

# Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

(1) Agency:

Department of Health

(2) Agency Number: 10-219

Identification Number:

**INDEPENDENT REGULATORY  
REVIEW COMMISSION  
RECEIVED**

SEP 19 2022

Independent Regulatory  
Review Commission

IRRC Number: 3290

(3) PA Code Cite: 28 Pa. Code §§ 1131, 1141, 1141a, 1151, 1151a, 1161, 1161a, 1171, 1171a, 1181, 1181a, 1191, 1191a, 1211, 1211a, 1230, 1230a

(4) Short Title: Medical Marijuana Regulations

(5) Agency Contacts (List Telephone Number and Email Address):

Primary Contact: Laura Mentch, (717) 547-3454 [RA-DHMMregulations@pa.gov](mailto:RA-DHMMregulations@pa.gov)

Secondary Contact:

(6) Type of Rulemaking (check applicable box):

- ☐ Proposed Regulation  
☒ Final Regulation  
☐ Final Omitted Regulation

- ☐ Emergency Certification Regulation;  
☐ Certification by the Governor  
☐ Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

The Medical Marijuana Program (Program) was created by the Medical Marijuana Act (35 P.S. §§ 10231.101 - 10231.2110) (the act), which became effective on May 17, 2016. Under the act, persons, including minors under the age of 18, with a serious medical condition, may, either themselves or through a caregiver, purchase medical marijuana within the Commonwealth. In order to implement the Program, the Department of Health (Department) periodically published temporary regulations relating to various sections of the act, which are effective for two years from the date of publication are to be followed by the promulgation of formal permanent regulations. The most recent set of temporary regulations are set to expire January 14, 2024, and the Department now seeks to promulgate the permanent regulations to replace the current temporary regulations.

In these final regulations, the Department amends the current temporary regulations to clarify those existing regulations, to maintain proper regulation commensurate with the evolution of the Program, and to respond to public comments.

(8) State the statutory authority for the regulation. Include specific statutory citation.

The Department's authority to promulgate these regulations is found in Section 301(b) of the act, which provides that the Department has the authority to promulgate all regulations necessary to carry out the provisions set forth in the act. (35 P.S. § 10231.301(b)).

**(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.**

The act required the Department to issue temporary regulations necessary to achieve the act's purpose within a particular time frame. The act provides that those temporary regulations would expire within two years of publication in the *Pennsylvania Bulletin*, and that all future regulations must be promulgated through the regulatory process set out in law. 35 P.S. § 10231.1107(b). Act 10 of 2020, section 1736-A.1, extended the expiration of the temporary regulations until November 20, 2021. Act 44 of 2021 further extended the Department's authority to promulgate temporary regulations until May 31, 2022. 35 P.S. § 10231.1107(b). Accordingly, the Department re-published the current temporary regulations on January 14, 2022, extending the expiration date to January 14, 2024. Regulations are necessary for compliance with, and enforcement of, the act.

There are no relevant state or federal court decisions relating to these regulations.

**(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.**

These final regulations are necessary for the continued viability of the Program established by the act. Replacing the current temporary regulations—which are set to expire on January 14, 2024—with the final regulations ensures that participants in the Program will continue to receive medicine and the Department may continue to monitor and regulate the Program, as required by the act.

Beyond the timing requirement, these final regulations are needed so that the regulatory scheme may keep pace with the evolution of the Program. Since the act was signed into law on April 17, 2016, the Program has undergone two separate application and permitting phases for medical marijuana organizations under chapter 6 of the act, and four permitting phases under chapter 20 of the act. During this time, the Department has experienced consistent growth in the number of patients and medical marijuana organizations that participate in the Program. The revised and additional provisions in the final regulations reflect the Department's efforts to keep pace with the growth and evolution of the program.

Those benefitting from these final regulations include any participant in the Program. As these regulations ensure the continued viability of the Program, all participants benefit from these final regulations.

Medical marijuana patients will benefit from these final regulations by being able to continue to receive medication to treat their serious medical conditions. Further, through the final regulations, practitioners are prohibited from charging an excessive fee in providing this service. Medical marijuana caregivers will also benefit, as they are able to continue to provide their services to those medical marijuana

patients who rely on the assistance of caregivers. As of July 28, 2022, there are over 39,000 registered caregivers, and over 414,000 active patients.

Further, the expected growth of the Program should result in increased competition among medical marijuana organizations, which should result in reduced product costs for cardholders. The Department is continuing to gather data on the impact of the Program, including on costs and increase in capacity, and is expecting program and product expansion, as more growers/processors operationalize.

Medical marijuana practitioners will benefit from these regulations through the continued ability to provide certifications to patients with qualifying medical conditions who, in the practitioner's professional opinion, will benefit from the use of medical marijuana. Practitioners also typically charge a fee for their consultations with patients to certify them to participate in the Program. As of July 28, 2022, there are over 1,800 approved practitioners.

Medical marijuana organizations (dispensaries and grower/processors) and their employees will benefit through the continued viability of the program, as a medical marijuana organization's existence depends on the program. These organizations will be able to continue to conduct business within the parameters of the act and regulations. There are currently 56 dispensary permittees, including the nine clinical registrants under Chapter 20 of the act (relating to research), with each dispensary permittee permitted to have up to three dispensary locations (up to six in the research arena), and 35 grower/processor permittees, also including research permit holders. The number of people employed by medical marijuana organizations is unknown.

In addition, the final regulations provide for the implementation of a research program, that allows for the approval of ten clinical registrants and academic clinical research centers and permits them to carry on research. The ability to do research on medical marijuana, and the Commonwealth is the only state that has a research component to its medical marijuana program, will ultimately provide valuable data on the use of medical marijuana and its efficacy. This ultimately will benefit patients, and the Commonwealth, since enabling patients to more effectively deal with serious medical conditions will benefit both the health care system, and the overall social and economic wellbeing of the state.

**(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.**

There are no federal standards that relate to these proposed regulations.

**(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?**

Thirty-six other states and the District of Columbia have statutes permitting the use of medical marijuana. The Medical Marijuana Programs in those other states are largely the same as Pennsylvania's, providing processes for the growth, processing, dispensing, and purchasing of medical marijuana and medical marijuana products. One notable difference between programs established in other states and Pennsylvania's program is that Pennsylvania is the only state that has established a research program for medical marijuana. This makes Pennsylvania's program unique and potentially the source of significant data regarding the use and efficacy of medical marijuana. This could be a significant benefit for those entities that are chosen to participate in the program as a clinical registrant or academic clinical research center, since it is expected that the results of the research may inform new products and lead to additional research and development in the area of medical marijuana. This may work to attract businesses and persons to the Commonwealth to participate in those studies.

With respect to medical marijuana organizations, many of the other states with medical marijuana programs issue permits to entities that dispense, grow and process or manufacture medical marijuana for medical treatment purposes. The industry is rigorously regulated in most states. Therefore, most entities choosing to apply for a permit in the Commonwealth have dealt with similarly regulated states or would be subject to similar regulation in other states.

**(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.**

No, these changes will not affect any other regulations of the promulgating agency or other state agencies. By law the Department's temporary regulations relating to the Medical Marijuana Program will expire on January 14, 2024.

**(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)**

The Department requested input throughout the temporary regulation drafting process, including regarding changes to the regulations, by surveying different groups of stakeholders, including permittees, approved laboratories, caregivers and patients. The Department held multiple meetings throughout 2019 and 2020 with the Pennsylvania Cannabis Coalition, who represents most of the medical marijuana permittees, and received feedback from the industry regarding proposed regulatory changes. Many regulatory changes were made based on stakeholder feedback. Additionally, all permittees have access to regional field supervisors and email resource accounts to convey questions and concerns. The Department regularly corresponds with permittees. The Department has also previously published each set of temporary regulations on its website and taken public comment. The evolution of these final regulations has come about, in part, because of those discussions and feedback.

The revisions to the temporary regulations set forth in the final regulations are necessary to ensure consistency throughout the regulations, and to ensure that the final regulations provide the necessary regulatory framework for continued program development and success. In addition, the implementation of the Program through the temporary regulations led to continuing discussions with patients, caregivers, growers/processors and dispensaries, and recommendations and comments about how the Program could better serve those stakeholders. The Department is offering these final regulations, having taken into



account those comments and recommendations, in order to ensure a safe and effective Program and that persons with serious medical conditions using medical marijuana in the Commonwealth can be sure that they are receiving a safe and effective product.

**(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?**

Because no Department of Labor standards apply to medical marijuana organizations, the Department cannot say with certainty whether any dispensary or grower/processor qualifies as a small business. Whether or not any of these regulated entities is a small business, however, the Department has not and would not consider less stringent requirements than those offered in these final regulations. The Department's need for strict oversight is driven by the nature of the Program, and the possibility of federal enforcement reaching into the state were it to appear that requirements ensuring the safety and security of medical marijuana and medical marijuana products being grown, shipped and produced by these regulated entities were lax. It is the Department's responsibility to ensure the safety, security, and effectiveness of the Program, which it does by monitoring through its regulations.

The final regulations apply to dispensaries, which is a type of business that has only legally existed in the Commonwealth since the act's inception. There are currently 56 dispensary permits issued by the Department, including those in the research arena. There are no current statewide standards that apply to this type of business entity to determine what would constitute a small business, and the Department has no way of making that determination, since it does not maintain information on the numbers of employees each dispensary employs. These final regulations mirror in large part the temporary regulations under which dispensaries are currently operating, so that the promulgation of these final regulations should have little effect.

