality, payments of fees, and enforcement of these rules.

17 DE Reg. 738 (01/01/14)

23 DE Reg. 667 (02/01/20)

Purpose

These regulations shall be liberally construed and applied to promote their underlying purpose of protecting the public's health.

23 DE Reg. 667 (02/01/20)

1.0 State of Delaware Medical Marijuana Code

These regulations shall hereby be known as the "State of Delaware Medical Marijuana Code."

23 DE Reg. 667 (02/01/20)

2.0 Definitions

The following words and terms, when used in these regulations, should have the following meaning, unless the context clearly indicates otherwise:

"**Act**" means the Delaware Marijuana Act, 16 **Del.C.** §§4901A *et seq.*

"**Applicant**" means any person applying to participate in the Delaware Medical Marijuana Program, hereinafter MMP.

"**Background check**" means any person required to obtain a background check under this chapter shall submit fingerprints and other necessary information to the State Bureau of Identification in order to obtain a report of the person's entire criminal history record from the State Bureau of Identification or a statement that the State Bureau of Identification Central Repository contains no such information relating to that person. The report will include the person's entire federal criminal history record from the Federal Bureau of Investigation pursuant to Federal Bureau of Investigation appropriation of Title II of Public Law 92-544 (28 U.S.C. § 534) or a statement that the Federal Bureau of Investigation's records contain no such information relating to that person. A person required to obtain a background check under this chapter is responsible for any costs associated with obtaining the background check.

"**Batch**" A batch is a collection of plants of the same strain and genetics, grown in the same room at the same time. The maximum batch size is five (5) pounds or 2268 grams.

"**Bona fide physician-patient relationship**" means a treatment or counseling relationship between a physician and patient in which all the following are present:

- (1) The physician has reviewed the patient's relevant medical records and completed a full assessment of the patient's medical history and current medical condition, including a relevant, in-person, medical evaluation of the patient.
- (2) The physician has created and maintained records of the patient's condition in accord with medically accepted standards.
- (3) The patient is under the physician's continued care for primary medical care or the debilitating condition that qualifies the patient for the Medical Marijuana Program.

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(4) The physician has a reasonable expectation that he or she will provide follow-up care to the patient to monitor the efficacy of the use of medical marijuana as a treatment of the patient's debilitating medical condition.

(5) The relationship is not for the sole purpose of certifying for medical marijuana.

"Cannabidiol" or **"CBD"** is a cannabinoid found in cannabis with mild psychoactive properties that does not induce a euphoric high.

"Cannabidiol-Rich medical marijuana" or **"CBD-Rich"** means a marijuana strain or product formulation that has elevated levels of cannabidiol ("CBD") and contains the profile of CBD and tetrahydrocannabinol ("THC") concentrations approved by the Department, based upon the recommendation of the Medical Marijuana Act Oversight Committee.

"Cardholder" means a registered patient or a registered designated caregiver who has been issued and possesses a valid registry identification card.

"Compassion center agent" means a principal officer, board member, employee, or agent of a registered compassion center who is 21 years of age or older and has not been convicted of an excluded felony offense, and has not been convicted of a drug misdemeanor within five years.

"Compassionate use card" means a card issued by the Department for conditions not covered in the Act or regulations. The compassionate use card has additional requirements for approval.

"Concentrate" means any product created when marijuana flowers are refined into something purer and more potent. This umbrella term includes any type of hash (water hash, pressed hash), dry sieve (kief), as well as hash oils (CO₂ oil, shatter, wax, and rosin) and indicates that these products are a concentrated form of cannabis, carrying a higher potency.

"Consumer" means a person who is a patient in the Medical Marijuana Program, takes possession of marijuana, and is not functioning in the capacity of an operator of a marijuana business.

"Debilitating medical condition" means one or more of the following:

- (a) Terminal illness, cancer, positive status for human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), decompensated cirrhosis, amyotrophic lateral sclerosis (ALS or Lou Gehrig's Disease), post-traumatic stress disorder (PTSD), intractable epilepsy, autism with self-injurious or aggressive behavior, seizure disorder, glaucoma, chronic debilitating migraines, new daily persistent headache, and agitation of Alzheimer's disease or the treatment of these conditions;
- (b) A chronic or debilitating disease medical condition or its treatment that produces one or more of the following: cachexia or wasting syndrome; severe, debilitating pain that has not responded to previously prescribed medication or surgical measures for more than three months or for which other treatment options produced serious side effects; intractable nausea; seizures; or severe and persistent muscle spasms, including but not limited to those characteristic of multiple sclerosis;
- (c) Pediatric qualifying conditions are limited to any of the following related to a terminal illness: pain, anxiety, or depression; seizure disorder; severe debilitating autism; or a chronic or debilitating disease or medical condition where they have failed treatment involving one or more of the following symptoms: cachexia or wasting syndrome; intractable nausea; severe, painful and persistent muscle spasms; and chronic debilitating migraines and new daily persistent headache that are refractory to conventional treatment and interventions; or
- (d) Any other medical condition or its treatment added by the Department, as provided for in 16 **Del.C.** §4906A and Section 6.0 of this Code; or
- (e) Anxiety, which is restricted to CBD-Rich medical marijuana products.

"Delaware Enterprise Consolidated Cannabis Control System" or **"DEC3S"** is the statewide application which serves as patient registry, point of sale monitor, seed to sale inventory tracker and repository of medical marijuana product test results.

"Department" means the Delaware Department of Health and Social Services.

"Designated caregiver" means a person who:

- (a) Is at least 21 years of age unless the person is the parent or legal guardian of a minor who is a qualifying patient;
- (b) Has agreed to assist with a patient's medical use of marijuana;
- (c) Has not been convicted of an excluded felony offense; and

(d) Assists no more than five qualifying patients with their medical use of marijuana.

"Direct Sales" means sales of marijuana products within the State of Delaware directly to the registered patients without the use of an independent retailer or other intermediary.

"Division" means the Delaware Division of Public Health.

"Employee" or **"Agent"** refers to an individual having supervisory or management duties, an individual on the payroll, a volunteer, an individual performing work under contractual agreement, or any other individual working in a marijuana business.

"Excluded felony offense" means:

- (a) A violent crime defined in 11 **Del.C.** §4201(c), that was classified as a felony in the jurisdiction where the person was convicted; or
- (b) A violation of a state or federal controlled substance law that was classified as a felony in the jurisdiction where the person was convicted, not including:
 - (1) An offense for which the sentence, including any term of probation, incarceration, or supervised release, was completed 10 or more years earlier; or
 - (2) An offense that consisted of conduct for which 16 **Del.C.** Ch. 49A would likely have prevented a conviction, but the conduct either occurred prior to July 1, 2011, or was prosecuted by an authority other than the State of Delaware.

"Food-Contact Surface" means a surface of equipment or a utensil with which food normally comes into contact; or a surface of equipment or a utensil from which food may drain, drip or splash into a food or onto; or a surface normally in contact with food.

"Imminent Health Hazard" means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on the number of potential injuries and the nature, severity, and duration of the anticipated injury.

"Inspection" means a visit by an employee of the Department for the purpose of ensuring compliance with the requirements of these rules.

"Intractable epilepsy" means an epileptic seizure disorder for which standard medical treatment does not prevent or significantly ameliorate recurring, uncontrolled seizures or for which standard medical treatment results in harmful side effects.

"Marijuana" means the same as defined in 16 **Del.C.** §4701.

"Marijuana Infused Food Products" refers to a non-time/temperature controlled (non-TCS) for safety food as specified in these regulations that is offered for sale directly to consumers and only at a licensed Compassion Center.

"Marijuana Infused Food Establishment" refers to a licensed Compassion Center that has received an endorsement from the Department to make non-time/temperature controlled (non-TCS) marijuana infused food products.

"Medical Marijuana Act Oversight Committee" means the committee established to evaluate and make recommendations regarding the implementation of 16 **Del.C.** Ch. 49A.

"Medical marijuana oil" means a resinous matrix of cannabinoids obtained from the Cannabis plant by solvent extraction, formed into oil.

"Medical marijuana waste" means unused, surplus, returned, or out of date medical marijuana, recalled medical marijuana, and any plant debris, including dead plants, all unused plant parts, and roots.

"Medical use" means the acquisition, possession, use, delivery, transfer or transportation of marijuana or paraphernalia relating to the administration of marijuana to treat or alleviate a registered patient's debilitating medical condition or symptoms associated with the registered patient's debilitating medical condition.

"Pediatric Medical marijuana oil" means:

- a. "Cannabidiol oil" which is a processed Cannabis plant extract that contains at least 15% cannabidiol but no more than 7% tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least 50 milligrams of cannabidiol per milliliter but not more than 7% tetrahydrocannabinol.
- b. "THC-A oil" which is a processed Cannabis plant extract that contains at least 15% tetrahydrocannabinol acid but not more than 7% tetrahydrocannabinol, or a dilution of the resin of

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the Cannabis plant that contains at least 50 milligrams of tetrahydrocannabinol acid per milliliter but not more than 7% tetrahydrocannabinol.

- c. Any change in the oil formulation which is made by the Department based upon the recommendation of the Medical Marijuana Act Oversight Committee.

“Physician” means a properly licensed physician subject to 24 **Del.C.** Ch. 17, except as otherwise provided in this definition. If the qualifying patient is younger than 18 years of age, the physician must be a pediatric neurologist, pediatric gastroenterologist, pediatric oncologist, pediatric psychiatrist, developmental pediatrician or pediatric palliative care specialist.

“Poisonous and Toxic Materials” means substances that are not intended for ingestion, including cleaners and sanitizers; pesticides; necessary maintenance substances such as non-food grade lubricants; and personal care items such as medicines, first aid supplies, cosmetics and toiletries.

“Post-Traumatic Stress Disorder” means that a patient meets the diagnostic criteria for Post-Traumatic Stress Disorder (PTSD), per DSM-5 or subsequent current edition, including symptoms of intense physical reactions such as tachycardia, shortness of breath, rapid breathing, muscle-tension, and sweating.

“Processing area” refers to the area of the marijuana business where marijuana is prepared, trimmed, packaged or food prep and other food service activities occur.

“Producer” refers to employees of the Marijuana Infused Food Establishment involved with the production of marijuana infused products.

“Qualifying patient” means an individual who meets the qualifications to receive a registry identification card under this chapter.

“Registry identification card” means a document issued by the Department that identifies a person as one of the following:

- a. A registered qualifying adult patient.
- b. A registered designated caregiver for a qualifying adult patient.
- c. A registered designated caregiver for a pediatric patient.
- d. A registered adult compassionate use patient.
- e. A registered designated caregiver for an adult compassionate use patient.
- f. A registered designated caregiver for a pediatric compassionate use patient.
- g. A registered CBD-Rich patient.
- h. A registered designated caregiver for a CBD-Rich patient.

“Responsible Party” means the parent or legal guardian with responsibility and decision-making capability for a qualifying patient or applicant. The Responsible Party will have primary responsibility for purchase, handling and dispensing of the medical marijuana products for the person under the Responsible Party’s charge.

“Safety Compliance Facility” means a nonprofit organization permitted to test marijuana produced for medical use for potency and contaminants.

“Sanitization” refers to a heat or chemical treatment on cleaned food contact surfaces that is sufficient to yield a 99.999% reduction of the number of representative disease microorganisms of public health significance.

“Temperature Measuring Device” or **“TMD”** means a thermometer, thermocouple, thermistor or other device that indicates the temperature of food, air or water.

“Terminal Illness” means any disease, illness or condition sustained by any human being for which there is no reasonable medical expectation of recovery; which, as a medical probability, will result in the death of such human being regardless of the use or discontinuance of medical treatment implemented for the purpose of sustaining life or the life processes; and as a result of which, the human being’s health-care practitioner would not be surprised if death were to occur within 12 months.

“Tetrahydrocannabinol Delta 9” or **“THC”** is a decarboxylated cannabinoid found in cannabis with strongly psychoactive properties that induces a euphoric high.

“Time/Temperature Control for Safety Food” or **“TCS”** means a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.

“Tincture” means a mixture created from a concentrated extract of marijuana.

“Topical” means a mixture or extract of marijuana made into a balm, lotion, ointment or rubbing alcohol solution, that is applied transcutaneously for treatment.

“Usable marijuana” means the dried leaves and flowers of the marijuana plant, and any mixture or preparation of those dried leaves and flowers, including but not limited to tinctures, ointments, and other preparations including medical marijuana oil, but does not include the seeds, stalks, and roots of the plant. It does not include the weight of any non-marijuana ingredients combined with marijuana, such as ingredients added to prepare a topical administration, food, or drink.

“Written certification” means a document dated and signed by a physician, stating that in the physician’s opinion the patient is likely to receive therapeutic or palliative benefit from the medical use of marijuana to treat or alleviate the patient’s debilitating medical condition or symptoms associated with the debilitating medical condition. A written certification shall be made only in the course of a bona fide physician-patient relationship where the qualifying patient is under the physician’s care for the qualifying patient’s primary care or for the qualifying patient’s debilitating condition after the physician has completed an assessment of the qualifying patient’s medical history and current medical condition. The bona fide physician-patient relationship may not be limited to authorization for the patient to use medical marijuana or consultation for that purpose. The written certification shall specify the qualifying patient’s debilitating medical condition.