The final regulations also apply to growers/processors, which is also a type of business that has only legally existed in the Commonwealth since the act's inception. There are currently 35 grower/processor permits issued by the Department, including permits in the research arena. Again, there are no statewide standards allowing a definition of small business to be developed in this context, the Department does not keep information on the number of employees at each grower/processor, and there are no federal requirements that can be applied. These final regulations mirror in large part the temporary regulations under which growers/processors are currently operating, so that the promulgation of these final regulations should have little effect.

The final regulations apply to laboratories who choose to be approved by the Department to test medical marijuana and medical marijuana products by the Department. Laboratories are not required to participate in the Program. There are currently seven approved laboratories in the Commonwealth. These final regulations mirror in large part the temporary regulations under which laboratories are currently operating, so that the promulgation of these final regulations should have little effect.

The final regulations also apply to a clinical registrant (CR), each of which holds a grower/processor permit and a dispensary permit. Those entities are discussed above as growers/processors and dispensaries. These regulations also apply to a certified academic clinical research center (ACRC), which are educational institutions with medical schools. There are nine CRs and nine certified ACRCs in the Commonwealth. The Department may approve no more than ten CRs under the act. The final regulations allow for the implementation of the research program, which would be unable to advance without regulation.

These final regulations also apply to medical marijuana cardholders, which include both patients and caregivers. Medical marijuana patients and caregivers are required to comply with these proposed regulations to receive medication to treat serious medical conditions. Failure to comply with the final regulations could cut off the patient's or caregiver's access to a medication that could be helpful in treating the patient's serious medical condition. As of July 28, 2022, there were over 39,000 registered caregivers and over 414,000 active patients. These final regulations mirror in large part the temporary regulations under which the Program is currently operating, so that the promulgation of these final regulations should have little effect on patients and caregivers. Fees associated with obtaining medical marijuana identification cards would remain the same (\$50 annually), and the regulations would continue to provide for fee reductions for those showing financial hardship (\$25 annually). However, the final regulations provide that practitioners may not charge patients an excessive fee for services related to the patient becoming certified for medical marijuana use.

The regulations also apply to practitioners. Physicians must comply with the regulations in order to become practitioners able to certify patients so that the patient can obtain medical marijuana to treat the patient's serious medical condition. In addition to enabling physicians to become practitioners, and participate in the Program, the regulations also ensure that physicians who become practitioners have had the appropriate training and are able to safely and effectively treat and monitor patients. They also enable the Department to monitor practitioners, and to take the necessary action to ensure a safe and effective Program. As of July 28, 2022, there were over 1,800 approved practitioners. These final regulations mirror in large part the temporary regulations under which practitioners are currently certifying patients, so that the promulgation of these final regulations should have little effect on their practice. The final regulations do provide that practitioners may not charge patients an excessive fee for services related to the patient becoming certified for medical marijuana use, which does allow for additional action to be taken against practitioners by the Department, in coordination with the Department of State, in the event of a complaint regarding fees.

These final regulations also apply to the employees of the dispensaries, growers/processors and laboratories covered by the regulations, including other medical professionals employed by the dispensaries, like physicians' assistants and certified registered nurse practitioners. Although the Department does not have direct control over employees and medical professionals, except to require background checks in certain instances, the final regulations set standards for the operation of dispensaries and growers/processors. The final regulations enable the Department to require effective operations and safe and effective growth, production, sales and dispensing of medical marijuana and medical marijuana products. The Department does not have information on the number of these employees. Again, since the final regulations do not change extensively the requirements in the temporary regulations, there should be little effect on the way employees of these entities operate.

Finally, the final regulations would apply to any future participant in the Program. The effect on these groups of participants would be the same as explained above in this response.

**(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.**

Every group of individuals and entities listed in the response to Question 15 is required to comply. No Department of Labor standards apply to medical marijuana organizations, the Department, therefore, cannot say with certainty whether any dispensary or grower/processor qualifies as a small business.

With respect to medical marijuana organizations, there are currently 56 dispensary permittees, including those in the research arena, with each dispensary permittee permitted to have up to three dispensary locations (up to six in the research arena), and 35 grower/processor permittees, also including research permit holders.

There are currently nine accredited medical schools certified as ACRCs. Nine CRs have been approved to date.

Any laboratory that wishes to participate in the Program will be required to comply with these regulations. The Department has currently approved seven laboratories to do testing. The act does not place a limitation on the number of laboratories that may participate, and the Department continues to review laboratory applications.

Medical marijuana patients and caregivers are required to comply with these final regulations to receive medication to treat their or their patient's serious medical conditions. This number changes frequently. As of July 28, 2022, over 414,000 active patients participate in the Program and over 39,000 caregivers have registered.

As of July 28, 2022, there were over 1,800 approved practitioners. The act does not place a limit on the number of physicians that may apply to become practitioners.

---

**(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.**

These regulations allow medical marijuana organizations to continue to exist and operate legally within the Commonwealth. While the Program is currently operating at nearly the statutory capacity for permits, the fees included in the statute with respect to growers/processors would remain the same: applicants for a grower/processor permit would be required to pay a non-refundable application fee of \$10,000 and a refundable permit fee of \$200,000, in the event a permit is not awarded. They are also required, by statute, to have \$2,000,000 in capital, \$500,000 of which must be on deposit at a financial institution. With respect to dispensaries, the requirements that are set out in statute also remain the same; dispensary applicants are required to pay a non-refundable initial application fee of \$5,000 and a refundable permit fee of \$30,000 for each dispensary location, again, in the event a permit is not awarded. Permit renewal fees are \$10,000 and \$5,000 annually for growers/processors and dispensaries, respectively.

With respect to medical marijuana cardholders, fees associated with obtaining medical marijuana identification cards would remain the same (\$50 annually), and the final regulations provide for fee reductions for persons showing financial hardship (\$25 annually). The final regulations provide that practitioners may not charge a patient an excessive fee for services related to the patient becoming certified for medical marijuana use.

Further, the expected growth of the Program should result in increased competition among medical marijuana organizations, which should result in reduced product costs for cardholders. The Department is continuing to gather data on the impact of the Program, including on costs and increase in capacity, and is expecting program and product expansion as more growers/processors operationalize.

The social impact of the Program on individuals using medical marijuana products is still anecdotal since the Program has only been providing medical marijuana to the public for three years. The research component of the Program has just become operational. The Department is hopeful that the research done by the ACRCs and CRs will provide valuable data on the use of medical marijuana and its efficacy.

**(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.**

These regulations would benefit those participating in the Program by ensuring that medical marijuana patients would continue to receive the medicine provided by medical marijuana organizations. As the current temporary regulations are set to expire on January 14, 2024, the primary benefit of the final regulations is that they are necessary to maintain the regulatory scheme of the Program. Without regulations, the regulatory scheme laid out in the act, while sufficient to broadly oversee the production, sale, and dispensing of medical marijuana, lacks the specificity to fully ensure that there would be no concerns over safety and consistency of the products produced and the way the product is dispensed and sold.

The Department must ensure that the Program satisfies the concerns of federal law enforcement that medical marijuana is strictly regulated and that the production, sale, dispensing, and use is strictly controlled to prevent diversion for improper use. The creation through temporary regulations and continuation of strict regulatory requirements in the final regulations, along with strict enforcement procedures, would allow the Department to satisfy these concerns. The cost to participants in the Program associated with the implementation of a detailed and strict permitting program, therefore, is outweighed by the need to ensure that the Program is a safe and effective Program, providing an effective and safe medical tools to treat patients with serious medical conditions.

As of July 28, 2022, the Department has approved nine clinical registrants as part of the research portion of the Program. As Pennsylvania is the only state that has established a research program for medical marijuana, the benefit of successful applicants to research further benefits of medical marijuana provides a benefit to not only citizens of the Commonwealth, but to the medical marijuana industry, as information relating to differing strains, doses, and the best ways to use medical marijuana, will be studied. This will allow for production of the most effective strains. It will also allow the most effective recommendations and dosing for patients and allow them to gain the most benefit from the use of this medicine.

**(19) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.**

The costs provided in the current temporary regulations would be largely unchanged by the final regulations. New signage will result in miniscule costs to each permittee, depending on the quality of the sign desired. While one permittee estimated the cost at \$2,000, a computer-printed and laminated sign would serve the purpose. Permittees asserted that surveillance storage costs are approximately \$35,000 to \$40,000 higher than in other states due to Pennsylvania's lengthy two-year storage requirements. The storage requirements were initially four years, then lowered to two years and, in response to comments received on these final regulations and Act 44 of 2021, the Department lowered the storage requirements to 180 days. Permittees also asserted additional costs were associated with the new requirement to use

separate labs for harvest and process tests, claiming that lab pricing is lower when quantity is higher.<sup>1</sup> Permittees are currently required to conduct two lab tests and the only change being made is that two different labs conduct those tests. Since all permittees will have to comply with the new requirement to use different labs, all labs should adjust their pricing accordingly. To the extent that pricing is not adjusted, any increased lab cost should be offset by the decreased surveillance storage costs. Below are the associated costs for the various groups of participants in the Program.

### **Patients and Caregivers**

Patients and caregivers would be assessed a \$50 fee for an identification card application and an identification card renewal application and a \$25 fee for an identification card replacement. These requirements are statutory and were included in the temporary regulations that the Department implemented as required by the act. The Department can raise the replacement fee for a second and subsequent replacement cards and may alter that fee upon publication of notice in the *Pennsylvania Bulletin*. Further, the act provides that the Department may also waive an identification card application fee if the individual can demonstrate financial hardship. The act requires caregivers to undergo a background check. This is associated with minimal cost of approximately \$21.00. Again, these requirements were included not only in the act, but in the Department's temporary regulations. Many of these fees will be reduced or eliminated for qualifying patients demonstrating financial hardship under the Medical Marijuana Assistance Program, which is currently under development.

### **Practitioners/Medical Professionals**

Practitioners must register to become approved to recommend medical marijuana to patients, but at no cost to practitioners.

### **Grower/Processors**

Growers/processors are required to pay an initial application fee of \$10,000.00, and a permit fee of \$200,000.00, as required by the act. The initial application fee is not refundable; if the applicant does not receive a permit, the permit fee is refundable. The act requires that a grower/processor must also pay a renewal fee each year of \$10,000.00. It is refundable if the renewal is not granted. A fee of \$250.00 is statutorily required if the grower/processor requests permission from the Department to change its location or to alter its facility. These fee requirements were included in the act and these regulations merely echo statutory requirements.

In addition, growers/processors must obtain zoning and, in some cases, building approvals, construct or renovate facilities, and put into place surveillance and security systems that meet certain standards set out in the proposed regulations, as would those seeking to change location and making building renovations. Existing growers/processors have already incurred these costs, as they became operational under the Department's temporary regulations; these final regulations change very little from the temporary regulations relating to security and surveillance, although they do reduce the surveillance storage requirements, resulting in substantial savings to the permittee. In addition, the requirements in the final regulations that growers/processors hire and train staff and maintain a fleet of transportation vehicles that meet certain standards are altered very little from the temporary regulations; for the most part these costs have already been incurred, except for the training of new staff and the purchase of new vehicles.

---

<sup>1</sup> One permittee asserted the requirement to use two different labs would result in an annual increase of \$225,000 but did not explain how this number was calculated.

The final regulations do not alter the statutory requirement that growers/processors are required to purchase and install electronic tracking systems prescribed by the Department. This cost has already been incurred by existing growers/processors.

These final regulations do not alter the statutory requirement that growers/processors would be required to purchase seed and plants to commence operations. This cost has already been incurred by existing growers/processors.

### **Dispensaries**

Dispensaries are required to pay an initial application fee of \$5,000, and a permit fee of \$30,000 for each dispensary location, as is required by statute. The initial application fee is not refundable; however, if the applicant does not receive a dispensary permit, the permit fee is refundable. A dispensary must also pay a renewal fee each year of \$5,000, which is refundable if the permit renewal is not granted. A fee of \$250.00 is required if the dispensary seeks permission from the Department to relocate its operation or to alter its facility.

In addition, dispensaries must obtain zoning and, in some cases, building approvals, construct or renovate facilities, and put into place surveillance and security systems that meet certain standards set out in the final regulations. Existing dispensaries have already incurred these costs, as they became operational under the Department's temporary regulations; these final regulations change very little from the temporary regulations relating to security and surveillance, although they do reduce the surveillance storage requirements, resulting in substantial savings to the permittee.

These proposed regulations do not alter the statutory requirement that dispensaries must purchase and install electronic tracking systems that meet the requirements of the act and regulations, a cost that has already been incurred by existing dispensaries.

### **Laboratories**

The regulations do not require laboratories to pay an application fee but do require that they file an application with the Department to be approved to test medical marijuana. To be eligible for approval, a laboratory must have an accreditation from an accrediting body whose accreditation is accepted by the Department. Accrediting bodies do charge a fee to a laboratory for the accreditation, and there is a cost to obtaining the accreditation and maintaining it. One accrediting body estimates the costs to a laboratory to be approximately \$50,000.00 per year. These costs include maintaining the equipment to meet certain calibration standards, and the cost of auditing results. In addition, laboratories that choose to participate in the Program, and are approved to do so by the Department, are paid by growers/processors to perform the testing through contractual arrangements, offsetting the laboratory's cost of obtaining and maintaining accreditation.

In addition, any new laboratory seeking approval of an application, that does not already have a physical presence in the Commonwealth would need to obtain zoning and, in some cases, building approvals, and construct or renovate existing property to be able to provide the testing services. A new laboratory would have to purchase equipment, hire staff and have staff trained. To comply with the final regulations, laboratories that choose to participate and seek approval may have to hire staff, have staff trained, or purchase equipment to do the required testing. If a laboratory does not wish to participate in the program, however, there is no requirement that it do so. These costs are voluntarily undertaken to take advantage of a potential business opportunity. This is no change from the temporary regulations that previously applied to laboratories wishing to participate in the Program.

### **Clinical Registrants/Academic Clinical Research Centers**

The final regulations, like the temporary regulations, imposed no cost for an entity to apply to become an ACRC. The final regulations make no changes to the costs associated with CRs. There is no cost to apply to become an approved CR. However, the act requires that approved CRs pay the same permit fees to obtain a grower/processor permit and a dispensary permit as growers/processors and dispensaries that applied for a permit under sections 601-616 of the act. (35 P.S. §§ 10231.601-616). Under the act, a grower/processor is required to pay an initial application fee of \$10,000, an initial permit fee of \$200,000, and a renewal fee of \$10,000. A dispensary is required to pay an initial application fee of \$5,000, an initial permit fee of \$30,000 for each location and a renewal fee of \$5,000 that covers all locations.

**(20) Provide a specific estimate of the costs and/or savings to the local governments associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.**

These regulations do not alter the statutory requirement that medical marijuana organizations comply with local zoning laws. If a new medical marijuana organization were to seek zoning approval from a local government, or to move location, or a laboratory sought to perform services, local governments would be required to review those applications pursuant to local zoning ordinances. This could potentially lead to revenue from application fees, as well as costs associated with review of and litigation challenging these zoning decisions. Presumably, however, zoning matters are built into budgets of local governments. There is no way to estimate this type of cost.

**(21) Provide a specific estimate of the costs and/or savings to the state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.**

The Department has incurred and would continue to incur costs incident to hiring staff to administer and regulate the Program as it goes forward. This includes reviewing, and approving, applications for approval of a clinical registrant, applications for approval of an academic clinical research center, applications for a grower/processor permit, applications for a dispensary permit, applications for identification cards; operating and maintaining a patient and caregiver registry; monitoring the applications of patients and caregivers; and operating and maintaining a seed-to-sale electronic tracking system. The Department has incurred and will continue to incur legal costs associated with appeals and regulatory compliance.

The Department's costs are part of the program operations costs listed in section 23(a) below.

**(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.**

The regulations include requirements for applications, forms, reporting and recordkeeping that are substantially similar to those included in the Department's temporary regulations, and that have been complied with by the regulatory community since the implementation of the Program:

### **Patients/Caregivers**

The regulations continue to require that, to be registered as a patient or caregiver and to receive an identification card, or to receive a medical marijuana patient authorization letter, an individual must complete an electronic application that is a part of the Department's patient and caregiver registry. The online patient registration form can be found here: <https://padohmmp.custhelp.com/app/adult-patient-registration/session/L3RpbWUvMTU1NTM1ODgzNy9nZW4vMTU1NTM1ODgzNy9zaWQvZlU3d3NZaHJQZEdwRmw4NmhJU2ZqOE9Qc2dubEJRQ1glN0VuMUR4bWZoSkxXZXhaclpR3ljOFJmRnZMVUNVT0VINHlZVko5SmRHUUXlTW1vQjFybXFIQIB5U1ZWx1l6TTdwaDdYWSU3RXYxcHdKZWtQOGxQbVE4TXR0QSUyMSUyMQ%3D%3D>.

The online caregiver registration form can be found here: <https://padohmmp.custhelp.com/app/adult-patient-caregiver-registration/session/L3RpbWUvMTU1NTM1ODgzNy9nZW4vMTU1NTM1ODgzNy9zaWQvZlU3d3NZaHJQZEdwRmw4NmhJU2ZqOE9Qc2dubEJRQ1glN0VuMUR4bWZoSkxXZXhaclpR3ljOFJmRnZMVUNVT0VINHlZVko5SmRHUUXlTW1vQjFybXFIQIB5U1ZWx1l6TTdwaDdYWSU3RXYxcHdKZWtQOGxQbVE4TXR0QSUyMSUyMQ%3D%3D>. In addition, a caregiver will still be required to obtain a background check by applying for a background check in accordance with the act.

After successfully registering, a medical marijuana patient or caregiver must then apply for a medical marijuana identification (ID) card. The application for the ID card is done through the same sign-on site as the application for registration listed above. The ID card is valid for one year from the time of issuance. The ID card or medical marijuana patient authorization letter must be renewed each year through a similar application process.

Further, the final regulations provide that patients and caregivers have an obligation to contact the Department upon the occurrence of any of the following: (1) a change in the cardholder's name or address; (2) the withdrawal of a patient certification by a practitioner; (3) a decision by a patient or the patient's legal guardian to discontinue the services of a caregiver; (4) a decision by a caregiver to no longer serve as a caregiver for a patient; and (5) a decision by a patient, the patient's legal guardian or a parent on behalf of a patient to discontinue obtaining medical treatment from the practitioner who issued the patient certification.

These requirements are the same as in the temporary regulations.

### **Practitioners/Medical Professionals**

Practitioners who will issue patient certifications and medical professionals who will work in dispensaries are also required to register and be approved by the Department. The online practitioner registration form can be found here:

<https://padohmmp.custhelp.com/app/register/session/L3RpbWUvMTU1NTM1ODgzNy9nZW4vMTU1NTM1ODgzNy9zaWQvZlU3d3NZaHJQZEdwRmw4NmhJU2ZqOE9Qc2dubEJRQ1glN0VuMUR4bWZoSkxXZXhaclpR3ljOFJmRnZMVUNVT0VINHlZVko5SmRHUUXlTW1vQjFybXFIQIB5U1ZWx1l6TTdwaDdYWSU3RXYxcHdKZWtQOGxQbVE4TXR0QSUyMSUyMQ%3D%3D>.