17 DE Reg. 738 (01/01/14)

19 DE Reg. 409 (11/01/15)

23 DE Reg. 667 (02/01/20)

24 DE Reg. 485 (11/01/20)

3.0 Qualifying Patient Identification Card Application Requirements

- 3.1 The Department shall issue a registry identification card to an applicant for the purpose of participating in the medical marijuana program upon the written certification of the applicant’s physician, supporting application documents and a non-refundable application fee with a personal check or a cashier’s check made out to “State of Delaware-MMP”. The following information must be provided in the participant enrollment form submitted to the Department in order for a registry identification card to be obtained and processed.
- 3.2 An attached original written certification for patient eligibility form shall contain:
 - 3.2.1 The name, address and telephone number of the applicant’s physician;
 - 3.2.2 The physician’s clinical licensure;
 - 3.2.3 The patient applicant’s name and date of birth;
 - 3.2.4 The medical justification for the physician’s certification of the patient’s debilitating medical condition;
 - 3.2.5 The physician’s signature and date;
 - 3.2.6 The name and address of the applicant as they appear on the applicant’s government issued ID card, and date of birth of the applicant;
 - 3.2.7 The name, address and date of birth of the applicant’s primary caregiver or caregivers, if any;
 - 3.2.8 A reasonable xerographic copy of the applicant’s Delaware driver’s license or comparable State of Delaware or federal issued photo identification card verifying Delaware residence; State of Delaware issued identification card must be available for inspection/verification;
 - 3.2.9 The length of time the applicant has been under the care of the physician providing the medical provider certification for patient eligibility;
 - 3.2.10 The applicant’s signature and date; and
 - 3.2.11 A signed consent for release of medical information related to the patient’s debilitating medical condition, on a form provided by the medical marijuana program.
 - 3.2.12 A designation of type of card: Adult Patient, Pediatric Patient, Compassionate Use Adult Patient, Compassionate Use Pediatric Patient, or CBD-Rich Adult Patient.
- 3.3 If the qualifying patient is under the charge of a Responsible Party as defined in these regulations:
 - 3.3.1 The Responsible Party must be identified on the application.
 - 3.3.2 If the qualifying patient is of an age where an ID to meet subsections 3.2.6 and 3.2.8 above has not been issued, the Responsible Party’s ID shall be used. If the qualifying patient has a government issued ID, information and IDs for both individuals shall meet subsections 3.2.6 and 3.2.8 above.
 - 3.3.3 If the patient is under the age of 18, the physician must be a pediatric neurologist, pediatric gastroenterologist, pediatric oncologist, pediatric psychiatrist, developmental pediatrician or pediatric palliative care specialist and certify that:

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- 3.3.3.1 The qualifying patient has any of the following related to a terminal illness: pain, anxiety or depression; or
- 3.3.3.2 The qualifying patient has intractable epilepsy or seizure disorder;
- 3.3.3.3 The qualifying patient has a chronic or debilitating disease or medical condition where the patient has failed treatment involving one or more of the following symptoms: cachexia or wasting syndrome; intractable nausea; severe, painful and persistent muscle spasms; or chronic debilitating migraines and new daily persistent headache that are refractory to conventional treatment and interventions; or
- 3.3.3.4 The qualifying patient has severe debilitating autism.
- 3.3.4 Patients under the age of 18 will have distinctive identifying banner on their patient identification card limiting the patient to marijuana oil purchases only.
- 3.3.5 Responsible Parties for qualifying patients under the age of 18 will be issued an identification card with the same type of 10-digit alphanumeric identifier provided to the minor in question.
- 3.4 The Department shall issue a compassionate use card to an eligible individual who submits all of the following:
 - 3.4.1 A signed statement from the patient's physician that includes statements attesting to all of the following:
 - 3.4.1.1 The patient has a severe and debilitating condition;
 - 3.4.1.2 All current standard care practices and treatments have been exhausted and have been ineffective or the side effects are prohibitive with continued use;
 - 3.4.1.3 The physician will re-evaluate and document the efficacy of medical marijuana treatment;
 - 3.4.1.4 There are grounds supporting the potential for the patient to benefit from using medical marijuana;
 - 3.4.1.5 The treating physician must detail how medical marijuana will be integrated into the patient's comprehensive treatment plan, identifying all wrap-around services including counseling, other medications, or specialty care. The Department will review the comprehensive treatment plan, including the re-evaluation interval.
 - 3.4.1.6 If the patient is an adult, a signed statement from the patient acknowledging the patient's informed consent to treatment with medical marijuana and that the patient knows that there is limited or no evidence associated with medical marijuana's effectiveness in treating a condition that is not a debilitating medical condition under this chapter.
 - 3.4.1.6.1 If the patient is under 18 years of age, a signed statement from the patient's parent or legal guardian acknowledging the patient's informed consent to treatment with medical marijuana and that the patient's parent or legal guardian knows that there is limited or no evidence associated with medical marijuana's effectiveness in treating a condition that is not a debilitating medical condition under this chapter.
 - 3.4.2 The physician certifying a patient for a compassionate use card will re-evaluate the efficacy of medical marijuana treatment at the following intervals:
 - 3.4.2.1 For substance use disorder diagnoses, re-evaluate after 15 days for the first 90 days, and every 30 days thereafter;
 - 3.4.2.2 For mental health disorder diagnoses, re-evaluate every 30 days;
 - 3.4.2.3 For autoimmune disease diagnoses, re-evaluate every 30 days for the first 90 days, and every 90 days thereafter; and
 - 3.4.2.4 For other conditions, re-evaluate every 30 days, unless otherwise indicated or waived by the Department.
 - 3.4.3 The timeframe for reevaluation begins on the date the card is issued.
 - 3.4.4 The physician certifying a patient for a compassionate use card may require the re-evaluation of the patient at shorter intervals than listed if appropriate.
 - 3.4.5 Updated documentation of the re-evaluations for the compassionate use card must be transmitted to the Department by the certifying practice within five business days of the re-evaluation interval to prevent the compassionate use card from entering a suspension status.
- 3.5 CBD-Rich Medical Marijuana
 - 3.5.1 The Department shall issue a CBD-Rich card to a qualifying patient whose provider has certified that their debilitating medical condition is anxiety.
 - 3.5.2 A patient who qualifies for a CBD-Rich card may only purchase Cannabidiol-Rich medical marijuana products.

3.5.3 Any condition that is authorized under the Medical Marijuana Act for adult patients 18 years and older may be treated with CBD-Rich medical marijuana.

17 DE Reg. 738 (01/01/14)

19 DE Reg. 409 (11/01/15)

23 DE Reg. 667 (02/01/20)

24 DE Reg. 485 (11/01/20)

4.0 Designated Caregiver Registry Identification Card Application Requirements

4.1 The Department shall issue a registry identification card to a designated caregiver applicant for the purpose of managing the well-being of one to five qualified patients, including themselves if caregiver is a qualified patient, in response to the requirements of this rule upon the completion and approval of the designated caregiver application form, available from the medical marijuana program, and a non-refundable application fee, in the form of a personal check, money order or a cashier's check made out to "State of Delaware-MMP". In order for a registry identification card to be obtained and processed, the following information shall be submitted to the medical marijuana program:

4.1.1 Proof that the applicant is at least 21 years of age unless the person is the parent or legal guardian of a minor who is a qualifying patient;

4.1.2 A reasonable xerographic copy of the applicant's Delaware license or comparable State of Delaware or federal issued photo identification card verifying Delaware residence; State of Delaware issued identification card must be available for inspection/verification.

4.1.3 Written approval by the qualified patient or patients authorizing responsibility for managing the well-being of a qualified patient or patients with respect to the use of marijuana;

4.1.4 The name, address, telephone number, and date of birth of each qualified patient;

4.1.5 The name and address of the applicant as they appear on the applicant's government issued ID card, telephone number of the applicant; and

4.1.6 The applicant's signature and date.

4.2 Designated caregiver application requirements:

4.2.1 Criminal history screening requirements:

4.2.1.1 All designated caregiver applicants are required to consent to a nationwide and statewide criminal history screening background check every three years. All applicable application fees associated with the nationwide and statewide criminal history screening background check shall be paid by the designated caregiver applicant.

4.2.1.2 Individuals convicted of an excluded felony offense, as described in the definitions Section 2.0, and 16 **Del.C.** §4902A(7) are prohibited from serving as a designated caregiver. The applicant and qualified patient shall be notified by registered mail of his or her disqualification from being a designated caregiver.

17 DE Reg. 738 (01/01/14)

19 DE Reg. 409 (11/01/15)

23 DE Reg. 667 (02/01/20)

24 DE Reg. 485 (11/01/20)

5.0 Registry Identification Cards

5.1 Department inquiry:

5.1.1 The Department may verify information on each application and accompanying documentation by the following methods:

5.1.1.1 Contacting each applicant by telephone, mail, or if proof of identity is uncertain, the Department shall require a face-to-face meeting and the production of additional identification materials;

5.1.1.2 Contacting the Delaware Division of Professional Regulation to verify that the physician is licensed to practice medicine in Delaware and is in good standing; and

5.1.1.3 Contacting the physician to obtain further documentation that the applicant's medical diagnosis and medical condition qualify the applicant for enrollment in the medical use marijuana program.

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- 5.1.2 Upon verification of the information contained in an application submitted in response to this subsection, the Department shall approve or deny an application within 45 calendar days of receipt.
- 5.2 Department registry identification card: The Department shall issue a registry identification card within 30 calendar days of approving an application. A registry identification card shall contain a 10-digit alphanumeric identification, maintained by the Department, which identifies the qualified patient or designated caregiver. Unless renewed at an earlier date, suspended or revoked, or if the physician stated in the written certification that the qualifying patient would benefit from marijuana until a specified earlier date, a registry identification card shall be valid for a period of one year from the date of issuance and shall expire at midnight on the day indicated on the registry identification card as the expiration date.
- 5.3 Supplemental requirement:
- 5.3.1 A registered qualifying patient or registered designated caregiver who possesses a registry identification card shall notify the Department of any of the following within 10 calendar days of the change. An extension shall be granted by the medical marijuana program upon the showing of good cause.
- 5.3.1.1 A change in cardholder's name or address.
- 5.3.1.2 Knowledge of a change that would render the patient no longer qualified to participate in the program, such as a cure of the debilitating condition causing the need for Medical Marijuana.
- 5.3.1.3 Knowledge of a change that renders the patient's physician no longer a qualified "physician" as defined in Section 2.0 of these regulations; and
- 5.3.1.4 Knowledge of a change that renders the patient's caregiver no longer eligible as defined in these regulations.
- 5.3.2 Before a registered qualifying patient changes his or her designated caregiver, the qualifying patient must notify the Department in writing.
- 5.3.3 If a cardholder loses his or her registry identification card, he or she shall notify the Department in writing within 10 days of becoming aware the card has been lost. Upon notification, the Department shall issue a new registry identification card. Unless documentation in the initial application has changed, the qualified patient or designated caregiver shall not be required to submit a new application.
- 5.3.4 When a cardholder notifies the Department of items listed in subsection 5.3 but remains eligible, the Department shall issue the cardholder a new registry identification card with a new random 10-digit alphanumeric identification number within 10 days of receiving the updated information and the cardholder shall pay a \$20 fee. If the person notifying the Department is a registered qualifying patient, the Department shall also issue his or her registered designated caregiver, if any, a new registry identification card within 10 days of receiving the updated information.
- 5.3.5 If a registered qualifying patient ceases to be a registered qualifying patient or changes his or her registered designated caregiver, the Department shall promptly notify the designated caregiver by legal process server. The registered designated caregiver's protections under this chapter as to that qualifying patient shall expire 15 days after notification by the Department.
- 5.3.6 A cardholder who fails to make a notification to the Department that is required by subsection 5.3 is subject to a civil infraction, punishable by a penalty of no more than \$150.00 and is also subject to the immediate revocation of the registry identification card and all lawful privileges provided under the act.
- 5.3.7 If the registered qualifying patient's certifying physician notifies the Department in writing that either the registered qualifying patient has ceased to suffer from a debilitating medical condition or that the physician no longer believes the patient would receive therapeutic or palliative benefit from the medical use of marijuana, the card shall become null and void. However, the registered qualifying patient shall have 15 days to dispose of the patient's marijuana.
- 5.3.8 When a registered qualifying pediatric patient attains 18 years of age, the patient may request a new patient card releasing them from the pediatric restrictions. The new patient ID card will be issued at the card replacement cost \$20 and maintain the original expiration date.
- 5.4 Registry identification card application denial: The DHSS Secretary or designee shall deny an application if the applicant fails to provide the information required, if the Department determines that the information provided is false, or if the patient does not have a debilitating medical condition eligible for enrollment in the program, as determined by the DHSS Secretary. A person whose application has been denied shall not reapply for six months from the date of the denial, unless otherwise authorized by the Department, and is prohibited from all lawful privileges provided by this rule and act.

- 5.4.1 The Department shall deny an application or renewal of a qualifying patient's registry identification card if the applicant:
 - 5.4.1.1 Did not provide the required information and materials;
 - 5.4.1.2 Previously had a registry identification card revoked; or
 - 5.4.1.3 Provided false or falsified information.
- 5.4.2 The Department shall deny an application or renewal for a designated caregiver chosen by a qualifying patient whose registry identification card was granted if:
 - 5.4.2.1 The designated caregiver does not meet the requirements of subsection 4.2;
 - 5.4.2.2 The applicant did not provide the information required;
 - 5.4.2.3 The designated caregiver previously had a registry identification card revoked; or
 - 5.4.2.4 The applicant or the designated caregiver provides false or falsified information.
- 5.4.3 The Department shall notify the qualifying patient who has designated someone to serve as his or her designated caregiver if a registry identification card will not be issued to the designated caregiver.
- 5.4.4 Denial of an application or renewal is considered a final Department action, subject to judicial review. Jurisdiction and venue for judicial review are vested in the Superior Court.
 - 5.4.4.1 Denial of an application or renewal for a compassionate use registry identification card is not subject to judicial review.
- 5.5 Registry identification card renewal application: Each registry identification card issued by the Department is valid in accordance with subsection 5.2. A qualified patient or designated caregiver shall apply for a registry identification card renewal no less than 45 calendar days prior to the expiration date of the existing registry identification card in order to prevent interruption of possession of a valid (unexpired) registry identification card.
- 5.6 Non-transferable registration of registry identification card: A registry identification card shall not be transferred, by assignment or otherwise, to other persons or locations. Any attempt shall result in the immediate revocation of the registry identification card and all lawful privileges provided by this rule and act.
- 5.7 Automatic expiration of registry identification card by administrative withdrawal: Upon request the qualified patient or designated caregiver shall discontinue the medical marijuana program by an administrative withdrawal. A qualified patient or designated caregiver that intends to seek an administrative withdrawal shall notify the licensing authority in writing no less than 30 calendar days prior to withdrawal.

17 DE Reg. 738 (01/01/14)

19 DE Reg. 409 (11/01/15)

23 DE Reg. 667 (02/01/20)

6.0 Addition of Debilitating Medical Conditions

- 6.1 Any citizen may petition the Department to add conditions or treatments to the list of debilitating medical conditions listed in 16 **Del.C.** §4902A(3).
- 6.2 The Department shall not add a condition or treatment to the list of debilitating medical conditions unless it finds that (1) the medical condition or treatment is debilitating and (2) marijuana is more likely than not to have the potential to be beneficial to treat or alleviate the debilitation associated with the medical condition or treatment.
- 6.3 Contents of the petition: In connection with any petition to add conditions or treatments to the list of debilitating medical conditions listed in 16 **Del.C.** §4902A(3), a petitioner shall provide the following information to the Department:
 - 6.3.1 The extent to which the condition is generally accepted by the medical community and other experts as a valid, existing debilitating medical condition;
 - 6.3.2 If one or more treatments of the condition, rather than the condition itself, are alleged to be the cause of the patient's suffering, the extent to which the treatments causing suffering are generally accepted by the medical community and other experts as valid treatments for the condition;
 - 6.3.3 The extent to which the condition or treatments cause severe suffering, such as severe or chronic pain or severe nausea or vomiting, or otherwise severely impair the patient's ability to carry on activities of daily living;

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- 6.3.4 The ability of conventional medical therapies other than those that cause suffering to alleviate suffering caused by the condition or treatment;
 - 6.3.5 The extent to which evidence that is generally accepted among the medical community and other experts supports a finding that the use of marijuana alleviates suffering caused by the condition or treatment; and
 - 6.3.6 Letters of support from physicians or other licensed health care professionals knowledgeable about the condition or treatment.
 - 6.3.7 The evidence must indicate the intended patient population and whether it is generally accepted for both adult and pediatric use or limited to a particular population.
- 6.4 Evaluation of a petition
- 6.4.1 Upon review of materials submitted in response to subsection 6.3 above, the Division of Public Health (DPH) shall make a determination as to whether the petition has merit.
 - 6.4.2 A petition will be determined to have merit if it contains all of the material required in subsection 6.3 above and the debilitating condition that is the subject of the petition has not been considered through this process in the prior two years, unless significant, generally accepted, scientific discoveries have been made that are substantially likely to reverse the prior decision.
 - 6.4.3 A decision that a petition does not have merit will be made in writing, stating the reason or reasons it has been determined not to have merit and that it is the final decision, subject to judicial review.
 - 6.4.4 A final decision on a petition determined to have merit will be made within 180 days of receipt of the petition in response to the following process.
 - 6.4.4.1 DPH will post the complete petition on the Department's website for a 60-day public comment period.
 - 6.4.4.2 DPH will post notice of a public hearing no fewer than 10 days prior to the public hearing
 - 6.4.4.3 DPH will hold a public hearing within the 60-day public comment period.
 - 6.4.4.4 After the public hearing and closure of the 60-day public comment period, DPH will review the petition and comments. During this review, DPH may conduct additional research, including consultation with additional experts.
 - 6.4.4.5 DPH will draft a written decision on whether to grant the petition and add the debilitating medical condition for review and ultimate decision by the Department Secretary. This written decision will be detailed enough to provide the specific grounds and references to support the decision. The Department Secretary will issue the final decision on the petition.
 - 6.4.4.6 If the petition to add a debilitating medical condition is granted, draft regulations adding the condition to Section 2.0 will be drafted and published in response to the Administrative Procedures Act Process.
- 6.5 The approval or denial of any petition is a final decision of the Department subject to judicial review. Jurisdiction and venue are vested in the Superior Court.