The online registration form for medical professionals can be found here:

<https://padohmmp.custhelp.com/app/medicalprof-register/session/L3RpbWUvMTU1NTM1ODgzNy9nZW4vMTU1NTM1ODgzNy9zaWQvZlU3d3NZaHJQZEdwRmw4NmhJU2ZqOE9Qc2dubEJRQ1glN0VuMUR4bWZoSkxXZXhaclpR3ljOFJmRnZMVUNVT0VINHlZVko5SmRHUUXlTW1vQjFybXFIQIB5U1ZWx1l6TTdwaDdYWSU3RXYxcHdKZWtQOGxQbVE4TXR0QSUyMSUyMQ%3D%3D>.



The final regulations require that registered practitioners provide the Department with the patient certification with original signature after certifying a patient, as well as notify the Department of any subsequent modifications to a patient certification. Further, practitioners must notify the Department in writing in the event of a revocation of patient certification.

Under the statute and the final regulations, both practitioners and medical professionals are required to complete a four-hour training course approved by the Department and notify the Department upon completion. An entity that wishes to conduct such a course for continuing education credits to a physician registering to become a practitioner with the Medical Marijuana Program or any medical professional who wishes to be employed by a dispensary may apply online. The online application for approval to provide such a training course can be found here:

<https://www.health.pa.gov/topics/Documents/Programs/Medical%20Marijuana/DOH%20-%20Application%20for%20Approval%20to%20Provide%20a%204-hour%20Training%20Course%20in%20the%20Medical%20Marijuana%20Program.pdf>.

### **Dispensaries**

A dispensary applicant is required to apply for a permit and, if awarded a permit, maintain the standards in the final regulations to retain the permit received. This requirement has not changed from the temporary regulations. The permit application and required attachments can be found online here: <https://www.health.pa.gov/topics/programs/Medical%20Marijuana/Pages/Dispensaries.aspx>.

To apply for a permit, a dispensary must have local zoning approval to obtain or construct a facility, including reviewing and approving building plans; to hire and train staff, including developing and revising employment policies and procedures and employment files; to create plans and procedures for the operation of the facility; and to obtain and maintain an electronic tracking system. The dispensary must track the medical marijuana products from the time the dispensary purchases the medical marijuana products from a grower/processor to the dispensing of the medical marijuana products to the patient or caregiver. These requirements are the same as in the temporary regulations.

Under the final regulations, the Department will manage the permit application and review process and evaluate dispensary permit applications. This process has not changed from the temporary regulations. The Department must still monitor compliance with the standards to determine that a dispensary should retain a permit, including reviewing complaint and inspection files. The Department has access to, and will monitor, the electronic tracking system to track medical marijuana products from the dispensaries' purchase of medical marijuana products from the grower/processor through the dispensing to a patient or caregiver in order to prevent diversion of medical marijuana products and to promote public safety. None of these requirements in the final regulations has substantially changed from the those in the temporary regulations.

The final regulations provide that a dispensary has an obligation to notify the Department: (1) of any complaint made to the dispensary by a patient, caregiver, or practitioner who reports an adverse event from using a medical marijuana product; (2) any delivery vehicle accidents, diversions, losses, or other reportable events that occur during the transportation of medical marijuana products; (3) any unresolved discrepancy in the transport manifest when receiving a delivery of medical marijuana and follow-up report; (4) any complaint made to the dispensary by a patient, caregiver, or practitioner who reports an adverse event from using medical marijuana products dispensed by the dispensary; and (5) that it is applying for approval as a clinical registrant, through the submission of a request to do so.

Further, the regulations provide that a dispensary must maintain: (1) a full and complete plan of operation, to be provided to the Department at the time the Department deems the dispensary operational; (2) a log of any temporarily authorized individuals that enter the facility maintained for four years and made available upon request to the Department or to State or local law enforcement; (3) an electronic tracking system proscribed by the Department; and (4) transport manifests.

Finally, under the final regulations, medical marijuana organizations are required to comply with local zoning laws. If a new medical marijuana organization were to seek zoning approval from a local government, or to move location, the medical marijuana organization could be required to submit applications and present plans to obtain those approvals. This requirement is statutory, reflected in the final regulations as it was in the temporary regulations, and has not changed from the time of the implementation of the Program.

### **Growers/Processors**

Under the final regulations, a potential grower/processor must apply for a permit and maintain standards to retain the permit received. The final regulations do not change the requirements found in the temporary regulations. This application and required attachments can be found online here: <https://www.health.pa.gov/topics/programs/Medical%20Marijuana/Pages/Growers-Processors.aspx>.

To apply for a permit, the proposed regulations require the grower/processor to have local zoning approval for a grower/processor facility. This is not a change from the temporary regulations, nor from the requirements of the act. In addition, a grower/processor has to obtain or construct a facility, including reviewing and approving building plans; to hire and train staff, including developing and revising employment policies and procedures and employment files; to create plans and procedures for the operation of the facility; and to obtain and maintain a seed-to-sale tracking system with a daily beginning and ending inventory of seeds, immature medical marijuana plants, marijuana plants, medical marijuana, medical marijuana products, and medical marijuana waste. The grower/processor is required to track other information in the system, including tax records, testing and results, point of sale records, including transport manifests, waste disposal records, and recall records. These requirements were included in the temporary regulations and are currently being followed by permitted grower/processors.

Under the final regulations, the Department will manage the permit application and process and review and evaluate grower/processor applications. This process has not changed from the temporary regulations. The Department must monitor compliance with the standards to determine that a grower/processor should retain a permit, including review of complaint and inspection files. The Department has access to, and will monitor, the seed-to-sale electronic tracking system to track medical marijuana from the beginning to the end of the growth, production, and sale process in order to prevent diversion of medical marijuana and to promote public safety. None of these requirements in the final regulations has substantially changed from the temporary regulations.

The final regulations provide that once a grower/processor is deemed operational, it must provide the Department with a full and complete plan of operation for review. Growers/processors must also maintain: (1) a log of any temporarily authorized individuals that enter its facility for four years, that must be made available upon request to the Department or to State or local law enforcement; (2) an inventory log; (3) a log of all actions taken to detect pests or pathogens, and the measures taken for control; (4) a written process to maintain the sanitation and operation of equipment that comes into contact with medical marijuana; (5) a log recording the maintenance, cleaning, and calibration of equipment; (6) a transport manifest for each delivery vehicle; (7) an electronic tracking system proscribed by the Department, and (8) a record of each application of pesticide, recorded and maintained

for four years. These final regulations make only minor revisions to the temporary regulations for the sake of clarity and consistency.

Further, the final regulations provide that a grower/processor also has a mandatory duty to notify the Department of: (1) any unresolved discrepancy in a transport manifest; (2) its rationale for taking no further action on a reported adverse event caused by medical marijuana or a medical marijuana product; (3) any voluntary recalls of medical marijuana, or medical marijuana products; (4) the discovery of a condition that poses a risk to public health and safety relating to the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products grown or processed at its facility; (5) any delivery vehicle accidents, diversions, losses, or other reportable events that occur during the transportation of medical marijuana products; and (6) that it has applied for approval as a clinical registrant.

The final regulations also require that all permittees submit permit renewal applications annually, which are attached as Exhibits A1 and A2, respectively. All permittees are required to request approval for promotional events and advertising and marketing materials; the required form is attached as Exhibit B. Affiliations with, and un-affiliations from, permittees must be reported using the forms attached as Exhibits C1 and C2, respectively. Permittees must request approval to sell products, instruments, or devices using the required form attached as Exhibit D. Grower/processors must request approval for all packaging and labeling using the required form attached as Exhibit E. Dispensaries are required apply for an additional location if the location was not identified in the initial permit application using the required form attached as Exhibit F. Permittees must request approval for of alteration of a facility using the required form attached as Exhibit G. Permittees must file an application to relocate an operational facility using the form attached as Exhibit H and, once approved, must submit plans for closing and relocating using the form attached as Exhibit I.

Finally, under the final regulations, medical marijuana organizations are required to comply with local zoning laws. If a new medical marijuana organization were to seek zoning approval from a local government, or to move location, the medical marijuana organization could be required to submit applications and present plans to obtain those approvals. This requirement is statutory, reflected in final regulations as it was in the temporary regulations, and has not changed from the time of implementation of the Program.

### **Laboratories**

The final regulations require that a laboratory apply for approval and maintain standards to retain the approval received. The application to become an approved laboratory can be found online here: <https://www.health.pa.gov/topics/programs/Medical%20Marijuana/Pages/Laboratories.aspx>. To apply for approval, a laboratory must have an accreditation from an accrediting body whose accreditation is accepted by the Department.

The final regulations require that an existing laboratory renovate its facilities, hire staff, and provide training to obtain approval to participate in the Program. To the extent that a new laboratory intends to start up within Pennsylvania to provide this testing, the laboratory may have to obtain local zoning approval for a laboratory. A new laboratory would have to obtain or construct a facility, including reviewing and approving building plans; to hire and train staff, including developing and revising employment policies and procedures and employment files; to create plans and procedures for the operation of the facility; and to purchase equipment.

Under the final regulations, to participate in the Program, a laboratory must have in place certain policies on reporting to the Department and into the electronic tracking system, so that the Department can review and ensure compliance with the act and regulations. These include: (1) sampling policies and procedures; (2) a quality assurance program to ensure that its measurements are accurate, errors are controlled, and devices used for testing are routinely and properly calibrated; and (4) copies of four years of the certificates of analysis performed on samples submitted by a grower/processor. These final regulations make only minor revisions to the temporary regulations for the sake of clarity and consistency.

Further, the final regulations provide that a laboratory must report to the Department: (1) the entry into a written contract with a grower/processor by providing a copy of the contract to the Department; (2) the laboratory's intention to re-test a sample or test another sample from the same harvest batch, harvest lot, or process lot that failed a test; and (3) via written report, the test results of a test sample provided to the laboratory by the Department. These requirements for record keeping and reporting in the final regulations make only minor revisions to the temporary regulations for the sake of clarity and consistency.