17 DE Reg. 738 (01/01/14)

23 DE Reg. 667 (02/01/20)

24 DE Reg. 485 (11/01/20)

7.0 Registration and Operation of Compassion Centers

- 7.1 Requirements for operation of a compassion center.
 - 7.1.1 General requirements
 - 7.1.1.1 No person shall operate a compassion center without a Department-issued certificate of registration. The application and renewal requirements for a certificate of registration are in subsections 7.6 and 7.10 of these regulations.
 - 7.1.1.2 A compassion center shall be operated on a not-for-profit basis. A compassion center need not be recognized as a tax-exempt organization by the Internal Revenue Service and is not required to incorporate in response to Title 8; however, a compassion center shall maintain appropriate documentation of its not-for-profit status, and such documentation shall be available for inspection in response to subsection 7.2.7 of these regulations.
 - 7.1.1.3 A compassion center shall not acquire, possess, cultivate, manufacture, deliver, transfer, transport, supply or dispense marijuana for any purpose except to assist registered qualifying

- patients with the medical use of marijuana directly or through the qualifying patient's registered designated caregiver.
- 7.1.1.4 Use of pesticides is prohibited:
 - 7.1.1.4.1 There are no pesticides authorized for use on marijuana; as such, a compassion center shall not apply pesticides in the cultivation of marijuana.
 - 7.1.1.4.2 Prohibited pesticides include but are not limited to the following:
 - 7.1.1.4.2.1 Organochlorines;
 - 7.1.1.4.2.2 Organophosphates;
 - 7.1.1.4.2.3 Carbamates; and
 - 7.1.1.4.2.4 Insecticidal, fungicidal or growth regulatory compounds.
 - 7.1.1.5 Packaging of medical marijuana
 - 7.1.1.5.1 All marijuana products shall be in tamper resistant packaging.
 - 7.1.1.6 Labeling of medical marijuana
 - 7.1.1.6.1 All medical marijuana product labels will contain these minimum requirements:
 - 7.1.1.6.1.1 Name of the patient, patient number and date of sale.
 - 7.1.1.6.1.2 Name of the strain, cannabinoid profile, and quantity of the medical marijuana dispensed.
 - 7.1.1.6.1.3 A statement providing that "this product is for medical use only, not for resale" and indicating the medical marijuana is free of contaminants.
 - 7.1.1.7 Labeling shall include recommendations and instructions for use, including daytime or nighttime use and dosing.
 - 7.1.1.8 Online advertising and marketing are permitted subject to the limitations listed in 16 **Del.C.** Ch. 49A.
 - 7.1.2 Location of a compassion center: A compassion center shall not be located within 500 feet of the property line of a preexisting public or private school.
 - 7.1.3 Bylaws
 - 7.1.3.1 A compassion center shall, as part of its initial application, provide to the Department a true, correct, and current copy of its bylaws, and shall maintain such bylaws in accordance with the Act and these regulations.
 - 7.1.3.2 The bylaws of a compassion center shall include at a minimum:
 - 7.1.3.2.1 The ownership structure of the compassion center;
 - 7.1.3.2.2 The composition of the board of directors; and
 - 7.1.3.2.3 Such provisions relative to the disposition of revenues to establish and maintain the not-for-profit character of the compassion center.
 - 7.1.4 Maintenance of accurate books and records
 - 7.1.4.1 Registered compassion centers shall keep detailed financial reports of proceeds and expenses.
 - 7.1.4.2 Registered compassion centers shall maintain all inventory, sales and financial records in accordance with generally accepted accounting principles ("GAAP").
 - 7.1.4.3 An annual financial audit must be conducted by an independent audit firm and submitted to the Department with the compassion center's annual report.
 - 7.1.4.4 The Department or an audit firm contracted by the Department shall at all times have access to all books and records kept by any compassion center.
 - 7.1.5 Disposal of Unusable Marijuana
 - 7.1.5.1 The medical marijuana inventory system must be updated immediately when a plant is pulled out of inventory for destruction, starting the 72-hour destruction quarantine. The plant number, date and reason must be recorded. This information must be available for auditing by the department.
 - 7.1.5.2 Medical marijuana waste must be stored, secured, and managed in accordance with these regulations and approved operations manual procedures. Medical marijuana waste must be made unusable prior to the waste leaving a registered facility.
 - 7.1.5.3 Liquid waste from medical marijuana facilities shall be disposed of in compliance with the applicable County statutes and regulations including the International Plumbing Code.

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- 7.1.5.4 Medical marijuana waste shall be rendered unusable through grinding and incorporating the medical marijuana waste with non-consumable, solid wastes listed below such that the resulting mixture is at least 50% non-marijuana waste:
 - 7.1.5.4.1 Paper waste,
 - 7.1.5.4.2 Plastic waste,
 - 7.1.5.4.3 Cardboard waste,
 - 7.1.5.4.4 Food waste,
 - 7.1.5.4.5 Soil,
 - 7.1.5.4.6 Grease or other compostable oil waste,
 - 7.1.5.4.7 Other wastes approved by the Division of Public Health that will render the medical marijuana waste unusable.
- 7.1.5.5 After the medical marijuana waste is made unusable, the solid waste shall be:
 - 7.1.5.5.1 Disposed of as a solid waste at a solid waste site and disposal facility that has a Certificate of Designation from the local governing body,
 - 7.1.5.5.2 Deposited at a compost facility that has a Certificate of Designation from the Department of Natural Resources and Environmental Control (DNREC), or
 - 7.1.5.5.3 Composted on-site at a facility owned by the generator and operated in compliance with applicable County statutes and regulations.
- 7.2 Security requirements: A compassion center shall implement appropriate security and safety measures to deter and prevent the unauthorized entrance into areas containing marijuana and the theft of marijuana. Such measures shall include the following:
 - 7.2.1 Exterior of premises: With respect to the exterior of a compassion center:
 - 7.2.1.1 Access from outside the premises shall be kept to a minimum and be well controlled.
 - 7.2.1.2 The outside perimeter of the premises shall be well lighted.
 - 7.2.1.3 Entry into any area where marijuana is held shall be limited to authorized personnel.
 - 7.2.2 Alarm system:
 - 7.2.2.1 A compassion center shall have a fully operational security alarm system at each authorized physical address that will provide suitable protection against theft and diversion. For the purpose of these regulations, a fully operational security alarm system shall include:
 - 7.2.2.1.1 Immediate automatic or electronic notification to alert local or municipal law enforcement agencies to an unauthorized breach of security at the compassion center or at any other authorized physical address;
 - 7.2.2.1.2 Immediate automatic or electronic notification to local or municipal public safety personnel of a loss of electrical support backup system; and
 - 7.2.2.1.3 When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
 - 7.2.2.2 A compassion center shall conduct a maintenance inspection/test of the alarm system for each authorized location at intervals not to exceed 30 days from the previous inspection/test. A compassion center shall promptly make all necessary repairs to ensure the proper operation of the alarm system.
 - 7.2.2.3 In the event of a failure of the security system, due to loss of electrical support or mechanical malfunction, that is expected to exceed an eight-hour period, a compassion center shall:
 - 7.2.2.3.1 Within 24 hours of discovery of the event, notify the Department by telephone; and
 - 7.2.2.3.2 Provide alternative security measures approved by the Department or close the authorized physical addresses impacted by the failure/malfunction until the security alarm system has been restored to full operation.
 - 7.2.2.4 A compassion center shall maintain documentation in an auditable form for a period of at least 24 months after the event for:
 - 7.2.2.4.1 All maintenance inspections/tests conducted in response to subsection 7.2.2.2 of these regulations, and any servicing, modification or upgrade performed on the security alarm system. The record shall include, as a minimum, the date of the action, a summary of the

- actions performed and the name, signature and title of the individual who performed the actions;
- 7.2.2.4.2 Any alarm activation or other event which requires response by public safety personnel; and
- 7.2.2.4.3 Any unauthorized breach of security.
- 7.2.3 Video surveillance: A compassion center shall provide an appropriate video surveillance system that includes the following areas and access to recorded surveillance.
 - 7.2.3.1 Video surveillance should record access areas, customer service areas, growing areas, and anywhere the marijuana is handled, to include processing and packaging areas.
 - 7.2.3.2 Video footage will be digitally recorded and held for 90 days for routine footage or up to 36 months if video contains information of significance.
 - 7.2.3.3 A compassion center shall provide the Department with access to the video 24-hours a day, seven days a week through a secure internet connection.
- 7.2.4 Inventory controls
 - 7.2.4.1 Coding and computer interface: A compassion center shall:
 - 7.2.4.1.1 Employ a barcoding inventory control system to track batch, strain and amounts of marijuana in inventory and amounts sold, to include patients' card registration numbers. All plants, regardless of stage of growth must have the strain and barcode label affixed to the plant or container for immature plants.
 - 7.2.4.1.2 Be responsible for developing and hosting a secure computer interface to connect with DEC3S.
 - 7.2.4.2 Storage of marijuana: A compassion center shall ensure that usable marijuana is stored in a locked area with adequate security. For purpose of these regulations "adequate security," at a minimum, should be assessed, established and maintained based on:
 - 7.2.4.2.1 The quantity of usable marijuana that will be kept on hand at each authorized location;
 - 7.2.4.2.2 The compassion center's inventory system for tracking and dispensing usable marijuana;
 - 7.2.4.2.3 The number of principal officers, board members, agents, volunteers or employees who have or could have access to the usable marijuana;
 - 7.2.4.2.4 The geographic location of the compassion center (i.e.: high-crime or low-crime area);
 - 7.2.4.2.5 The scope and sustainability of the alarm system; and
 - 7.2.4.2.6 The root cause analysis of any breach of security and/or inventory discrepancy for usable marijuana at that location.
- 7.2.5 Comprehensive and monthly inventories
 - 7.2.5.1 A compassion center shall:
 - 7.2.5.1.1 Notify the Department and local law enforcement within 24 hours any time there is a suspected loss of marijuana and shall cooperate fully with any investigation into the suspected loss.
 - 7.2.5.1.2 Conduct an initial comprehensive inventory of all medical marijuana, including usable marijuana available for dispensing, mature marijuana plants and unusable marijuana, at each authorized location on the date the compassion center first dispenses medical marijuana.
 - 7.2.5.1.3 Conduct the comprehensive inventory required by subsection 7.2.5 of these regulations at intervals not to exceed 24 months from the date of the previous comprehensive inventory.
 - 7.2.5.1.4 Conduct a monthly inventory review of stored, usable marijuana.
 - 7.2.5.2 If an inventory conducted in response to subsection 7.2.5.1 of these regulations identifies a discrepancy, the Department and appropriate local law enforcement authorities will be notified of the discrepancy within 24 hours of discovery of the event.
 - 7.2.5.3 Documentation of all inventories conducted in response to subsection 7.2.5.1 of these regulations shall include, as a minimum, the date of the inventory, a summary of the inventory findings and the name, signature and title of the individual or individuals who conducted the inventory.
- 7.2.6 Maximum amount of compassion center inventory. A registered compassion center:
 - 7.2.6.1 Shall grow an amount of marijuana sufficient to meet the qualifying patient population demands as determined by the Division.

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- 7.2.6.2 Shall possess no more than 1,000 pounds of usable marijuana regardless of formulation unless a variance is approved by the OMM Director.
- 7.2.6.3 May not purchase usable marijuana or mature marijuana plants from any person other than another registered compassion center.
- 7.2.7 Compassion centers are subject to random inspection by the Department's Office of Medical Marijuana.
 - 7.2.7.1 During an inspection, the Department may review the compassion center's confidential records, including its financial and dispensing records, which may track transactions according to qualifying patients' registry identification numbers to protect their confidentiality and its security protocols.
 - 7.2.7.2 The Department will review the facility to ensure compliance with subsections 7.2 and 7.3 of these regulations.
 - 7.2.7.3 The Department will inspect the facility for the presence of pesticides listed in subsection 7.1.1.4, fungus and molds.
 - 7.2.7.4 The Department may collect samples for random quality sampling by a laboratory selected by the Department.
 - 7.2.7.4.1 The compassion center will be invoiced for the cost of random sampling testing.
 - 7.2.7.5 The Department will review the facility for compliance with applicable federal, state and local standards.
 - 7.2.7.6 Hazard Chemical Storage
 - 7.2.7.6.1 The Department will inspect the facility for the presence of butane, hexane, pentane, and propane; or extraction techniques that may produce hazardous conditions. Any form of alkane or petroleum hydrocarbon extraction is unauthorized in Delaware.
- 7.2.8 Dispensing marijuana
 - 7.2.8.1 Design and security features of medical marijuana containers.
 - 7.2.8.1.1 Marijuana shall be dispensed in sealed, tamperproof containers clearly identified as having been issued by the compassion center and that meet the requirements in subsection 7.3.10 of these regulations.
 - 7.2.8.1.2 Patients and designated caregivers should receive written instruction that the marijuana shall remain in this container when it is not being prepared for ingestion or being ingested.
 - 7.2.8.2 No marijuana shall be dispensed unless or until the patient or caregiver identification card has been verified as valid in the computer system identified in subsection 7.2.4.1.2 of these regulations.
 - 7.2.8.3 Maximum amount of usable marijuana to be dispensed.
 - 7.2.8.3.1 A compassion center or principal officer, board member, agent, volunteer or employee of a compassion center:
 - 7.2.8.3.1.1 Shall not dispense, deliver or otherwise transfer marijuana to a person other than a qualifying patient or to such patient's other designated caregiver.
 - 7.2.8.3.1.2 Shall not dispense more than three ounces of usable marijuana to a qualifying patient directly or through a qualifying patient's caregiver during a 14-day period.
 - 7.2.8.3.1.3 Shall not dispense an amount of usable marijuana to a qualifying patient or a qualifying patient's caregiver that the compassion center principal officer, board member, agent, volunteer or employee knows would cause the recipient to possess more marijuana than is permitted under the Act or these regulations.
 - 7.2.8.3.1.4 Shall dispense pediatric medical marijuana oils as described in Section 2.0 of these regulations to qualified patients under the age of 18 years. Patients under the age of 18 are restricted from purchasing products other than pediatric medical marijuana oil.
 - 7.2.8.3.1.4.1 Any materials used in production of marijuana products will have Generally Recognized As Safe (GRAS) documentation and used as directed.
 - 7.2.8.3.1.5 Cannabidiol-Rich medical marijuana must contain near equal concentrations of tetrahydrocannabinol and Cannabidiol, regardless of the form.
 - 7.2.8.3.1.5.1 Flower strains produced to be compliant as CBD-Rich marijuana must be clearly identified.
 - 7.2.8.3.1.5.2 Concentrates, vapes, capsules and edibles produced to be CBD-Rich compliant must be clearly identified.

7.2.8.3.2 In addition to any other penalties that may be applicable under the Act or these regulations, any person found to have violated subsection 7.2.8 of these regulations is not eligible to be an employee, agent, principal officer or board member of any compassion center and such person's registry identification card shall be immediately revoked.

- 7.3 Operations manual. A compassion center shall, as part of its initial application, provide to the Department a true, correct and current copy of its operating manual, and shall maintain such operating manual in accordance with the Act and these regulations. Such manual shall include, as a minimum, the following requirements:
- 7.3.1 Procedures for the oversight of the compassion center including, but not limited to, documentation of the reporting and management structure of the compassion center;
 - 7.3.2 Procedures for safely dispensing medical marijuana to registered qualifying patients or their registered designated caregiver;
 - 7.3.3 Procedures to ensure accurate record keeping, including protocols to ensure that quantities purchased do not suggest re-distribution;
 - 7.3.4 Employee security policies;
 - 7.3.5 Safety and security procedures, including a disaster plan with procedures to be followed in case of fire or other emergencies;
 - 7.3.6 Personal safety and crime prevention techniques;
 - 7.3.7 A job description or employment contract developed for all employees and a volunteer agreement for all volunteers which includes duties, responsibilities, authority, qualification and supervision;
 - 7.3.8 The compassion center's alcohol and drug free workplace policy;
 - 7.3.9 A description of the compassion center's outreach activities to registered qualifying patients or their registered designated caregiver, which shall as a minimum include:
 - 7.3.9.1 Providing each new registered patient who visits the compassion center with frequently asked questions, designed by the Department, that explain the limitations on the right to use medical marijuana under state law;
 - 7.3.9.2 Ingestion options of usable marijuana provided by the compassion center;
 - 7.3.9.3 Safe smoking techniques that shall be provided to registered qualifying patients; and
 - 7.3.9.4 Potential side effects and how this information shall be communicated.
 - 7.3.10 A description of the packaging of the useable marijuana that the compassion center shall be utilizing which shall, as a minimum, include:
 - 7.3.10.1 The name of the strain, batch, and quantity;
 - 7.3.10.2 The statement "this product is for medical use only, not for resale"; and
 - 7.3.10.3 Details indicating (1) the medical marijuana is free of contaminants and (2) the levels of active ingredients in the product.
 - 7.3.11 A description of the documentation that will accompany a registered compassion center agent when transporting marijuana on behalf of the registered compassion center. In response to 16 **Del.C.** §4918A(b), the documentation must specify, at least, the amount of marijuana being transported, the date the marijuana is being transported, the registry identification number of the registered compassion center, and a contact number to verify that the marijuana is being transported on behalf of the registered compassion center.
 - 7.3.12 Detailed procedures regarding the random sampling of medical marijuana. OMM staff will supervise selection of samples from the curing vessels with the Compassion Center staff.
 - 7.3.12.1 Compassion Center staff will prepare additional barcode labels and tamper-proof containers for each plant scheduled to be sampled and develop a transportation manifest, initiating the chain of custody process for the batch of plants being tested;
 - 7.3.12.2 The Compassion Centers will not sell or prepare products from the batch being tested until the Safety and Compliance Center enter the values into the DEC3S program, releasing the material for use or sale;
 - 7.3.12.3 Any concentrates or other infused products must be sent to the Safety and Compliance Center for testing, using the manifest process listed above before the batch being tested is cleared for sale;
 - 7.3.12.4 Sample results will be loaded into the DEC3S system by the Safety and Compliance Center allowing Compassion Centers to sell the material or incorporate it into other products; and

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- 7.3.12.5 Compassion Centers will coordinate directly with the Safety and Compliance Center on invoicing and payment for testing services.
- 7.4 Required training. Each compassion center shall develop, implement and maintain on the premises an on-site training curriculum, or enter into contractual relationships with outside resources capable of meeting employee, agent and volunteer training needs. Each employee, agent or volunteer, at the time of initial appointment, shall receive, as a minimum, training in the following:
- 7.4.1 Professional conduct, ethics, and state and federal laws regarding patient confidentiality;
 - 7.4.2 Informational developments in the field of medical use of marijuana;
 - 7.4.3 The proper use of security measures and controls that have been adopted; and
 - 7.4.4 Specific procedural instructions for responding to an emergency, including robbery or violent accident.
- 7.5 Personnel
- 7.5.1 Records. Each compassion center shall maintain:
- 7.5.1.1 A personnel record for each employee, agent or volunteer for a period of at least six months after termination of the individual's affiliation with the compassion center. The record shall include, as a minimum, the following:
 - 7.5.1.1.1 An application for employment or to volunteer;
 - 7.5.1.1.2 A record of any disciplinary action taken;
 - 7.5.1.1.3 Documentation of all required training. Documentation shall include a signed statement from the individual indicating the date, time and place of said training and topics discussed, including the name and title of presenters;
 - 7.5.1.2 A record of the source of any funds that will be used to open or maintain the compassion center, including the name, address, and date of birth of any investor contributing more than \$5,000; and
 - 7.5.1.3 A record of any instances in which a business or not-for-profit that any of the prospective board members managed or served on the board of was convicted, fined, censured, or had a registration or license suspended or revoked in any administrative or judicial proceeding.
- 7.5.2 Registry identification cards and background checks for principal officers, board members, agents, volunteers or employees of a compassion center.
- 7.5.2.1 In response to the requirements of this rule, and upon the approval of the submitted application, the Department shall issue a registry photo identification card to each principal officer, board member, agent, volunteer or employee of a compassion center who is associated with the compassion center and meets the requirements under these regulations. In order for a registry identification card to be obtained, the following items shall be submitted to the medical marijuana program.
 - 7.5.2.1.1 Documentation verifying that the applicant is at least 21 years of age;
 - 7.5.2.1.2 A reasonable xerographic copy of the applicant's Delaware license or comparable State of Delaware or federal issued photo identification card verifying Delaware residence; identification card must be available for inspection/verification;
 - 7.5.2.1.3 A written and signed statement from an officer or executive staff member of the compassion center stating that the applicant is associated with the compassion center and in what capacity;
 - 7.5.2.1.4 The name, address and telephone number of the applicant;
 - 7.5.2.1.5 The name, address and telephone number of the compassion center with which the agent is associated;
 - 7.5.2.1.6 The applicant's signature and date;
 - 7.5.2.1.7 A non-refundable, non-returnable application or renewal fee of \$125 in the form of a check made out to "State of Delaware-MMP".
 - 7.5.2.2 In response to 16 **Del.C.** §§4914A and 4915A, each principal officer, board member, agent, volunteer or employee of a compassion center shall consent to a full nationwide and statewide criminal history screening background check.
 - 7.5.2.2.1 Each applicant shall submit a full State Bureau of Identification (SBI) criminal history screening check and a full nationwide criminal history screening check to demonstrate compliance with the eligibility requirements of these regulations.

- 7.5.2.2.2 All applicable fees associated with the required criminal history screening background checks shall be paid by the compassion center or the applicant.
- 7.5.2.2.3 In response to 16 **Del.C.** §4919A(n), individuals convicted of an excluded felony offense, as described in the definitions Section 2.0, and 16 **Del.C.** §4902A(7), within five years from the date of application, are prohibited from being a compassion center agent.
- 7.5.2.3 The Department may verify information on each application and the accompanying documentation as set forth in subsection 5.1 of these regulations.
- 7.5.2.4 The Department shall notify the compassion center in writing of the purpose for denying the registry identification card in accordance with § 4918A of the Act. The DHSS Secretary or designee shall deny an application if the applicant fails to provide the information required or if the Department determines that the information provided is false. Denial of an application or renewal is considered a final Department action, subject to judicial review. Jurisdiction and venue for judicial review are vested in the Superior Court.
- 7.5.2.5 The Department shall issue each principal officer, board member, agent, volunteer or employee of a compassion center a registry identification card within 30 days of receipt of the information required by subsections 7.5.2.1 and 7.5.2.2. The registry identification card shall contain such information as set forth in §4911A of the Act and subsection 7.5.2 of these regulations.
- 7.5.2.6 Each compassion center shall notify the Department in writing within ten days of when a principal officer, board member, agent, volunteer or employee ceases to work at the compassion center. The individual's registry identification card shall be deemed null and void and the individual shall be liable for any other penalties that may apply to the individual's nonmedical use of marijuana.
- 7.5.3 Expiration date of registry identification cards. The registry identification card of a principal officer, board member, agent, volunteer or employee shall expire one year after its issuance, or upon the expiration of the compassion center's registration certificate, whichever comes first.
 - 7.5.3.1 Every principal officer, board member, agent, volunteer or employee of a compassion center must have a valid, unexpired registry identification card issued by the Office of Medical Marijuana.
- 7.6 Application for operation of a compassion center. Applicants shall only be accepted during an open application period announced by the Department and shall include the following items:
 - 7.6.1 A non-refundable application fee, made payable to the Division of Public Health, Medical Marijuana Program, in the amount of \$5,000;
 - 7.6.2 The proposed legal name, articles of incorporation and bylaws of the compassion center;
 - 7.6.3 The proposed physical address or addresses of the compassion center, including any additional addresses to be used for the secure cultivation of medical marijuana, and with the following details:
 - 7.6.3.1 If precise addresses are known, evidence of compliance to the following rules shall be included:
 - 7.6.3.1.1 Compliance to the local zoning laws for each physical address to be utilized as a compassion center or for the secure cultivation of medical marijuana;
 - 7.6.3.1.2 Evidence that all of the physical addresses identified in this subsection are not located within 500 feet of a property line of a preexisting public or private school;
 - 7.6.3.2 If precise addresses have not been determined, identification of the general locations where it would be sited, and when it would be established;
 - 7.6.4 A description of the enclosed, locked facility, meeting all requirements of subsection 7.2 that would be used in the cultivation of marijuana, including steps to ensure that the marijuana production shall not be visible from the street or other public areas;
 - 7.6.5 Evidence of the compassion center's not-for-profit status, which can be:
 - 7.6.5.1 Documentation of recognition as a tax-exempt organization by the United States Internal Revenue Service; or
 - 7.6.5.2 Other written materials which will allow the Department to determine the compassion center's ability to comply with the revenue criteria contained in 16 **Del.C.** §4914A and §4915A.
 - 7.6.6 The name, address, and date of birth of each principal officer and board member of the compassion center;
 - 7.6.7 A description of proposed security and safety measures which demonstrate compliance with subsection 7.2 of these regulations;
 - 7.6.8 A draft operations manual which demonstrates compliance with subsection 7.3 of these regulations;

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- 7.6.9 An example of the design and security features of medical marijuana containers which demonstrates compliance with subsection 7.2.8 of these regulations;
- 7.6.10 A list of all persons or business entities having direct or indirect authority over the management or policies of the compassion center;
- 7.6.11 A list of all persons or business entities having 5.0% or more ownership in the compassion center, whether direct or indirect and whether the interest is in profits, land or building, including owners of any business entity which owns all or part of the land or building; and
- 7.6.12 The identities of all creditors holding a security interest in the premises, if any.
- 7.7 Complete application required. Only applications which the Department has determined to be complete (i.e. adequately addresses all requirements in these regulations and 16 **Del.C.** §§4914A and 4915A) shall be eligible for review in response to subsection 7.8 of these regulations.
- 7.8 Compassion center application review criteria. The Department shall evaluate applications for a compassion center registration certificate using an impartial and numerically scored competitive bidding process developed by the Department in accordance with 16 **Del.C.** §4914A(b) and these regulations. The Department shall consider the following criteria:
 - 7.8.1 Documentation of not-for-profit status, consistent with subsection 7.6.5 of these regulations;
 - 7.8.2 The suitability of the proposed location or locations, including but not limited to compliance with any local zoning laws and the geographic convenience to patients from throughout the State of Delaware to compassion centers if the applicant were approved;
 - 7.8.3 The principal officer and board members' character and relevant experience, including any training or professional licensing related to medicine, pharmaceuticals, natural treatments, botany, or marijuana cultivation and preparation and their experience running business or not-for-profit entities;
 - 7.8.4 The proposed compassion center's plan for operations and services, including its staffing and training plans, whether it has sufficient capital to operate, and its ability to provide an adequate supply and variety of medical marijuana and medical marijuana based products to the registered patients in the State;
 - 7.8.5 The sufficiency of the applicant's plans for record keeping;
 - 7.8.6 The sufficiency of the applicant's plans for safety, security, and the prevention of diversion, including proposed locations and security devices employed;
 - 7.8.7 The applicant's plan for making medical marijuana available on an affordable basis to registered qualifying patients enrolled in Medicaid or receiving Supplemental Security Income or Social Security Disability Insurance;
 - 7.8.8 The applicant's plan for safe and accurate packaging and labeling of medical marijuana, which shall include, without limitations, these minimum requirements for packaging and labeling:
 - 7.8.8.1 The name of the strain, batch, and quantity of the medical marijuana;
 - 7.8.8.2 A statement providing that "this product is for medical use only, not for resale";
 - 7.8.8.3 Details indicating the medical marijuana is free of contaminants;
 - 7.8.8.4 Details indicating the levels of active ingredients in the product; and
 - 7.8.9 The applicant's ability to grow marijuana without use of pesticides.
- 7.9 Issuance of a registration certificate authorizing operation of a compassion center. When an applicant to operate a compassion center is notified that the Department has approved its application, it shall submit the following additional items to the Department before the registration certificate authorizing operation of a compassion center will be issued.
 - 7.9.1 A certification fee, made payable to "State of Delaware-MMP" in the amount of \$40,000;
 - 7.9.2 The legal name, articles of incorporation, and bylaws of the compassion center;
 - 7.9.3 The physical address of the compassion center and any additional addresses to be used for the secure cultivation of marijuana, including:
 - 7.9.3.1 Evidence demonstrating the following:
 - 7.9.3.1.1 Compliance with all local zoning laws for each physical address to be utilized as a compassion center or for the secure cultivation of medical marijuana; and
 - 7.9.3.1.2 That none of the physical addresses identified in subsection 7.9.3 of these regulations are located within 500 feet of the property line of preexisting public or private schools;

- 7.9.3.2 It is not necessary to resubmit any information provided in response to subsection 7.6.3.1 of these regulations unless there has been a change in that information;
- 7.9.4 Any updates to previously submitted information including, but not limited to, information about officers, principals, board members, agents, employees, and compliance with subsections 7.2 and 7.3 of these regulations;
- 7.9.5 A current certificate of occupancy, or equivalent document, to demonstrate compliance with the provisions of the State Fire Code for each physical address to be utilized as a compassion center or for the secure cultivation of medical marijuana.
- 7.10 Expiration, termination, or renewal of a registration certificate authorizing operation of a compassion center.
 - 7.10.1 Expiration: A compassion center's registration shall expire two years after its registration certificate is issued. The compassion center may submit a renewal application at any time beginning 90 days prior to the expiration of its registration certificate. Such renewal application must be submitted a minimum of 30 days prior to the expiration of its registration certificate to avoid suspension of the certificate.
 - 7.10.2 Renewal. The Department shall grant a compassion center's renewal application within 30 days of its submission if the following conditions are all satisfied:
 - 7.10.2.1 The compassion center submits materials required under subsection 7.9 of these regulations, including a summary annual report with financial audit attached, a comprehensive inventory with a cover letter and the \$40,000 fee, which shall be refunded if the renewal application is rejected;
 - 7.10.2.2 The Department has not ever suspended the compassion center's registration for violations of the Act or these regulations;
 - 7.10.2.3 Inspections conducted pursuant to the Act and these regulations do not raise any serious concerns about the continued operation of the registered compassion center applying for renewal; and
 - 7.10.2.4 The applicant continues to meet all of the requirements for the operation of a compassion center as set forth in the Act and in these regulations.
 - 7.10.3 Suspension: The Department will suspend a registration certificate authorizing the operation of a compassion center, with or without notice, for any violation of an applicable law or regulation.
 - 7.10.4 Termination: Upon receipt of written notice that a registration certificate has been terminated, the compassion center has 30 business days to request, in writing, a hearing, for the purpose of review of such action. The hearing process shall follow the procedures in subsections 9.4 through 9.5.10 of these regulations:
 - 7.10.4.1 A written decision will be issued by the Department within 30 days of the completion of the hearing. The decision will lift the suspension or terminate a registration certificate. The written decision will state with specificity the reasons for the decision.
 - 7.10.4.2 The termination of a registration certificate is a final decision of the Department, subject to judicial review. Jurisdiction and venue are vested in the Superior Court.
- 7.11 Non-transferable registration certificate authorizing operation of a compassion center.
 - 7.11.1 A registration certificate authorizing operation of a compassion center shall not be transferred by assignment or otherwise to other persons or locations. Unless the compassion center applies for and receives an amended registration certificate authorizing operation of a compassion center, the registration certificate shall be void and returned to the Department when one or more of the following situations occur:
 - 7.11.1.1 A change in ownership of the compassion center;
 - 7.11.1.2 A change in one or more authorized physical locations; or
 - 7.11.1.3 The compassion center discontinues its operation.
 - 7.11.2 A compassion center shall provide the Department with a written notice of any change described in subsection 7.11 of these regulations at least 60 days prior to the proposed effective date of the change. The Department may waive all or part of the required advance notice to address emergent or emergency situations.
 - 7.11.3 Transactions which usually do not constitute a change of ownership include the following:
 - 7.11.3.1 Changes in the membership of the board of directors or board of trustees; or
 - 7.11.3.2 Two or more legal entities merge and the entity to whom the registration certificate authorizing operation of a compassion center was issued survives.