Finally, a laboratory wishing to participate in the Program, and seeking to build new facilities, could be required to obtain zoning approval from a local government, and to submit applications and to present plans to obtain those approvals.

#### **Clinical Registrants/Academic Clinical Research Centers**

The final regulations require that, to be an approved CR, an applicant must file an application for approval with the Department with all pertinent supporting documentation. The application to become a CR can be found online here:

<https://www.health.pa.gov/topics/programs/Medical%20Marijuana/Pages/Research.aspx>. This includes supplying an application to be a grower/processor or an application to be a dispensary, if the applicant lacks one or the other permit, or both, if the applicant lacks both permits. A CR must have both a grower/processor permit and a dispensary permit. If a CR applicant already holds a grower/processor permit or a dispensary permit, or both, the CR applicant must also submit a request for conversion of an existing permit to the Department. A CR must renew its approval annually by submitting a renewal application.

The final regulations provide that a CR must submit to the Department a written report of the findings of its research program or research study within 365 days of the completion of an approved research program or research study or within 30 days of publication in a peer-reviewed medical journal.

The final regulations provide that an accredited medical school must apply to the Department to be approved as a certified ACRC. The application to become an academic clinical research center can be found online here:

<https://www.health.pa.gov/topics/programs/Medical%20Marijuana/Pages/Research.aspx>.

#### **(22a) Are forms required for implementation of the regulation?**

Yes.

**(22b) If forms are required for implementation of the regulation, attach copies of the forms here. If your agency uses electronic forms, provide links to each form or a detailed description of the**

**information required to be reported. Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.**

Applicable forms are attached. Additional required forms are discussed and the links are provided in the answer to Question 22.

**(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.**

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
<b>SAVINGS:</b>	\$	\$	\$	\$	\$	\$
Regulated Community						
Local Government						
State Government						
Total Savings						
<b>COSTS:</b>						
Regulated Community <sup>2</sup>	2,580,000	620,000	620,000	620,000	620,000	620,000
Local Government <sup>3</sup>						
State Government						
Total Costs	2,580,000	620,000	620,000	620,000	620,000	620,000
<b>REVENUE LOSSES:</b>						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses						

**(23a) Provide the past three year expenditure history for programs affected by the regulation.**

Program	FY -3	FY -2	FY -1	Current FY
---------	-------	-------	-------	------------

<sup>2</sup> The Department expects to accept fees from approved CRs. The Department may register up to ten CRs. While there is no cost associated with being approved as a CR or an ACRC, a CR applicant must also obtain or have a permit to be a grower/processor and a dispensary, and there are application fees associated with those permits. A grower/processor is required to pay an initial application fee of \$10,000, an initial permit fee of \$200,000 and a renewal fee of \$10,000. A dispensary is required to pay an initial application fee of \$5,000, an initial permit fee of \$30,000 for each location (up to six per permit) and a renewal fee of \$5,000 that covers all locations. The calculation for the current FY includes only one CR dispensary location. Additional dispensary locations may be added at any time for a fee of \$30,000 for each dispensary location. This current FY calculation also includes permit renewal fees for 25 growers/processors and 50 dispensaries. Following FYs include permit renewal fees for 25 grower/processors and 50 dispensaries as well as the CR permit renewal fees. The calculation for the current FY assumes four additional dispensary locations.

<sup>3</sup> The Department is not able to quantify the additional cost to local governments of potential zoning cases and appeals.

	2018-2019	2019-2020	2020-2021	2021-2022
Medical Marijuana Program	10,559,000	11,179,000	31,552,000	32,079,000

**(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:**

- (a) An identification and estimate of the number of small businesses subject to the regulation.**
- (b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.**
- (c) A statement of probable effect on impacted small businesses.**
- (d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.**

(a) Due to the fact that the Medical Marijuana Program has only been operating in the Commonwealth since 2017, and that medical marijuana has not been legalized at the federal level, there are no Department of Labor standards and the Department cannot say with certainty whether any dispensary or grower/processor qualifies as a small business. Similar issues arise with respect to the practitioner groups providing certifications and laboratories doing testing. The following information is provided for the purposes of information and not to be taken as a declaration of an entity's status as a small business. The Department will respond to the questions assuming that some, if not all, of the medical marijuana organizations may be considered small businesses.

The final regulations apply to dispensaries, which is a type of business that has only legally existed in the Commonwealth since the act's inception. There are currently 56 dispensary permits issued by the Department. The Department does not maintain information on the numbers of employees each dispensary employs. In addition, the federal government does not recognize a dispensary as a legal entity, so information from the federal Department of Labor cannot be utilized to determine which dispensaries are small businesses. Dispensary applications must include information on diversity and each applicant has been scored on diversity.

The final regulations apply to growers/processors, which is also a type of business that has only legally existed in the Commonwealth since the act's inception. There are currently 35 grower/processor permits issued by the Department. Again, the Department does not keep information on the number of employee at each grower/processor, and there are no federal requirements that can be applied, because, as with dispensaries, the business activities conducted by growers/processors, while legal in Pennsylvania, are not recognized as legal by the federal government. Like dispensaries, grower/processor applications must include information on diversity, and each applicant has been scored on diversity.

The final regulations apply to laboratories approved by the Department to test medical marijuana and medical marijuana products by the Department. There are currently seven approved laboratories in the Commonwealth.

The final regulations also apply to nine CRs, each of which holds a grower/processor permit and a dispensary permit. Those types of entities are discussed above. The final regulations also apply to certified ACRCs, which are educational institutions with medical schools. As of July 28, 2022, there are

nine CRs and nine certified ACRCs in the Commonwealth. The Department may approve no more than ten CRs under the act.

(b) The final regulations make little change to the reporting, recordkeeping and other administrative requirements for the operation of the Program that are in the temporary regulations:

#### **Dispensaries**

The final regulations require, as do the temporary regulations, that a dispensary apply for and obtain a permit from the Department. A dispensary is required to hire and train staff, including developing and revising employment policies and procedures and employment files, and create plans and procedures for the operation of the facility. A dispensary is required to maintain and update an electronic tracking system for sales and dispensing of medical marijuana products. The dispensary must track the medical marijuana products from the time the dispensary purchases the medical marijuana products from a grower/processor to the dispensing of the medical marijuana products to the patient or caregiver.

Costs relating to these requirements are addressed in the response to Question 19.

#### **Grower/Processors**

The final regulations require, as do the temporary regulations, that growers/processors apply for and obtain a permit from the Department. A grower/processor is required to hire and train staff, including developing and revising employment policies and procedures and employment files, and to create plans and procedures for the operation of the facility. A grower/processor is required as part of its plans and procedures for operation to take medical marijuana waste disposal into account.

A grower/processor is required to enter information regarding a daily beginning and ending inventory of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products, and medical marijuana waste into the electronic seed-to-sale tracking system. The grower/processor must also track other information in the system, including tax records, testing and results, and point-of-sale records, including transport manifests, medical marijuana disposal records, and recall records. A grower/processor is required by law and regulation to educate its employees and principals on how to report information in the electronic seed-to-sale system.

Costs related to these requirements are addressed in the response to Question 19.

#### **Laboratories**

The final regulations require laboratories to apply for and obtain approval from the Department, as do the temporary regulations. A laboratory seeking Department approval is not charged a fee for the application for laboratory approval but is required to secure accreditation for medical marijuana testing from an accrediting body accepted by the Department. Accrediting bodies do charge a fee to a laboratory for obtaining and maintaining accreditation. These costs include maintaining the equipment to certain calibration standards, and auditing results. The Department expects that these costs will be offset through fees charged to growers/processors by laboratories for the testing required under the act.

The final regulations require a laboratory to hire and train staff, including developing and revising employment policies and procedures and employment files, and create plans and procedures for the operation of the facility and purchasing equipment and training staff.

#### **Clinical Registrants/Academic Clinical Research Centers**

Under the final regulations, to be an approved CR, an applicant must apply for approval with the Department. A CR applicant must apply for, or hold, a grower/processor permit and a dispensary permit. If a CR applicant already holds a grower/processor permit or a dispensary permit, or both, the CR applicant must also apply for conversion of an existing permit to the Department. A CR must renew its approval annually by submitting a renewal application. An accredited medical school must apply to the Department to be approved as a certified ACRC. Fees are listed in the Department's response to Question 19.

(c) The Department does not anticipate any impact to small businesses other than that already addressed in discussions of the impact on the regulated community.

(d) No alternative method to achieving the purpose of the final regulations was considered, as the statute requires that the Department to first issue temporary regulations necessary to achieve the act's purpose within a particular time frame, that those temporary regulations expire within two years of publication in the *Pennsylvania Bulletin*, and that all future regulations would be required to be promulgated through the regulatory process set out in law. Regulations are necessary for compliance with, and enforcement of, the act, as is discussed in the response to Question 10.

**(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.**

The final regulations include provisions to allow for patients who may have mobility issues, or who, for some other reason, cannot obtain an ID card, to be issued a medical marijuana patient authorization letter. The Department has also reiterated in the final regulations the statutory requirements allowing for fee reduction if an applicant demonstrates financial hardship. Beyond that, the Department has not developed any other special provisions.

**(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.**

No other alternative provisions were considered.

**(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:**

- a) The establishment of less stringent compliance or reporting requirements for small businesses;
- b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
- c) The consolidation or simplification of compliance or reporting requirements for small businesses;
- d) The establishment of performance standards for small businesses to replace design or operational standards required in the regulation; and
- e) The exemption of small businesses from all or any part of the requirements contained in the regulation.



Due to the fact that the Medical Marijuana Program has only been operating in the Commonwealth since 2017, and the fact that medical marijuana has not been legalized at the federal level, so that no Department of Labor standards apply to medical marijuana organizations, the Department cannot say with certainty whether any dispensary, grower/processor, or lab qualifies as a small business. Whether or not any of these regulated entities are small businesses, however, the Department has not and would not consider less stringent requirements than those offered in these final regulations. The Department's need for strict oversight is driven by its responsibility to ensure the safety, security, and effectiveness of the Program.

**(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.**

No data has been considered.

**(29) Include a schedule for review of the regulation including:**

- A. The length of the public comment period: \_\_\_\_\_
- B. The date or dates on which any public meetings or hearings will be held: \_\_\_\_\_
- C. The expected date of delivery of the final-form regulation: \_\_\_\_\_
- D. The expected effective date of the final-form regulation: \_\_\_\_\_
- E. The expected date by which compliance with the final-form regulation will be required: \_\_\_\_\_
- F. The expected date by which required permits, licenses or other approvals must be obtained: \_\_\_\_\_

A. The agency accepted public comment for 30 days after publication of the proposed rulemaking in the *Pennsylvania Bulletin*.

B. Given that stakeholders had input on the temporary and proposed regulations, and these final regulations are substantially similar, there are no expected public meetings or hearings.

C. The Department expects to publish the final-form rulemaking in sufficient time for the final-form rulemaking to become effective prior to the expiration of the current temporary regulations.

D. The Department expects that the final-form rulemaking will be effective on the date of publication.

E. Compliance will be required on the date of publication of the final-form rulemaking.

F. No deadlines are required for permits, licenses, or other approvals.

**(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.**

The Department continually reviews the validity and efficacy of its regulations and will do so with these regulations as well.

## EXHIBIT A1

## Office of Medical Marijuana Grower/Processor: Permit Renewal Application 28 Pa. Code § 1141.36

Pursuant to 28 Pa. Code § 1141.36, a medical marijuana organization wishing to renew its permit shall submit a Permit Renewal Application with the applicable fee to the Department prior to the current permit's expiration.

If the Department determines that a Permit Renewal Application is complete but lacking sufficient information upon which to make a determination, the Department will notify the medical marijuana organization in writing of the factors that require additional information and documentation. The medical marijuana organization shall have 30 days from the mailing date of the notice to provide the requested information and documentation to the Department. A medical marijuana organization's failure to provide the requested information to the Department by the deadline may be grounds for denial of the Permit Renewal Application.

### Submission of Permit Renewal Application

All sections of the Permit Renewal Application must be completed. All sections must be saved as a PDF file on a single USB drive in accordance with the following file naming format: [Name on permit]\_[Name of document]\_Permit Renewal Application.

Send the Permit Renewal Application package, along with the required fee, to the following address:

Office of Medical Marijuana  
Permit Renewal Application  
Department of Health  
Room 628, Health and Welfare Building  
625 Forster Street  
Harrisburg, PA 17120

Please ensure the Permit Renewal Application is properly signed and dated. A signature may be scanned and provided electronically in a PDF file.

### Fees

Pursuant to 28 Pa. Code § 1141.28, the following fee must be submitted with the Permit Renewal Application in the form of a certified check or money order made payable to "Commonwealth of Pennsylvania." The permit renewal fee must be enclosed in a separate envelope within the Permit Renewal Application package. The permit renewal fee for the Permit Renewal Application is refundable if the renewal permit is not granted.

Permit Renewal Fee for a grower/processor permit: \$10,000

### Permit Information

Permit Name:	Permit Number:	Submission Date:
Business Primary Contact Name:	Business Primary Contact Phone Number:	Business Primary Contact Email Address:

### Primary Contact Information

Name:		
Address:		
City:	State:	Zip Code:
Phone:	Fax:	Email:

### Facility Information

Name of Facility:	
Street Address:	
City:	Zip Code:
Municipality:	County:
Facility Primary Contact Name:	Facility Primary Contact Email:
Facility Primary Contact Phone:	Primary Contact role at Facility:

### Documentation

Please submit the following:

- ☐ A narrative of the medical marijuana organization's history in complying with the Medical Marijuana Act.
- ☐ A narrative concerning the medical marijuana organization's ability to carry on the activity for which the permit was issued. The statement should include information regarding shortages of medical marijuana product or waitlists relevant to the medical marijuana organization's operation that occurred during the 12 months prior to the date the Permit Renewal Application was submitted.
- ☐ A copy of current, non-expired proof of comprehensive liability insurance coverage and workers' compensation insurance coverage for the permitted location during the renewal period.
- ☐ Information regarding any charge, or any initiated, pending or concluded investigation, during the prior renewal period by any governmental or administrative agency with respect to:
  - Any incident involving the theft, loss or possible diversion of medical marijuana by the medical marijuana organization or from the medical marijuana organization's facility.
  - Compliance by the medical marijuana organization with the laws of the Commonwealth with respect to any substance in section 4 of The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. § 780-104).
- ☐ **Diversity Plan:** Report on efforts to meet the diversity goals of the act and the effectiveness of the medical marijuana organization's diversity plan. The report must include information regarding the following, as applicable:
  - (1) Representation of diverse participants in the medical marijuana organization's workforce.
  - (2) Efforts to reach out to and recruit diverse participants for employment, including for executive and managerial positions.
  - (3) Employee retention efforts.
  - (4) A list of all contracts entered into or transactions conducted by the medical marijuana organization for goods or services with diverse groups.

### Attestations

- ☐ I acknowledge that all current principals, financial backers, operators and employees listed in the Permit Renewal Application have (1) received approval through the Department's affiliation process and (2) completed the required two-hour training required by 28 Pa. Code § 1141.48.
- ☐ I acknowledge that the Department is in possession of the location's most updated Plan of Operation, that a copy of the Plan of Operation is kept onsite at the facility, and that the medical marijuana organization follows its established Plan of Operation.
- ☐ I acknowledge that the medical marijuana organization complies with the Medical Marijuana Act, its regulations, and all other laws of the Commonwealth.

☐ I acknowledge that a false statement made by me in this Permit Renewal Application is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation).

---

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Title in medical marijuana organization

Questions about this application may be submitted to: [RA-DHMMRCompliance@pa.gov](mailto:RA-DHMMRCompliance@pa.gov)

## EXHIBIT A2

**Office of Medical Marijuana  
Dispensary: Permit Renewal Application  
28 Pa. Code § 1141.32 & 1141.36**

Pursuant to 28 Pa. Code § 1141.36, a medical marijuana organization wishing to renew its permit shall submit a Permit Renewal Application with the applicable fee to the Department prior to the current permit's expiration.

If the Department determines that a Permit Renewal Application is complete but lacking sufficient information upon which to make a determination, the Department will notify the medical marijuana organization in writing of the factors that require additional information and documentation. The medical marijuana organization shall have 30 days from the mailing date of the notice to provide the requested information and documentation to the Department. A medical marijuana organization's failure to provide the requested information to the Department by the deadline may be grounds for denial of the Permit Renewal Application.

**Submission of Permit Renewal Application**

All sections of the Permit Renewal Application must be completed. All sections must be saved as a PDF file on a single USB drive in accordance with the following file naming format: [Name on permit]\_[Name of document]\_Permit Renewal Application.

Send the Permit Renewal Application package, along with the required fee, to the following address:

Office of Medical Marijuana  
Permit Renewal Application  
Department of Health  
Room 628, Health and Welfare Building  
625 Forster Street  
Harrisburg, PA 17120

Please ensure the Permit Renewal Application is properly signed and dated. A signature may be scanned and provided electronically in a PDF file.

**Fees**

Pursuant to 28 Pa. Code § 1141.28, the following fee must be submitted with the Permit Renewal Application in the form of a certified check or money order made payable to "Commonwealth of Pennsylvania." The permit renewal fee must be enclosed in a separate envelope within the Permit Renewal Application package. The permit renewal fee for the Permit Renewal Application is refundable if the renewal permit is not granted.

Permit Renewal Fee for a dispensary permit: \$5,000

**Permit Information**

Permit Name:	Permit Number:	Submission Date:
Business Primary Contact Name:	Business Primary Contact Phone Number:	Business Primary Contact Email Address:



### Facility Information

Name of Primary Facility:	
Street Address:	
City:	Zip Code:
Municipality:	County:
Facility Primary Contact Name:	Facility Primary Contact Email:
Facility Primary Contact Phone:	Primary Contact role at Facility:

Name of Second Facility (if applicable):	
Street Address:	
City:	Zip Code:
Municipality:	County:
Facility Primary Contact Name:	Facility Primary Contact Email:
Facility Primary Contact Phone:	Primary Contact role at Facility:

Name of Third Facility (if applicable):	
Street Address:	
City:	Zip Code:
Municipality:	County:
Facility Primary Contact Name:	Facility Primary Contact Email:
Facility Primary Contact Phone:	Primary Contact role at Facility:

### Documentation

Please submit the following:

- ☐ A narrative of the medical marijuana organization's history in complying with the Medical Marijuana Act.
- ☐ A narrative concerning the medical marijuana organization's ability to carry on the activity for which the permit was issued.
- ☐ A copy of current, non-expired proof of comprehensive liability insurance coverage and workers' compensation insurance coverage for the permitted location during the renewal period.
- ☐ Information regarding any charge, or any initiated, pending or concluded investigation, during the prior renewal period by any governmental or administrative agency with respect to:
  - Any incident involving the theft, loss or possible diversion of medical marijuana by the medical marijuana organization or from the medical marijuana organization's facility.
  - Compliance by the medical marijuana organization with the laws of the Commonwealth with respect to any substance in section 4 of The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. § 780-104).