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- 7.11.4 Management agreements are generally not considered a change in ownership if the entity to whom the registration certificate authorizing operation of a compassion center was issued continues to retain ultimate authority for the operation of the compassion center; however, if the ultimate authority is surrendered and transferred from the entity to whom the registration certificate authorizing operation of a compassion center was issued to a new manager, then a change of ownership has occurred.
- 7.12 Compassion centers that offer medical marijuana home delivery to registered patients must develop and field a computer inventory system that integrates with DEC3S.
- 7.12.1 Compassion centers must pre-register qualified patients for home delivery.
- 7.12.2 Compassion centers must establish protocols for identifying the patient and receiving payment.
- 7.12.3 Compassion centers must use a comprehensive manifest and invoicing program to ensure the correct products are delivered to the appropriate, positively identified patient.
- 7.12.4 Compassion centers will be responsible for submitting a plan to the Office of Medical Marijuana detailing how safe transportation and delivery services will be accomplished. This plan must be approved by OMM before delivery services can begin.
- 7.12.4.1 The Office of Medical Marijuana may rescind approval of the home delivery plan for failure to comply with the approved plan, these regulations or the Medical Marijuana Act.

17 DE Reg. 738 (01/01/14)

19 DE Reg. 409 (11/01/15)

23 DE Reg. 667 (02/01/20)

24 DE Reg. 485 (11/01/20)

8.0 Registration and Operation of Safety Compliance Facilities

- 8.1 General Requirements for Operation of a Safety Compliance Facility
- 8.1.1 A Safety Compliance Facility may only operate if they have been issued a valid registration certificate from the Department.
- 8.1.2 A Safety Compliance Facility must be operated in accordance with the International Organization for Standardization 17025 (ISO 17025) standards as confirmed by accreditation by a third-party accrediting body or a qualified auditing organization using ISO 17025 criteria approved by the Department.
- 8.2 Security Requirements
- 8.2.1 A Safety Compliance Facility shall implement appropriate security and safety measures to deter and prevent the unauthorized entrance into areas containing marijuana and the theft of marijuana. Such measures shall include the following:
- 8.2.1.1 Exterior of premises
- 8.2.1.1.1 With respect to the exterior of a Safety Compliance Facility:
- 8.2.1.1.1.1 Access from outside the premises shall be kept to a minimum and be well controlled;
- 8.2.1.1.1.2 The outside perimeter of the premises shall be well lit; and
- 8.2.1.1.1.3 Entry into any area where marijuana is held shall be limited to authorized personnel.
- 8.2.1.2 Alarm system
- 8.2.1.2.1 A Safety Compliance Facility shall have a fully operational security alarm system that will provide suitable protection against theft and diversion. For the purpose of these regulations, a fully operational security alarm system shall include:
- 8.2.1.2.1.1 Immediate automatic or electronic notification to alert local or municipal law enforcement agencies of an unauthorized breach of security at the Safety Compliance Facility or at any other authorized physical address;
- 8.2.1.2.1.2 Immediate automatic or electronic notification to local or municipal public safety personnel of a loss of electrical support backup system; and
- 8.2.1.2.1.3 When appropriate, the security system shall provide protection against tampering with computers or electronic records done to conceal theft or diversion.
- 8.2.1.2.2 A Safety Compliance Facility shall conduct a maintenance inspection/test of the alarm system for each authorized location at intervals not to exceed 30 days from the previous inspection/test. A Safety Compliance Facility shall promptly make all necessary repairs to ensure the proper operation of the alarm system.

8.2.1.2.3 In the event of a failure of the security system, due to loss of electrical support or mechanical malfunction, that is expected to exceed an eight-hour period, a Safety Compliance Facility shall:

8.2.1.2.3.1 Within 24 hours of discovery of the event, notify the Department by telephone; and

8.2.1.2.3.2 Provide alternative security measures approved by the Department or close the authorized physical addresses affected by the failure/malfunction until the security alarm system has been restored to full operation.

8.2.1.2.4 A Safety Compliance Facility shall maintain documentation in an auditable form for a period of at least 24 months after the event for:

8.2.1.2.4.1 All maintenance inspections/tests conducted in response to subsection 8.2.1.2.4 of these regulations, and any servicing, modification or upgrade performed on the security alarm system. The record shall include, at a minimum, the date of the action, a summary of the actions performed and the name, signature and title of the individual who performed the actions.

8.2.1.2.4.2 Any alarm activation or other event which requires response by public safety personnel; and

8.2.1.2.4.3 Any unauthorized breach of security.

8.2.1.3 Video surveillance

8.2.1.3.1 A Safety Compliance Facility shall provide an appropriate video surveillance system that includes the following areas and access to recorded surveillance.

8.2.1.3.1.1 Video surveillance should record access areas and anywhere the marijuana is handled;

8.2.1.3.1.2 Video footage will be digitally recorded and held for an appropriate time period consistent with the Division of Public Health's Records Retention Policy; and

8.2.1.3.1.3 A Safety Compliance Facility shall provide the Department with access to the video 24-hours a day, seven days a week through a secure internet connection.

8.2.1.4 Inventory controls

8.2.1.4.1 Coding and computer interface

8.2.1.4.1.1 A Safety Compliance Facility shall employ a barcoding inventory control system to track the source, strain, batch and weight of marijuana sample in inventory.

8.2.1.4.2 Storage of marijuana

8.2.1.4.2.1 A Safety Compliance Facility shall ensure that marijuana is stored in a locked area with adequate security. For purpose of these regulations "adequate security," at a minimum, should be assessed, established and maintained based on:

8.2.1.4.2.1.1 The quantity of marijuana present;

8.2.1.4.2.1.2 The geographic location of the Safety Compliance Facility (i.e.: high-crime or low-crime area); and

8.2.1.4.2.1.3 The scope and sustainability of the alarm system.

8.3 Operations Manual

8.3.1 A Safety Compliance Facility shall, as part of its initial application, provide to the Department a true, correct and current copy of its operations manual, and shall maintain such operations manual in accordance with the Act and these regulations. Such manual shall include, at a minimum, the following requirements:

8.3.1.1 Procedures for the oversight of the Safety Compliance Facility including, but not limited to, documentation of the reporting and management structure of the Safety Compliance Facility;

8.3.1.2 Procedures to ensure accurate record keeping;

8.3.1.3 Employee security policies;

8.3.1.4 Safety and security procedures, including a disaster plan with procedures to be followed in case of fire or other emergencies;

8.3.1.5 Crime prevention techniques;

8.3.1.6 A job description or employment contract developed for all employees which includes duties, responsibilities, authority, qualification and supervision;

8.3.1.7 The Safety Compliance Facility's alcohol and drug free workplace policy;

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- 8.3.1.8 A description of the documentation that will accompany a registered Safety Compliance Facility agent when transporting marijuana on behalf of the registered Safety Compliance Facility. As required by 16 **Del.C.** §4918A(b), the documentation must specify, at least, the amount of marijuana being transported, the date the marijuana is being transported, the registry identification number of the registered Safety Compliance Facility, and a contact number to verify that the marijuana is being transported on behalf of the registered Safety Compliance Facility;
 - 8.3.1.9 Detailed procedures regarding the testing of medical marijuana. As part of its initial application, a Safety Compliance Facility shall provide to the Department detailed procedures regarding the testing of medical marijuana, and shall adhere to such procedures in connection with the operation of the Safety Compliance Facility;
 - 8.3.1.9.1 Each batch of medical marijuana harvested by a compassion center shall be tested in accordance with this regulation.
 - 8.3.1.10 Such procedures shall include a description of how the marijuana will be tested including:
 - 8.3.1.10.1 What tests are conducted;
 - 8.3.1.10.2 What testing procedures are used;
 - 8.3.1.10.3 How results are loaded into DEC3S;
 - 8.3.1.10.4 How disposal of samples is tracked;
 - 8.3.1.10.5 The selection process; and
 - 8.3.1.10.6 The number of samples tested.
 - 8.3.1.11 What equipment will be used to test and report on including:
 - 8.3.1.11.1 Potency and cannabinoid profile;
 - 8.3.1.11.2 Contaminates including mold, mildew and organic material;
 - 8.3.1.11.3 Plant growth regulators;
 - 8.3.1.11.4 Pesticides;
 - 8.3.1.11.5 Microbiological contaminants and mycotoxins; and
 - 8.3.1.11.6 Residual solvents.
 - 8.3.1.12 What levels or combination of contaminants mandate elimination of a batch.
- 8.4 Required Training
- 8.4.1 Each Safety Compliance Facility shall develop, implement and maintain on the premises an on-site training curriculum, or enter into contractual relationships with outside resources capable of meeting employee and agent training needs. Each employee or agent at the time of initial appointment, shall receive, as a minimum, training in the following:
 - 8.4.1.1 Professional conduct, ethics, and state and federal laws;
 - 8.4.1.2 The proper use of security measures and controls that have been adopted; and
 - 8.4.1.3 Specific procedural instructions for responding to an emergency, including robbery or an accident resulting in injury, fire or damage to critical equipment.
- 8.5 Personnel Records
- 8.5.1 Each Safety Compliance Facility shall maintain a personnel record for each employee or agent for a period of at least six months after termination of the individual's affiliation with the Safety Compliance Facility. The record shall include, as a minimum, the following:
 - 8.5.1.1 An application for employment or to volunteer;
 - 8.5.1.2 A record of any disciplinary action taken;
 - 8.5.1.3 Documentation of all required training. Documentation shall include a signed statement from the individual indicating the date, time and place of said training and topics discussed, including the name and title of presenters.
- 8.6 Application for Operation of a Safety Compliance Facility
- 8.6.1 A Safety Compliance Facility may only operate if they have been issued a valid registration certificate from the Department. When applying for a Safety Compliance Facility registration certificate, the applicant shall submit the following in accordance with these regulations:
 - 8.6.1.1 The proposed legal name of the Safety Compliance Facility;
 - 8.6.1.2 The proposed physical address of the Safety Compliance Facility;

- 8.6.1.3 The name, address, and date of birth of each principal officer and board member of the Safety Compliance Facility, provided that all such individuals shall be at least 21 years of age; and
- 8.6.1.4 Any information required by the Department to evaluate the applicant pursuant to the competitive bidding process.
- 8.7 Safety Compliance Facility Application Review Criteria
 - 8.7.1 The Department shall evaluate applications for Safety Compliance Facility registration certificates using an impartial and numerically scored process developed by the Department in accordance with this chapter. The registration considerations shall consist of the following criteria:
 - 8.7.1.1 The proposed principal officers' and board members' relevant experience, including any training or professional licensing related to analytical testing, medicine, pharmaceuticals, natural treatments, botany, or marijuana cultivation, preparation, and testing and their experience running businesses or not-for-profits;
 - 8.7.1.2 The suitability of the proposed location, including compliance with any local zoning laws and the geographic convenience to compassion centers throughout the state of Delaware;
 - 8.7.1.3 The sufficiency of the applicant's plans for safety, security, and the prevention of diversion, including proposed locations and security devices employed; and
 - 8.7.1.4 The proposed Safety Compliance Facility's plan for operations and services, including its staffing and training plans, and whether it has sufficient capital to operate.
- 8.8 Issuance of Registration Certificate Authorizing Operation of a Safety Compliance Facility
 - 8.8.1 An application for a Safety Compliance Facility registration certificate must be denied if any of the following conditions are met:
 - 8.8.1.1 Applicant failed to submit the materials required by this subsection, including if the plans do not satisfy the security, oversight, or recordkeeping regulations issued by the Department;
 - 8.8.1.2 Applicant would not be in compliance with local zoning regulations issued in accordance with 16 **Del.C.** §4917A; or
 - 8.8.1.3 Applicant does not meet the requirements of 16 **Del.C.** §4919A.
 - 8.8.2 After a Safety Compliance Facility is approved, but before it begins operations, it shall submit a registration fee paid to the Department in the amount of \$40,000 and, if a physical address had not been finalized when it applied, its physical address.
 - 8.8.3 The Department shall issue a renewable registration certificate with an identification number after a satisfactory compliance inspection by the Department.
- 8.9 Registry Identification Cards for Principal Officers, Board Members, Agents, Volunteers or Employees of a Safety Compliance Facility
 - 8.9.1 An application for a registry identification cards must be denied if any of the following conditions are met:
 - 8.9.1.1 If the prospective principal officer or board members has been convicted of an excluded felony offense;
 - 8.9.1.2 If the prospective principal officer or board members has served as a principal officer or board member for a registered Safety Compliance Facility or registered compassion center that has had its registration certificate revoked; or
 - 8.9.1.3 If the principal officer or board members is younger than 21 years of age.
 - 8.9.2 A record of the source of any funds that will be used to open or maintain the Safety Compliance Facility, including the name, address, and date of birth of any investor contributing more than \$5,000.
 - 8.9.3 A record of any instances in which a business or not-for-profit that any of the prospective board members managed or served on the board of was convicted, fined, censured, or had a registration or license suspended or revoked in any administrative or judicial proceeding.
- 8.10 Expiration Date
 - 8.10.1 A Safety Compliance Facility registration shall expire two years after its registration certificate is issued. The Safety Compliance Facility may submit a renewal application at any time beginning 90 days prior to the expiration of its registration certificate. Such renewal application must be submitted a minimum of 30 days prior to the expiration of its registration certificate to avoid suspension of the certificate.
- 8.11 Expiration, Termination or Renewal of a Registration Certificate Authorizing Operation of a Safety Compliance Facility