- ☐ **Diversity Plan (§ 1141.32):** Report on efforts to meet the diversity goals of the act and the effectiveness of the medical marijuana organization's diversity plan. The report must include information regarding the following, as applicable:
- (1) Representation of diverse participants in the medical marijuana organization's workforce.
  - (2) Efforts to reach out to and recruit diverse participants for employment, including for executive and managerial positions.
  - (3) Employee retention efforts.
  - (4) A list of all contracts entered into or transactions conducted by the medical marijuana organization for goods or services with diverse groups.

**Attestations**

☐ I acknowledge that the medical marijuana organization complies with the Medical Marijuana Act, its regulations, and all other laws of the Commonwealth.

☐ I acknowledge that a false statement made by me in this Permit Renewal Application is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation).

\_\_\_\_\_  
Signature:

\_\_\_\_\_  
Date:

\_\_\_\_\_  
Printed Name:

\_\_\_\_\_  
Title in Medical Marijuana Organization

Questions about this application may be submitted to: [RA-DHMMRCompliance@pa.gov](mailto:RA-DHMMRCompliance@pa.gov)

## EXHIBIT B

**Office of Medical Marijuana**  
**Request for Approval: Promotional, Advertising or Marketing Materials**  
**28 Pa. Code § 1141.50**

Pursuant to regulation § 1141.50 (relating to advertising by a medical marijuana organization), promotional, advertising and marketing materials shall be approved by the Department prior to their use.

To request approval for promotional, advertising or marketing materials, submit 1) this form, 2) a Request Form Cover Page, and 3) all additional documentation listed below. A request will be deemed incomplete, and not considered, until all required documentation has been submitted.

**Submitting your Request**

All documents must be saved as a PDF file with the following file naming format: [name on permit]\_[name of document]. Files should be submitted in a singular correspondence via email to [RA-DHMMRCompliance@pa.gov](mailto:RA-DHMMRCompliance@pa.gov).

Please ensure the application is properly signed and dated. A signature may be scanned and provided electronically in a PDF file.

**Documentation**

Please submit the following:

- All materials that the medical marijuana organization is requesting to be approved by the Office of Medical Marijuana
- A description of the event or events in which the medical marijuana organization will be using the attached materials
- A description of the audience that will be receiving the promotional, advertising or marketing material

**Additional Attestation**

I acknowledge that none of the materials attached to this form will be used by the Medical Marijuana Organization to provide to patients, caregivers, practitioners, medical professionals or any member of the general public, either free or for sale, at the facility or site of the medical marijuana organization.

Permit ID Number: \_\_\_\_\_

\_\_\_\_\_  
Signature Date

\_\_\_\_\_  
Name Role in MMO

For Internal Use Only Request ID # _____ Date Submitted _____ Intake Initials _____
--

## EXHIBIT C1

**OFFICE OF MEDICAL MARIJUANA**  
**REPORTING INDIVIDUALS AFFILIATED**  
**WITH A MEDICAL MARIJUANA ORGANIZATION**

**Note:** This form must be submitted by a medical marijuana organization for each financial backer, principal, operator and employee listed in the initial permit application and for each financial backer, principal, operator and employee added by the organization after the submission of the initial permit application. After each financial backer, principal, operator and employee submits fingerprints for a FBI criminal background check, the medical marijuana organization shall submit this form and other required documentation, by email, to the Department, at [RA-DHMMOAFILIATIONS@pa.gov](mailto:RA-DHMMOAFILIATIONS@pa.gov). To complete the FBI criminal background check process, each principal, financial backer, operator and employee shall also submit by email to the Department, at [RA-DHMMOAFILIATIONS@pa.gov](mailto:RA-DHMMOAFILIATIONS@pa.gov), the original State criminal history report received from the Pennsylvania State Police. If the principal, financial backer, operator or employee resides outside of Pennsylvania, they must submit that state's background check results.

Please follow the attached instructions to complete this form and submit the documents at the bottom of this page.

<b>Medical Marijuana Organization (MMO)</b>	
Name of MMO:	Submission Date:
Permit Number:	Region:
Primary Contact:	Phone Number:
Entity Type: <input type="checkbox"/> Public <input type="checkbox"/> Private	
<b>Classification Information</b>	
The individual listed in this form is one of the following (check all the following that apply):	
<input type="checkbox"/> Financial Backer <input type="checkbox"/> Principal <input type="checkbox"/> Operator <input type="checkbox"/> Employee	
<input type="checkbox"/> Medical Professional <input type="checkbox"/> Owner of Securities <input type="checkbox"/> Owner of 5% or more of entity	
<b>Individual's Information</b>	
Name:	
Mailing Address:	Email address:
	Telephone Number:
	Cell Phone Number:
Please select individual's necessary MJ Freeway Access:	
<input type="checkbox"/> No Access <input type="checkbox"/> General Access <input type="checkbox"/> Admin Access	
<input type="checkbox"/> <b>Proof of employee fingerprint submission attached</b>	
<b>Attestation</b>	
Employees may work in a supervised capacity pending completion of their background check. If unable to be affiliated, the employee must be immediately terminated. 35 P.S. § 10231.602(a)(4). By checking the box below, I acknowledge compliance with this statement. <input type="checkbox"/>	
<b>Attestation</b>	
I acknowledge that I am not using this form to effectuate the transfer or sale of a medical marijuana permit from the entity to which the permit was initially issued, as permits are nontransferable pursuant to 35 P.S. § 10231.603(b). I further acknowledge that a false statement made by me in this document is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation).	
Signature _____	Date _____
Printed Name _____	Title in MMO _____
<b>Submit this form via email with required attachments to: <a href="mailto:RA-DHMMOAFILIATIONS@pa.gov">RA-DHMMOAFILIATIONS@pa.gov</a></b>	

**Instructions:**

All documents must be submitted via email to [RA-DHMMOAFILIATIONS@pa.gov](mailto:RA-DHMMOAFILIATIONS@pa.gov).

When submitting this form and the required documents, the email subject line should use the following naming format: *Permittee Number\_Permittee Name\_Affiliation* to ensure processing for the correct entity. The email may only include documentation for the one permittee listed in the subject line. Any email containing several permittees will not be accepted or processed.

Please submit the following in one email:

1. Completed Form - REPORTING INDIVIDUALS AFFILIATED WITH A MEDICAL MARIJUANA ORGANIZATION
2. Proof of employee fingerprint submission (receipt)
3. State background check results.
  - a. If the individual resides outside of Pennsylvania, the appropriate state background check must be submitted.

Failure to follow these instructions will result in the return of the documents for correction and delay the processing of your affiliations.

Hardcopy documents mailed, shipped, or delivered will not be accepted, processed or approved, unless specifically requested.

**Medical Marijuana Organization (MMO)**

**Name of MMO:** the Permit Name issued by the Department of Health, not the DBA or Management Services Agreement name.

**Permit Number:** include only **one** permit number per Affiliation Form. If the employee is to be affiliated to several permits, an Affiliation Form is required for each permit and should be submitted via email with all required documents attached.

**Primary Contact:** name of person who completes this form and can provide information on the contents of this form, if needed.

**Entity Type:** select the correct box if the entity is publicly owned or privately owned.

**Classification Information**

Select the correct box(s) to indicate if the individual is a Financial Backer, Principal, Operator or Employee. Further, if the individual is a Medical Professional, select the Medical Professional box. The individual will not be processed as a Medical Professional unless this box is selected.

If the individual owns securities, select that box. Furthermore, if they own 5% or more of the entity, please check that box.

**Please note:** If you need a Medical Professional's affiliation expedited to allow them to consult with patients, the email subject line should use the following naming format: *Permittee Number\_Permittee Name\_Affiliation\_MED PROF URGENT* and the request will be processed accordingly.

If the classification is Financial Backer, Principal, or Operator, proof of completion of the 2-hour mandatory training must be attached to this form.

If the classification is Employee, the employee has 90 days from hire to complete the training. Proof of completion of the 2-hour training must be kept at the employment location and made available upon request during an inspection.

### **Individual's Information**

**Name:** The Legal name of the individual. Nicknames, alias' or shortened versions of the legal name is not acceptable. This should match the legal name on the FBI and state background checks.

**Mailing Address:** This is required for every individual.

**MJ Freeway Access:** Please specify if the individual needs access to MJ Freeway. Not all employees require access, and it should only be granted to those who require it. General Access is appropriate for all those wishing to access and transact in the system's "normal" operational functions. Admin Access should only be granted to select individual(s) who you wish to name as your custodian of the MJ Freeway system.

**Proof of employee fingerprint submission attached:** The receipt from the location where the individual submitted fingerprints is acceptable. If the receipt is not attached to the email, do not select this box. Enrollment to be fingerprinted is not an acceptable proof of employee fingerprint submission.

**Please Note:** If the individual's fingerprints are rejected due to poor quality of prints, the individual has 30 days to be reprinted.

**Attestation:** Acknowledge by selecting the box, sign and date. Failure to acknowledge the above form will result in the return of the documents for correction and delay the processing of your affiliations.



## EXHIBIT C2

**OFFICE OF MEDICAL MARIJUANA**  
**REPORTING INDIVIDUALS NO LONGER AFFILIATED**  
**WITH A MEDICAL MARIJUANA ORGANIZATION**

**Note:** This form must be submitted by a medical marijuana organization for each financial backer, principal, operator and employee listed in the initial permit application and for each financial backer, principal, operator and employee who is no longer affiliated with the medical marijuana organization. A medical marijuana organization shall submit this form electronically to the Office of Medical Marijuana.