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- 8.11.1 Registration certificates may be renewed every two years. The registered Safety Compliance Facility may submit a renewal application beginning 90 days prior to the expiration of its registration certificate. The Department shall grant a renewal application within 30 days of its submission if the following conditions are all satisfied:
- 8.11.1.1 The registered Safety Compliance Facility submits a renewal application and the required \$40,000 renewal fee, which shall be refunded if the renewal application is rejected;
 - 8.11.1.2 The Department has not suspended the registered Safety Compliance Facility's registration certificate for violations of this chapter or regulations adopted pursuant to this chapter;
 - 8.11.1.3 The inspections authorized by 16 **Del.C.** §4919A(u) do not raise serious concerns about the continued operation of the registered Safety Compliance Facility applying for renewal;
 - 8.11.1.4 The Annual Report provided pursuant to 16 **Del.C.** §4922A, confirms a continued need for the facility;
 - 8.11.1.5 The applicant continues to meet all of the requirements for the operation of a Safety Compliance Facility as set forth in the Act and in these regulations; and
- 8.11.2 Suspension
- 8.11.2.1 The Department may suspend a registration certificate authorizing the operation of a Safety Compliance Facility for any violation of an applicable law or regulation.
- 8.11.3 Termination
- 8.11.3.1 Upon receipt of written notice that a registration certificate has been terminated, the Safety Compliance Facility has 30 business days to request, in writing, a hearing, for the purpose of review of such action. The hearing process shall follow the procedures in subsections 9.4 through 9.5.10 of these regulations:
 - 8.11.3.1.1 A written decision will be issued by the Department within 30 days of the completion of the hearing. The decision will lift the suspension or terminate a registration certificate. The written decision will state with specificity the reasons for the decision; and
 - 8.11.3.1.2 The termination of a registration certificate is a final decision of the Department, subject to judicial review. Jurisdiction and venue are vested in the Superior Court.
- 8.12 Non-transferable Registration Certificate Authorizing Operation of a Safety Compliance Facility
- 8.12.1 A registration certificate authorizing operation of a Safety Compliance Facility shall not be transferred by assignment or otherwise to other persons or locations. Unless the Safety Compliance Facility applies for and receives an amended registration certificate authorizing operation of a Safety Compliance Facility, the registration certificate shall be void and returned to the Department upon one or more of the following occurrences:
- 8.12.1.1 A change in ownership of the Safety Compliance Facility;
 - 8.12.1.2 A change authorized physical location; or
 - 8.12.1.3 The Safety Compliance Facility discontinues its operation.
- 8.12.2 A Safety Compliance Facility shall provide the Department with a written notice of any change described in subsection 8.12.1 of these regulations at least 60 days prior to the proposed effective date of the change. The Department may waive all or part of the required advance notice to address emergent or emergency situations.
- 8.12.3 Transactions which usually do not constitute a change of ownership include the following:
- 8.12.3.1 Changes in the membership of the board of directors or board of trustees; or
 - 8.12.3.2 Two or more legal entities merge and the entity to whom the registration certificate authorizing operation of a Safety Compliance Facility was issued survives.
 - 8.12.3.3 Management agreements are generally not considered a change in ownership if the entity to whom the registration certificate authorizing operation of a Safety Compliance Facility was issued continues to retain ultimate authority for the operation of the Safety Compliance Facility. However, if the ultimate authority is surrendered and transferred from the entity to whom the registration certificate authorizing operation of a Safety Compliance Facility was issued to a new manager, then a change of ownership has occurred.
- 8.13 Inspection
- 8.13.1 The Safety Compliance Facility will be available to State regulators for inspections, both scheduled and unscheduled, during normal business hours.

17 DE Reg. 738 (01/01/14)

23 DE Reg. 667 (02/01/20)

24 DE Reg. 485 (11/01/20)

9.0 Monitoring and Corrective Actions

9.1 On-site visits/interviews

- 9.1.1 The Department or its designee may perform on-site interviews of a qualified patient or designated caregiver to determine eligibility for the program. The Department may enter the premises of a qualified patient or designated caregiver during business hours for purposes of interviewing a program applicant. Twenty-four (24) hours' notice will be provided to the qualified patient or designated caregiver prior to an on-site interview.
- 9.1.2 All qualified patients or designated caregivers shall provide the Department or the Department's designee immediate access to any material and information necessary for determining eligibility with these requirements.
- 9.1.3 Failure by the qualified patient or designated caregiver to provide the Department access to the premises or information may result in action up to and including the revocation of the qualified patient or designated caregiver registry identification card and referral to state law enforcement.
- 9.1.4 Any failure to adhere to these rules, documented by the Department during an interview, may result in sanctions, including suspension, revocation, non-renewal or denial of licensure and referral to state or local law enforcement.
- 9.1.5 The Department shall refer credible criminal complaints against a qualified patient or designated caregiver to the appropriate state or local authorities.

9.2 Corrective action

- 9.2.1 If violations of these requirements are cited as a result of monitoring or police contact, the qualified patient or primary caregiver shall be provided with an official written report of the findings within 30 days following the monitoring visit.
- 9.2.2 Unless otherwise specified by the Department, the qualified patient or designated caregiver shall correct the violation within 5 calendar days of receipt of the official written report citing the violation.
- 9.2.3 The violation shall not be deemed corrected until the Department verifies in writing after receiving notice of the corrective action that the corrective action is satisfactory.
- 9.2.4 If the violation has not been corrected, the Department may issue a notice of contemplated action to revoke the qualified patient's or designated caregiver's registry identification card.
- 9.2.5 Suspension of registry identification card without prior hearing
 - 9.2.5.1 In accordance with the 16 **Del.C.** Ch. 49A, if immediate action is required to protect the health and safety of the general public, the Department may suspend the qualified patient or designated caregiver registry identification card without notice.
 - 9.2.5.1.1 A qualified patient or designated caregiver whose registry identification card has been summarily suspended may request a record review no later than 30 calendar days after the registry identification card was summarily suspended.
 - 9.2.5.1.2 The record review requested subsequent to a summary suspension shall be conducted by the Department.
 - 9.2.5.1.3 The Department shall conduct the record review on the summary suspension by reviewing all documents submitted by both card holder and the Department.
 - 9.2.5.1.4 The sole issue at a record review on a summary suspension is whether the card holder's registry identification card shall remain suspended pending a final adjudicatory hearing and ruling.
 - 9.2.5.1.5 A card holder given notice of summary suspension by the Division may submit a written request to the Department for a record review. To be effective, the written request shall:
 - 9.2.5.1.5.1 Be made within 30 calendar days, as determined by the postmark, from the date of the notice issued by the Department;
 - 9.2.5.1.5.2 Be properly addressed to the medical marijuana program;
 - 9.2.5.1.5.3 State the applicant's name, address, and telephone numbers;

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9.2.5.1.5.4 Provide a brief narrative rebutting the circumstances of the suspension; and

9.2.5.1.5.5 Additional documentation must be included with the request for a record review.

9.2.5.1.6 A card holder may request a hearing under subsection 9.4 following the record review.

9.3 Suspension, Revocation and Appeal Process

9.3.1 Participation in the medical marijuana program by a qualified patient or designated caregiver does not relieve the qualified patient or designated caregiver from:

9.3.1.1 Criminal prosecution or civil penalties for activities not authorized in this rule and act;

9.3.1.2 Liability for damages or criminal prosecution arising out of the operation of a vehicle while under the influence of marijuana; or

9.3.1.3 Criminal prosecution or civil penalty for possession, distribution or transfers of marijuana or use of marijuana:

9.3.1.3.1 In a school bus or public vehicle;

9.3.1.3.2 On school grounds or property;

9.3.1.3.3 In the workplace of the qualified patient's or designated caregiver's employment;

9.3.1.3.4 At a public park, recreation center, youth center or other public place;

9.3.1.3.5 To a person not approved by the Department pursuant to this rule;

9.3.1.3.6 Outside Delaware or attempts to obtain or transport marijuana from outside Delaware; or

9.3.1.3.7 That exceeds the allotted amount of usable medical use marijuana.

9.3.1.4 Criminal prosecution or civil penalties related to growing or cultivating marijuana.

9.3.2 Revocation of registry identification card

9.3.2.1 Violation of any provision of this rule may result in either the summary suspension of the qualified patient's or designated caregiver's registry identification card, or a notice of contemplated action to suspend or revoke the qualified patient's or designated caregiver's registry identification card, and all lawful privileges under the act.

9.3.3 Grounds for revocation or suspension of registry identification card, denial of renewal application for registry identification card.

9.3.3.1 A registry identification card may be revoked or suspended, and a renewal application may be denied for:

9.3.3.1.1 Failure to comply with any provisions of these requirements;

9.3.3.1.2 Failure to allow a monitoring visit by authorized representatives of the Department;

9.3.3.1.3 The discovery of repeated related criminal misconduct or criminal law violations of these requirements during monitoring visits.

9.4 Request for hearing

9.4.1 A qualified patient or designated caregiver whose registry identification card has been summarily suspended, or who has received a notice of contemplated action to suspend or revoke, may request a hearing for the purpose of review of such action. A cardholder whose card was summarily suspended and who requested a record review under subsection 9.2.5 may request a hearing following the record review. The request for hearing shall be filed within 30 calendar days of the date the action is taken, the notice of contemplated action is received, or the record review decision is received. The request shall include the following:

9.4.1.1 A statement of the facts relevant to the review of the action;

9.4.1.2 A statement of the provision of the act and the rules promulgated under the act that are relevant to the review of the action;

9.4.1.3 A statement of the arguments that the qualified patient/designated caregiver considers relevant to the review of the action; and

9.4.1.4 Any other evidence considered relevant.

9.5 Hearing procedure

9.5.1 As soon as possible, but in no event later than 60 calendar days after the request for hearing is received, the Department shall convene a hearing.

9.5.2 Notice of the hearing shall be issued in accordance with §10122 of Title 29.

9.5.2.1 There shall be no public notice of the hearing in accordance with §4920A of Title 16.

- 9.5.3 An individual may request an expedited hearing.
- 9.5.3.1 The Department shall schedule the hearing on an expedited basis provided that the Department receives the individual's written request for an expedited hearing within five (5) calendar days from the date on which the individual received notification of the Department's decision to suspend the individual's card, or the date on which the individual received the final determination following the record review.
- 9.5.3.2 The Department shall convene an expedited hearing within 15 calendar days of the receipt by the Department of such a request.
- 9.5.3.3 The Department shall make a determination based upon the evidence presented.
- 9.5.3.4 A written copy of the determination and the reasons upon which it is based shall be sent to the individual within 30 calendar days.
- 9.5.4 Telephonic hearings
- 9.5.4.1 An individual cardholder may request a telephonic hearing at the time of the request for a hearing. Immediately after the parties agree to conduct the hearing by telephone, notice of the telephonic hearing shall be made to all parties and shall include all necessary telephone numbers.
- 9.5.4.2 Any party that has agreed to a telephonic hearing, but subsequently requests an in-person hearing shall do so in writing to the Department no later than 10 calendar days before the scheduled date of the hearing. The decision to grant or deny the request for an in-person hearing shall be at the discretion of the Department for good cause shown. The Department's decision to grant or deny the hearing shall be issued in writing and shall include the specific reasons for granting or denying the request. Should the Department grant the request, the hearing shall be rescheduled to a time convenient for all parties. Should the Department deny the request, the telephonic hearing shall proceed as scheduled.
- 9.5.4.3 The location or locations of the parties during the hearing shall have a speaker telephone and technology available so that all shall hear the proceedings and documents shall be transmitted between witnesses and the Department.
- 9.5.4.4 Failure to provide the correct telephone number or failure to be available at the commencement of the hearing shall be treated as a failure to appear and shall subject the petitioner to a default judgment.
- 9.5.4.5 The in-person presence of some parties or witnesses at the hearing does not prevent the participation of other parties or witnesses by telephone with prior approval of the Department.
- 9.5.5 During an administrative hearing:
- 9.5.5.1 The individual has the right to be represented by counsel.
- 9.5.5.2 All statements made shall be under oath.
- 9.5.5.3 The individual has the right to examine and cross-examine witnesses.
- 9.5.5.4 The individual has the right to present evidence.
- 9.5.6 A stenographic recording will be made by a qualified court reporter. At the request and expense of any party, such record shall be transcribed with a copy to the other party.
- 9.5.7 Following the hearing, the Department shall make a determination based upon the evidence presented.
- 9.5.8 Upon reaching its conclusion of law and determining an appropriate disciplinary action, the Department shall issue a written decision and order in accordance with §10128 of Title 29.
- 9.5.9 All decisions of the Department shall be final and conclusive. Where the individual is in disagreement with the action of the Department, the individual may appeal the Department's decision to the Superior Court within 30 days of service or of the postmarked date of the copy of the decision mailed to the individual. The appeal shall be on the record to the Superior Court and shall be as provided in §§10142 - 10145 of Title 29.
- 9.5.10 A written copy of the determination and the reasons upon which it is based shall be sent to the patient or caregiver cardholder within 30 calendar days.

17 DE Reg. 738 (01/01/14)

23 DE Reg. 667 (02/01/20)

24 DE Reg. 485 (11/01/20)

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- 10.1 Delaware Department of Health and Social Services adopts these regulations pursuant to the authority vested by 16 **Del.C.** §122. These regulations establish registration procedures and standards of practice for conducting marijuana infused food processing operations in Compassion Center kitchens that safeguard public health and provide to consumers food that is tested for safety, potency and consistency. A marijuana infused food establishment that prepares, sells or dispenses edible marijuana products must:
- 10.1.1 Before preparing, selling or dispensing an edible marijuana product, obtain written authorization from the Division to prepare, sell or dispense edible marijuana products; and
 - 10.1.2 If the marijuana business prepares edible marijuana products, ensure that the edible marijuana products are prepared according to the applicable requirements set forth in these regulations.
- 10.2 Each compassion center and facility for the production of edible marijuana products or marijuana-infused products shall, in consultation with the Division, cooperate to ensure that all edible marijuana products and marijuana-infused products offered for sale:
- 10.2.1 Are labeled clearly and unambiguously as medical marijuana;
 - 10.2.2 Are not presented in packaging that is appealing to children. These requirements include:
 - 10.2.2.1 Tamper or child-resistant packaging;
 - 10.2.2.2 Opaque or plain in design;
 - 10.2.2.3 Resealable for any product intended for more than a single use;
 - 10.2.2.4 Prohibited from using bright colors, defined as colors that are “neon” in appearance;
 - 10.2.2.5 Prohibited from imitating or having a semblance to any existing branded consumer products, including foods, beverages and toys;
 - 10.2.2.6 Prohibited from using cartoons, cartoon-like font, caricatures, fruit, human or animal shapes, pictures/photographs images, or picture/photographs of product;
 - 10.2.2.7 Prohibited from featuring a design, symbol, or celebrity brand or name that resembles a non-cannabis consumer product;
 - 10.2.2.8 Prohibited from featuring images of minors or words that refer to products that are commonly associated with minors or marketed to minors; and
 - 10.2.2.9 Each single serving of an edible contained in multiple serving package shall be marked, stamped or otherwise imprinted with the following symbol:



CONTAINS THC
NOT SAFE FOR KIDS OR PETS

- 10.2.3 Are regulated and sold on the basis of the concentration of THC and/or CBD in the products and not by weight; and
 - 10.2.4 Are packaged and labeled in such a manner as to allow tracking by DEC3S.
- 10.3 Labeling
- 10.3.1 Products shall be properly labeled with the following: Name of Compassion Center, phone and website of compassion center that produced the edible, name of product, net weight, date of production / lot number, barcode, refrigeration of the product if required and cannabinoid profile.
 - 10.3.2 Labels shall include a list of ingredients in decreasing order by weight, serving size and how many servings per package, batch, serial number and barcodes.
 - 10.3.3 Labels shall include the following statement: “This food is made in a Marijuana Infused Food Establishment and is NOT subject to routine Government Food Safety Inspections” with a seal stating “tested for contaminants”.
 - 10.3.4 Labels shall be printed in at least 6-point type, as long as the information can be easily read using standard reading glasses, in a color that provides a clear contrast to the background label.
 - 10.3.5 Additional information as required by the Division must be made available for review upon request from the consumer, including the following:
 - 10.3.5.1 The date on which the product was manufactured;
 - 10.3.5.2 If the product is perishable, a suggested use-by date;

- 10.3.5.3 The total milligrams of active cannabinoids and terpenoids in the product, as provided by the independent testing laboratory that tested the product;
- 10.3.5.4 A list of all ingredients including amount in grams of sodium, sugar, carbohydrates and total fat per serving and all major food allergens as identified in 21 U.S.C. §§343;
- 10.3.5.5 A warning that states: "Caution: When eaten or swallowed, the intoxicating effects of this drug may be delayed by 2 or more hours."
- 10.3.5.6 If a marijuana extract was added to the product, a disclosure of the type of extraction process and any solvent, gas or other chemical used in the extraction process, or any other compound added to the extract;
- 10.3.5.7 A warning that states: "This product may have intoxicating effects and may be habit forming."
- 10.3.5.8 The statement: "This product is unlawful outside of the State of Delaware."
- 10.3.5.9 A medical marijuana dispensary must provide with all edible marijuana products and marijuana-infused products sold at retail accompanying material that discloses any products applied to the marijuana plants and growing medium during production of the marijuana used to create the extract added to the edible marijuana products or marijuana-infused products and the type of extraction method used, including, without limitation, any solvents, gases or other chemicals or compounds used to produce or that are added to the extract, and contains the following warnings:
 - 10.3.5.9.1 "The impairment effects of edible products may be delayed by two hours or more. This product has not been analyzed or approved by the FDA to treat, cure, or prevent any disease. There is limited information on the side effects of using this product, and there may be associated health risks.
 - 10.3.5.9.2 "This product contains or is infused with marijuana or active compounds of marijuana.";
 - 10.3.5.9.3 "This product should not be used by women who are pregnant or breast feeding."
 - 10.3.5.9.4 "For use only by the person named on the label of the dispensed product. Keep out of the reach of children."
 - 10.3.5.9.5 "Products containing marijuana can impair concentration, coordination and judgment. It is against the law drive or operate a vehicle or machinery under the influence of this product."
 - 10.3.5.9.6 "FOR USE BY ADULTS 18 and OLDER, KEEP THIS PRODUCT AWAY FROM CHILDREN."

10.4 Packaging

- 10.4.1 The immediate food contact surface of any product packaging material shall be food grade in quality, and therefore meet the food safety requirements of 16 **Del.C.** Ch. 33.
- 10.4.2 Any product containing marijuana must be packaged in child-resistant packaging in accordance with 16 C.F.R. §1700.
- 10.4.3 Marijuana-infused products must be packaged in plastic which is 4 millimeters or more in thickness and must be heat-sealed without an easy-open tab, dimple, and corner or flap so that it is difficult for a child to open and as a tamperproof measure.
- 10.4.4 Any container or packaging containing usable marijuana, edible marijuana products or marijuana-infused products must protect the contents from contamination and must not impart any toxic or deleterious substance to the usable marijuana or marijuana product.

10.5 Exemptions

- 10.5.1 Establishments registered as marijuana infused food establishments in Delaware shall be exempt from the Cottage Food Regulations.
- 10.5.2 Establishments registered under these regulations shall be exempt from the State of Delaware Food Code, 16 **DE Admin. Code** 4458.

10.6 Inspections

- 10.6.1 The Division may conduct one or more preoperational inspections to verify that the marijuana infused food establishment is:
 - 10.6.1.1 Constructed and equipped in accordance with the registration application;
 - 10.6.1.2 Has established standard operating procedures as specified; and
 - 10.6.1.3 Is otherwise in substantial compliance with these regulations.
- 10.6.2 Additional inspections both scheduled and no-notice will be conducted at the discretion of the Division and as deemed necessary by the Division.

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15 DE Reg. 1728 (06/01/12)

17 DE Reg. 738 (01/01/14)

23 DE Reg. 667 (02/01/20)

24 DE Reg. 485 (11/01/20)

11.0 Limitations

11.1 Registration

11.1.1 Marijuana Infused Food Establishments are only permitted to engage in direct sales with consumers in the State of Delaware.

11.1.2 Online sales are not permitted. Online advertising and marketing are permitted subject to the limitations listed in 16 **Del.C.** Ch. 49A.

11.1.3 Wholesale or other sales to resellers or food establishments are not permitted by a Marijuana Infused Food Establishment.

11.1.4 A Marijuana Infused Food Establishment shall only produce those specific food products listed on their registration.

11.1.5 Approved sources of non-marijuana ingredients:

11.1.5.1 Each facility for the production of edible marijuana products or marijuana-infused products shall ensure that it obtains non-marijuana ingredients for edible marijuana products or marijuana-infused products from sources that comply with the requirements of federal and state law and regulations and are approved by the Division, including, without limitation, commercial and retail businesses.

11.1.6 The production of edible marijuana products or marijuana-infused products for sale shall not use non-marijuana ingredients prepared or stored in a private home.

11.2 Allowable Products

11.2.1 Products produced in a Marijuana Infused Food Establishment are limited to non-TCS baked goods and candy.

11.2.2 The manufacturing of baked goods shall be allowed in a Marijuana Infused Food Establishment to include cookies, muffins and brownies.

11.2.3 Bakery items which as a finished product contain components such as fruit filling, cream filling or meat are prohibited.

11.2.4 Candy products including, but not limited to chewables, fudge, lollipops, chocolates, and hard candy, are allowed to be manufactured in a Marijuana Infused Food Establishment provided the final products are non-TCS.

11.2.5 All labeling requirements set forth in subsection 16.2 must be met before the product is sold.

11.2.6 Products may not exceed 10mg of THC-Delta 9 or 25mg of CBD per serving.

11.2.7 Marijuana infused products are limited to five servings per package.

11.2.8 Products infused with THC, must have the letters "THC" molded into the product.

11.3 Application

11.3.1 Compassion Centers seeking registration as a Marijuana Infused Food Establishment must submit to the Division an application demonstrating that they meet the requirements set forth in these regulations. The application shall include:

11.3.1.1 The name, mailing address, e-mail address, telephone, and signature of the person applying for the registration and the name, mailing address, and physical address of the Marijuana Infused Food Establishment;

11.3.1.2 Information about products and processes including but not limited to products to be made, ingredients, example labels, processes and products;

11.3.1.3 Floor plan of the processing area identifying appliances to be used, food contact surfaces (types of materials used for contact surfaces must be described,) areas for refrigeration and dry good storage, and restroom facilities;

11.3.1.4 Proof of completion of training that satisfies Section 13.0; and

11.3.1.5 A statement signed by the applicant that:

11.3.1.5.1 Attests to the accuracy of the information provided in the application;

- 11.3.1.5.2 Affirms that the applicant will comply with these regulations; and
- 11.3.1.5.3 Allow the Division access to the establishment as specified under subsection 10.6 and to the records specified under subsection 7.5.

11.3.2 Compassion Centers may first apply to the Division for an endorsement as a Marijuana Infused Food Establishment on or after July 1, 2020.

11.3.3 Following the submission of an application demonstrating that all requirements of these regulations have been met, up to and including the on-site inspection, the producer may begin sales to consumers in accordance with these regulations.

11.3.4 Upon registration by the Division, a Marijuana Infused Food Establishment and associated activities shall comply with the standards established by these regulations.

11.3.5 It shall be a violation of these regulations to operate in Delaware as a Marijuana Infused Food Establishment, as defined by these regulations, if not registered with the Division.

11.3.6 Registration with the Division does not exempt the Marijuana Infused Food Establishment from other state, county or local codes unless specifically listed in subsection 10.5.

11.3.7 If the proposed Marijuana Infused Food Establishment uses a private well as a source of potable water, the well must be in compliance with State of Delaware Regulations Governing Public Drinking Water, 16 **DE Admin. Code** 4462.

- 11.3.7.1 Private wells shall comply with chemical and bacteriological standards; a satisfactory analysis is required before a registration may be issued. Completion of any required sampling is the responsibility of the Compassion Centers.

- 11.3.7.2 Tests conducted within 60 days of the date of the initial or renewal application will be accepted to demonstrate compliance.

11.3.8 Establishments served by a public water supply and sewage systems do not require further evaluation.

11.4 Renewal

11.4.1 Registration must be renewed bi-annually.

- 11.4.1.1 Marijuana Infused Food Establishments must maintain a Medical Marijuana Compassion Center License through the Division.

19 DE Reg. 409 (11/01/15)

23 DE Reg. 667 (02/01/20)

24 DE Reg. 485 (11/01/20)

12.0 Marijuana Infused Food Establishment Endorsement Requirements

12.1 Conditions of the Marijuana Infused Food Establishment Endorsement

12.1.1 Upon acceptance of the endorsement to operate a Marijuana Infused Food Establishment issued by the Division the Compassion Center shall:

- 12.1.1.1 Allow representatives of the Division access to the Marijuana Infused Food Establishment during hours of operation and other reasonable times. After the Division representative presents official credentials and an intent to conduct an inspection the producer shall allow the Division representative to determine if the Marijuana Infused Food Establishment is in compliance with these regulations by allowing access to the establishment, allowing inspection, and providing information and records to which the Division is entitled according to law;

- 12.1.1.2 Comply with Division directives including time frames for corrective actions specified in inspection reports and other directives issued by the Division regarding the Marijuana Infused Food Establishment. Comply with the conditions of a granted variance, and conditions of approved facility plans and specifications;

- 12.1.1.3 Accept notices issued and served by the Division according to the law. Be subject to the administrative, civil, injunctive, and criminal remedies authorized in law for failure to comply with the regulations or Division directives, including time frames for corrective actions specified in inspection reports;

- 12.1.1.4 Immediately discontinue operations and notify the Division if an imminent health hazard may exist because of an emergency such as fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne illness

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outbreak, gross unsanitary occurrence or condition, or other circumstance that may endanger health;

12.1.1.5 Immediately contact the Division to report an illness of an employee who is diagnosed with Norovirus, Salmonella typhi (Typhoid fever), Shigella spp., Shiga toxin-producing E. Coli including 0157:H7, Hepatitis A virus or nontyphoidal salmonella;

12.1.1.6 Replace existing facilities and equipment with facilities and equipment that comply with the Code if:

12.1.1.6.1 The Division directs the replacement because the surfaces and equipment constitute a public health hazard or nuisance or no longer comply with the criteria upon which the surfaces and equipment were accepted; or

12.1.1.6.2 The Division directs the replacement of the facilities and equipment because of a change of ownership.

12.1.1.7 Prepare and maintain a current written contingency plan for use in initiating and affecting a product recall.

12.2 Safe Production of Marijuana Infused Products

12.2.1 Each facility for the production of edible marijuana products or marijuana-infused products shall ensure that:

12.2.1.1 Pasteurized eggs or egg products are substituted for raw eggs in the preparation of edible marijuana products or marijuana-infused products.

12.2.1.2 Marijuana products and ingredients only have contact with the surfaces of:

12.2.1.2.1 Equipment and utensils that are cleaned and sanitized; or

12.2.1.2.2 Single-service and single-use articles that have not previously been used.

12.2.1.3 All ingredients must be cooked thoroughly to a safe temperature for the proper time.

12.3 Quality Control Unit

12.3.1 Each facility for the production of edible marijuana products or marijuana-infused products shall have a quality control unit that:

12.3.1.1 Has the responsibility and authority to approve or reject all components, product containers, closures, in-process materials, packaging materials, labeling and marijuana or marijuana products;

12.3.1.2 Has the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated and resolved;

12.3.1.3 Is responsible for approving or rejecting marijuana or marijuana products manufactured, processed, packaged or held under contract by another Compassion Center;

12.3.1.4 Is responsible for approving or rejecting all procedures or specifications which may impact the identity, strength, quality and purity of the marijuana or marijuana products.

12.3.2 Each Compassion Center or Marijuana Infused Food Establishment shall:

12.3.2.1 Set forth the responsibilities and procedures applicable to the quality control unit in writing; and

12.3.2.2 Follow the written responsibilities and procedures set forth pursuant to subsection 7.3.12.3.

23 DE Reg. 667 (02/01/20)

13.0 Training Requirements

At least one employee during hours of operation shall be on location and have shown proficiency in food safety through passing a test that is part of a program approved by the Office of Food Protection.

23 DE Reg. 667 (02/01/20)

14.0 Producer Requirements

14.1 The producer shall ensure that:

14.1.1 Only approved food items shall be made in the Marijuana Infused Food Establishment;

14.1.2 Only persons necessary to the Marijuana Infused Food Establishment shall be allowed in the food preparation, food storage or ware washing areas during operation;

- 14.1.3 Producers and employees are effectively cleaning their hands, by routinely hand washing per specifications provided by the Division;
- 14.1.4 Producers or employees are properly cooking TCS ingredients, being particularly careful in cooking those foods known to cause severe foodborne illness and death, and routinely monitor cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated;
- 14.1.5 Producers or employees are properly sanitizing cleaned multiuse equipment and utensils before they are reused, through routine monitoring of solution temperature and exposure time for hot water sanitizing, and chemical concentration, pH, temperature, and exposure time for chemical sanitizing per specifications provided by the Division;
- 14.1.6 Producers and employees shall prevent cross-contamination of ready to eat food with bare hands by properly using suitable utensils such as deli tissue, spatulas, tongs, single use gloves, or dispensing equipment; and
- 14.1.7 Producers and employees are informed in a verifiable manner of their responsibility to report to the producer, information about their health and activities as they relate to diseases that are transmissible through food.

23 DE Reg. 667 (02/01/20)

15.0 Facility Requirements

15.1 Indoor Areas

15.1.1 Materials that are smooth, durable and easily cleanable shall be installed in the following areas:

15.1.1.1 Food preparation

15.1.1.1.1 Each facility for the production of edible marijuana products or marijuana-infused products shall ensure that:

15.1.1.1.1.1 The surfaces of equipment and utensils that have direct contact with marijuana products are clean to sight and touch;

15.1.1.1.1.2 The surfaces of cooking equipment and pans that have direct contact with marijuana products are kept free of encrusted grease deposits and other soil accumulations;

15.1.1.1.1.3 The surfaces of equipment that do not have direct contact with marijuana products are kept free of an accumulation of dust, dirt, residue and other debris.

15.1.1.2 Food preparation area surfaces

15.1.1.2.1 Each facility for the production of edible marijuana products or marijuana-infused products shall ensure that the surfaces of equipment and utensils that have direct contact with marijuana products are cleaned:

15.1.1.2.1.1 Each time there is a change from working with raw marijuana products to working with finished marijuana products;

15.1.1.2.1.2 Between uses with potentially hazardous marijuana products and ingredients, using the appropriate time and temperature controls to ensure the safety of the marijuana products;

15.1.1.2.1.3 At any time during operation when contamination may have occurred;

15.1.1.2.1.4 If they come into contact with potentially hazardous marijuana products or ingredients, surfaces and utensils are cleaned throughout the day at least once every 4 hours.

15.1.1.2.1.5 The surfaces of utensils and equipment that have direct contact with marijuana products or ingredients that are not potentially hazardous are cleaned:

15.1.1.2.1.5.1 At any time when contamination may have occurred;

15.1.1.2.1.5.2 At a frequency specified by the manufacturer; or

15.1.1.2.1.5.3 If the manufacturer does not specify a frequency, at a frequency necessary to prevent the accumulation of soil or mold.

15.1.1.3 Dry food storage

15.1.1.3.1 All elements involved in the production of marijuana infused products will be stored at least 12 inches off the floor on shelving or other generally recognized food storage container.

15.1.2 Carpeting of any kind, shall not be used in the following areas:

15.1.2.1 Food preparation; or

15.1.2.2 Dry food storage.

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15.1.3 Utility lines shall be installed inside walls, above ceiling or below floors, where possible.

15.1.4 Insect control devices shall not be installed over food preparation surfaces.

15.2 Artificial Interior Lighting

15.2.1 Provide minimum illumination intensities

15.2.1.1 At least 50-foot candles at a surface where a producer or employee is working with food or working with utensils or equipment such as knives, slicers, and grinders or where the producer or employee safety is a factor.

15.3 Animals

15.3.1 No animals/pets shall be permitted in the kitchen area of a Marijuana Infused Food Establishment during the preparation, packaging, or handling of any marijuana infused food products. Employees with service animals, as defined by the Americans with Disabilities Act, must comply with state and federal food codes regarding the presence of service animals in food establishments.

15.4 Poisonous and Toxic Materials

15.4.1 Toxic substances shall be stored so they cannot contaminate food preparation or cooking equipment in kitchen areas.

15.4.2 Rodent bait shall be contained in covered, tamper-resistant bait stations. Toxic tracking powders shall not be used as a pesticide and nontoxic tracking powders shall not contaminate food, equipment or utensils.

15.4.3 All medicines and first aid supplies shall be labeled and stored in a kit or container out of food preparation areas.

15.5 Plumbing in a Marijuana Business

15.5.1 The plumbing shall meet the requirements of all municipal, county or state codes.

15.5.2 Marijuana Infused Food Establishments shall have convenient access to permanent restroom facilities equipped with running potable water, paper towels and soap.

15.6 Sewage Disposal

15.6.1 Individual sewage disposal systems require the approval of the Department of Natural Resources and Environmental Control prior to operating the establishment.

15.7 Temperature Measuring Devices (TMD)

15.7.1 In mechanically refrigerated food storage units, TMD shall be located to measure the air temperature in the warmest part of the unit.

15.7.2 TMD shall be readily accessible for use in ensuring attainment and maintenance of required food temperatures.

15.7.3 TMD shall be accurate to $\pm 1^{\circ}$ Celsius or $\pm 2^{\circ}$ Fahrenheit to measure food temperatures.

15.7.4 TMD shall not have sensors constructed of glass, except if encased in shatterproof coating.

15.8 Refrigeration and Cold Holding Equipment

15.8.1 Freezer units shall be capable of maintaining stored food solidly frozen.

15.8.2 Refrigeration and cold holding units shall be capable of maintaining stored foods at 41° Fahrenheit or below.

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16.0 Product Requirements

16.1 Testing

16.1.1 All batches of food are required by the Division to be laboratory tested through the Safety Compliance Facility for safety and cannabinoid profile. Testing of food products shall be the financial responsibility of the Compassion Center.

16.2 Recall Plan

16.2.1 The Marijuana Infused Food Establishment shall:

16.2.1.1 Prepare and maintain a current written contingency plan for use in initiating and affecting a recall of products;

16.2.1.2 Use sufficient coding of regulated products to make possible positive identification and to facilitate effective recall of all violated lots;

16.2.1.3 Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records shall be maintained for 3 years.

16.3 Reporting and Records

16.3.1 A Marijuana Infused Food Establishment must maintain records for each batch of product indicating type of finished product, date of production, lot number, and date and location of sales. These records shall be maintained for 3 years.

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17.0 Compliance and Enforcement Procedures

17.1 A person may not operate a Marijuana Infused Food Establishment without a valid endorsement to operate issued by the Division.

17.2 If the Division determines that a Marijuana Infused Food Establishment is operating without a valid endorsement; that one or more conditions exist which represent an imminent health hazard; or that serious violations, repeat violations, or general unsanitary conditions are found to exist, administrative action may occur.

17.2.1 Administrative action on the Marijuana Infused Food Establishment will be conducted in accordance with the following:

17.2.1.1 Operation without an endorsement

17.2.1.1.1 Immediate Closure Order

17.2.1.1.1.1 If a Marijuana Infused Food Establishment is found operating without an endorsement as required by subsection 7.1 of this regulation, the Division shall order the establishment immediately closed.

17.2.1.1.2 Notice of Closure

17.2.1.1.2.1 The closure shall be effective upon receipt of a written notice by the producer or employee of the Marijuana Infused Food Establishment. A closure notice statement recorded on the inspection report by a representative of the Division constitutes written notice.

17.2.1.1.3 Duration of Closure

17.2.1.1.3.1 The Marijuana Infused Food Establishment shall remain closed until an endorsement application; applicable fees and any required plans have been received and approved by the Division.

17.2.1.2 Imminent Health Hazards

17.2.1.2.1 Endorsement suspension without hearing

17.2.1.2.1.1 If some condition is determined to exist in a Marijuana Infused Food Establishment which presents an imminent health hazard to the public, or for any violation of an applicable law or regulation, the Division may suspend the endorsement of the Marijuana Infused Food Establishment without a prior hearing. The suspension shall be effective upon receipt of written notice by the producer or employee of the marijuana establishment. A suspension statement recorded on an inspection report by the Division constitutes written notice.

17.2.1.3 Serious Violations, Repeat Violations and General Unsanitary Conditions

17.2.1.3.1 When conditions exist in a marijuana establishment that represent serious violations, repeat violations or general unsanitary conditions, the Division may initiate a corrective action plan.

17.2.2 In response to the order to close, the facility may:

17.2.2.1 Take no action, in which case the order to close shall remain in effect.

17.2.2.1.1 Take action to correct the unsafe and unsanitary practices identified during the survey.

17.2.2.1.1.1 The facility may submit evidence through a written plan of correction showing that the deficient practices, identified during the investigation, have been addressed and corrected.

17.2.2.1.1.2 A change of location for the facility does not nullify an order to close and an acceptable plan of correction must still be submitted.

17.2.2.1.1.3 The Department shall determine if the plan of correction is acceptable.

17.2.2.1.1.4 Once accepted, the Department shall schedule a revisit as soon as possible.

17.2.2.2 Request, in writing, an administrative hearing with the Department to contest the order to close.

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- 17.2.2.2.1 Such request must be received within 10 calendar days from the date on which the order to close was issued.
- 17.2.2.2.1.1 As soon as possible, but in no event later than 60 calendar days after the issuance of the closure order, the Department shall convene a hearing on the reasons for closure.
- 17.2.2.2.1.2 The Department shall make a determination based upon the evidence presented.
- 17.2.2.2.1.2.1 A written copy of the determination and the reasons upon which it is based shall be sent to the facility within 30 calendar days of the hearing.
- 17.2.2.2.2 During an administrative hearing:
- 17.2.2.2.2.1 The facility has the right to be represented by counsel;
- 17.2.2.2.2.2 All statements made shall be under oath;
- 17.2.2.2.2.3 The facility has the right to examine and cross-examine witnesses and present evidence;
- 17.2.2.2.2.4 A stenographic record will be made by a qualified court reporter. At the request and expense of any party, such record shall be transcribed with a copy to the other party; and
- 17.2.2.2.2.5 The decision of the Department shall be based upon sufficient legal evidence. If the charges are supported by such evidence, the Department may continue, modify or revoke the closure order.
- 17.2.2.2.3 Upon reaching its conclusion of law and determining an appropriate disciplinary action, the Department shall issue a written decision and order in accordance with §10128 of Title 29.
- 17.2.2.2.4 All decisions of the Department shall be final and conclusive. Where the facility is in disagreement with the action of the Department, the facility may appeal the Department's decision to the Superior Court within 30 days of service or of the postmarked date of the copy of the decision mailed to the facility. The appeal shall be on the record to the Superior Court and shall be as provided in §§10142 - 10145 of Title 29.

17.2.3 Examination of Food

- 17.2.3.1 Food may be examined or tested by the Division contract lab as often as necessary for enforcement of this regulation.
- 17.2.3.2 All food shall be wholesome and free from spoilage. Food that is spoiled or unfit for human consumption shall not be kept on the premises.

17.3 Penalties

17.3.1 Operation in Violation of Regulation

- 17.3.1.1 Any person who violates a provision of this regulation, and any person who is the holder of a permit or who otherwise operates a food establishment that does not comply with the requirements of this regulation shall be subject to the penalties found in 16 **Del.C.** §4914 and these regulations.

17.4 Injunction

- 17.4.1 The Division may seek to enjoin violations of the regulation.

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24 DE Reg. 485 (11/01/20)

18.0 Random Sampling Procedures

- 18.1 Compassion Centers will coordinate with the Office of Medical Marijuana (OMM) for collection of samples by State Regulators, who will supervise randomly chosen samples of each batch for testing by the Testing Center. Sample results will be loaded into the DEC3S system by the testing center allowing Compassion Centers to sell the material or incorporate it into other products.
- 18.2 Sampling
- 18.2.1 Compassion centers may create any size batch they deem appropriate, but not more than five (5) pounds.
- 18.2.2 The minimum sample size is set at 0.5% of batch weight. A one (1) pound batch would require a two (2) gram sample and a five (5) pound batch would require an 11-gram sample. The minimum sample size for testing is one (1) gram.
- 18.2.3 All medical marijuana products will be tested as directed in subsection 18.3 of these regulations.
- 18.3 Compassion Center's Responsibility:

- 18.3.1 Compassion Centers will coordinate harvest schedules with the Office of Medical Marijuana (OMM) and the Testing Center.
 - 18.3.1.1 After the marijuana has been harvested, dried and cured, the OMM staff will supervise selection of random samples from the curing vessels with the Compassion Center staff.
 - 18.3.1.2 Compassion Center staff will prepare additional barcode labels and tamper-proof containers for each batch and develop a transportation manifest, initiating the chain of custody process for the batch of plants being tested.
- 18.3.2 The Compassion Centers will not sell or prepare products from the batch being tested until the testing centers enter the values into the DEC3S program, releasing the material for use or sale.
- 18.3.3 Compassion Centers will be invoiced for payment of testing services directly from the Testing Center.
- 18.3.4 All concentrates or other infused products must be sent to the Testing Center using the process listed above before they are cleared for sale.
- 18.4 Testing Facility Responsibility:
 - 18.4.1 The testing center will receive samples from the Office of Medical Marijuana (OMM) staff and co-sign the sample manifest after verification of sample barcodes. The testing center will enter the samples into the lab portion of DEC3S. The Testing Center will process the samples for the following profile, terpenes and contaminants:
 - 18.4.1.1 Tetrahydrocannabinol (THC).
 - 18.4.1.2 Tetrahydrocannabinolic Acid (THCA).
 - 18.4.1.3 Cannabidiol (CBD).
 - 18.4.1.4 Cannabidiolic Acid (CBDA).
 - 18.4.1.5 Cannabigerol (CBG).
 - 18.4.1.6 Cannabinol (CBN).
 - 18.4.1.7 That the presence of contaminants does not exceed the levels in the most current version of the American Herbal Pharmacopoeia Monograph or the guidance from the Division of Public Health.
 - 18.4.2 Contaminants include, but are not limited to, all of the following:
 - 18.4.2.1 Residual solvent or processing chemicals.
 - 18.4.2.2 Foreign material, including, but not limited to, hair, insects, or similar or related adulterant.
 - 18.4.2.3 Microbiological impurity, including total aerobic microbial count, total yeast mold count, *P. aeruginosa*, *aspergillus* spp., *s. aureus*, aflatoxin B1, B2, G1, G2, or ochratoxin A, *E. coli*, and coliforms.
 - 18.4.2.4 Residual levels of volatile organic compounds shall be below the lesser of either the specifications set by the United States Pharmacopeia (U.S.P. Chapter 467) or those set by the Division of Public Health.
 - 18.4.3 Terpenes described in the most current version of the cannabis inflorescence monograph published by the American Herbal Pharmacopoeia. Terpene testing will be done as required by the compassion centers to inform patients of the products formulation.
 - 18.4.4 After the sample testing has been completed,
 - 18.4.4.1 Testing Center will update DEC3S with the values associated with the tests. If the samples pass all tests, the barcode is unlocked, and Compassion Centers will be able to sell or use the marijuana in making other products or concentrates.
 - 18.4.4.2 Testing Center will certify destruction of the sample after DEC3S is updated.
- 18.5 Delaware Consolidated Cannabis Control System (DEC3S) Actions:
 - 18.5.1 The Delaware Consolidated Cannabis Control System (DEC3S) will be used throughout the sample collection, manifest and barcode verification procedures.
 - 18.5.2 Batches will be listed as unavailable for sale until the Testing Center completes the sample testing and enters the results into DEC3S, unlocking them for sale.
 - 18.5.3 The cannabinoid profile values will be available for the Compassion Centers to list on the packaging of the medical marijuana product.
 - 18.5.4 If a sample tested fails one or more of the listed standards, the DEC3S will lockout those barcodes until remediation action is completed and the batch is resubmitted for testing.

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18.5.4.1 If remediation is not possible, the compassion center will coordinate with the Office of Medical Marijuana on the batches disposition or the batch must be scheduled for destruction.

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24 DE Reg. 485 (11/01/20)

19.0 Severability

In the event any particular clause or section of these regulations should be declared invalid or unconstitutional by any court of competent jurisdiction, the remaining portions shall remain in full effect.

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20.0 Variance

20.1 A licensee may seek a variance from these regulations by making a request for variance to the Division. The Division may grant a variance by modifying or waiving the requirements of these regulations if, in the opinion of the Division, a health hazard or nuisance will not result from the variance

20.2 A variance shall not be transferable from person to person, nor from location to location.

20.3 If a variance is granted, the Division shall retain the information specified below in its records for the variance:

20.3.1 A statement of the proposed variance of the requirement of these regulations, citing the relevant section of these regulations;

20.3.2 An analysis of the rationale for how the potential public health hazards or nuisances will be alternatively addressed by the proposal; and

20.3.3 Any other information requested by the Division that may be deemed necessary to render judgment.

20.4 A variance is rendered void upon occurrence of one or more of the following: the physical facility is demolished; a remodeling project in the facility includes the areas addressed in the variance.

15 DE Reg. 1728 (06/01/12)

17 DE Reg. 738 (01/01/14)

19 DE Reg. 409 (11/01/15)

23 DE Reg. 667 (02/01/20)

24 DE Reg. 485 (11/01/20)