Medical Marijuana Organization (MMO)	
Name of MMO:	Submission Date:
Permit Number:	Region:
Primary Contact:	Phone Number:
Classification Information	
The individual listed in this form is one of the following (check all the following that apply):	
<input type="checkbox"/> Financial Backer <input type="checkbox"/> Principal <input type="checkbox"/> Operator <input type="checkbox"/> Employee	
Individual's Information	
Name:	
Mailing Address:	Email address:
	Telephone Number:
	Cell Phone Number:
Job Title:	
Date Individual Left Organization:	
Attestation	
<p>I acknowledge that I am not using this form to effectuate the transfer or sale of a medical marijuana permit from the entity to which the permit was initially issued, as permits are nontransferable pursuant to 35 P.S. § 10231.603(b). I further acknowledge a false statement made by me in this document is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation).</p>	
Signature	Date
Printed Name	Title in MMO
Submit this document electronically to : <a href="mailto:tabosack@pa.gov">tabosack@pa.gov</a>	

## EXHIBIT D

## Office of Medical Marijuana

### Request for Approval: Medical Marijuana Product, Instrument or Device

### 28 Pa. Code § 1151.28

Pursuant to 28 Pa. Code § 1151.28, (relating to the forms of medical marijuana a grower/processor may process for dispensing) any medical marijuana product, instrument, or device manufactured, produced, or assembled must be approved by the Department.

To request approval for a medical marijuana product, instrument, or device, submit 1) this form, 2) a Request Form Cover Page, and 3) all additional documentation listed below. **A request will be deemed incomplete, and not considered, until all required documentation has been submitted.**

#### Submitting your Request

All documents must be saved as a PDF file with the following file naming format: [name on permit]\_[name of document]. Files should be submitted in a singular correspondence via email to [RA-DHMMRCompliance@pa.gov](mailto:RA-DHMMRCompliance@pa.gov).

Please ensure the application is properly signed and dated. A signature may be scanned and provided electronically in a PDF file.

#### Documentation

Please submit the following:

- 1) The name of the product, instrument, or device for which the permittee is requesting approval by the Office of Medical Marijuana. You may also submit physical instruments or devices to the Office of Medical Marijuana, 625 Forster St., Harrisburg, PA 17120, for consideration.
- 2) The medical purpose for the product, instrument, or device.
- 3) The process for creating the product, instrument, or device (including if it necessitates the purchasing of additional manufacturing tools).
- 4) A product description, including the intended use of the product, instrument, or device by a patient.
- 5) Detailed information regarding the formulation of the final form product to include the name and amount of each additional active ingredient or material used in the product that alters the dosage level, color, appearance, smell, taste, effect or weight of the final form product.
- 6) The Material Safety Data Sheet for each additional active ingredient or material used in the final form product that alters the dosage level, color, appearance, smell, taste, effect or weight of the final form product.
- 7) A picture, or link to a website with a picture, of the product, instrument, or device.

#### Additional Attestation

I acknowledge that none of the products, instruments or devices discussed in this form and any attachments will be used by the medical marijuana organization outside of the specific use listed above.

Permit ID Number: \_\_\_\_\_

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name

\_\_\_\_\_  
Role in MMO

**Complete the following for any product containing additional active ingredients or materials that alters the dosage level, color, appearance, smell, taste, effect, or weight of the medical marijuana. Excipients must be pharmaceutical grade, unless otherwise approved by the Department. 28 Pa. Code §§ 1141.21 and 1151.27(f); 35 P.S. § 10231.702(a)(5). Attach additional pages if necessary. Complete all sections.**

- List the name and amount of each additional active ingredient or material used in the final form product. You may not simply list the name of an externally sourced product. You must list each ingredient contained in that externally sourced product.
- Utilize the following links to determine whether each additional active ingredient or material used in the final form product is permitted by the United States Food and Drug Administration. 35 P.S. §§ 10231.102(3)(i) and 10231.702(a)(5):

[FDA Database of Inactive Ingredients](#)

[SCOGS \(Select Committee on GRAS Substances\)](#)

[21 CFR 101.22 Subpart B--Specific Food Labeling Requirements](#)

[eCFR :: 21 CFR 172.515 -- Synthetic flavoring substances and adjuvants.](#)

[eCFR :: 21 CFR 182.60 -- Synthetic flavoring substances and adjuvants.](#)

- If the additional active ingredient or material is permitted by the FDA, provide the following information for that additional active ingredient or material:

Route of Administration:

Dosage Form:

CAS Number:

UNII Number:

Maximum Potency per unit dose:

- Indicate whether the additional active ingredient or material constitutes a known hazard such as Diacetyl, CAS number 431-03-8 and pentanedione, CAS number 600-14-6. 35 P.S. § 10231.702(a)(5). Include the Material Safety Data Sheet for each additional active ingredient or material used in the final form product that alters the dosage level, color, appearance, smell, taste, effect, or weight of the final form product.

- Utilizing the following link, indicate whether there are any known drug interactions for each additional active ingredient or material used in the final form product:

[Drug Interactions Checker](#)

- Describe why each additional added ingredient or material used in the final form product is necessary, including justification for its intended medical use.

#### Additional Attestation

I acknowledge that all information provided on this form and on any attachment to it is true and correct and that there are no intentional misrepresentations, falsifications or omissions. I acknowledge that any intentionally false, misleading or omitted information is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation). I understand that any knowingly false or intentionally misleading statement or intentionally omitted information in this document and attachment(s) could result in withdrawal of any approval resulting from this submission and, additionally, could constitute grounds for action under 28 Pa. code 1141.47.

Permit ID Number: \_\_\_\_\_

\_\_\_\_\_  
Signature Date

\_\_\_\_\_  
Name Role in MMO

For Internal Use Only Request ID # _____ Date Submitted _____ Intake Initials _____
--

## EXHIBIT E

**Office of Medical Marijuana**  
**Request for Approval: Packaging and Labeling of Medical Marijuana**  
**Products**  
**28 Pa. Code § 1151.34**

Pursuant to 28 Pa. Code § 1151.34 (Packaging and labeling of medical marijuana products), a grower/processor shall obtain the prior written approval of the Department of the content of any label to be affixed to a medical marijuana product package.

To request approval for any new or modified packaging and labeling submit 1) this form, 2) a Request Form Cover Page, and 3) all additional documentation listed below. A request will be deemed incomplete, and not considered, until all required documentation has been submitted.

**Section 1: Submitting your Request**

All documents must be saved as a PDF file with the following file naming format: [name on permit]\_[name of document]. Files should be submitted in a singular correspondence via email to [RA-DMJMRC@pa.gov](mailto:RA-DMJMRC@pa.gov).

Please ensure the application is properly signed and dated. A signature may be scanned and provided electronically in a PDF file.

**Section 2: Requirements – Packaging**

Signing and submitting this form attests that the new or modified packaging minimizes exposure to oxygen and is:

- (1) Child-resistant.
- (2) Tamper-proof or tamper-evident.
- (3) Light-resistant or opaque, or both.
- (4) Resealable.

**Section 3: Requirements – Labels**

Signing and submitting this form attests that the new or modified label(s) are:

- (1) Easily readable.
- (2) Made of weather-resistant and tamper-resistant materials.
- (3) Conspicuously placed on the package.

**Section 4: Requested Documentation for Requirements – Labels**

Please include a photograph(s) of the package(s) and label(s) identifying the following required items.

- (4) Name, address, and permit number of the grower/processor.
- (5) Form, quantity, and weight of medical marijuana included in the package.
- (6) Number of individual doses contained within the package and the species and percentage of THC and CBD.
- (7) An identifier that is unique to a particular harvest batch of medical marijuana, including the number assigned to each harvest lot or process lot in the harvest batch.
- (8) Date the medical marijuana product was packaged.
- (9) Employee identification number of the employee preparing the package and packaging the medical marijuana product.
- (10) Employee identification number of the employee shipping the package, if different than the employee described in item (9).
- (11) Name and address of the dispensary to which the package is to be sold.
- (12) Date of expiration of the medical marijuana product.
- (13) Instructions for proper storage of the medical marijuana product in the package.
- (14) A warning stating: This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the practitioner who issued the certification and, in the case of



breastfeeding, the infant's pediatrician. This product might impair the ability to drive or operate heavy machinery. Keep out of reach of children.

- (15) A warning that the medical marijuana product must be kept in the original container in which it was dispensed.  
(16) A warning that the unauthorized use is unlawful and will subject the purchaser to criminal penalties.

#### Section 5: Restrictions - Labels

Signing and submitting this form attests that the new or modified label(s) do not bear:

- (1) Any resemblance to the trademarked, characteristic, or product-specialized packaging of any commercially available food or beverage product.
- (2) Any statement, artwork or design that could reasonably lead an individual to believe that the package contains anything other than medical marijuana.
- (3) Any seal, flag, crest, coat of arms or other insignia that could reasonably mislead an individual to believe that the product has been endorsed, manufactured or approved for use by any state, county or municipality or any agency thereof.
- (4) Any cartoon, color scheme, image, graphic or feature that might make the package attractive to children.

#### Additional Attestation

I acknowledge the packaging and labeling submitted in this form adhere to the requirements of 28 Pa. Code § 1151.34 (Packaging and labeling of medical marijuana products).

Permit ID Number: \_\_\_\_\_

\_\_\_\_\_  
Signature Date

\_\_\_\_\_  
Name Role in MMO

For Internal Use Only

Request ID # \_\_\_\_\_

Date Submitted \_\_\_\_\_

Intake Initials \_\_\_\_\_

## EXHIBIT F

## Office of Medical Marijuana Request for Approval: Additional Dispensary Location 28 Pa. Code § 1161.40

An applicant for a dispensary permit shall include a primary dispensary facility location and may include up to two additional dispensary facility locations, in its initial permit application. Pursuant to regulation § 1161.40, a permittee may file an application for additional dispensary facility locations at a later date.

A dispensary may not begin operations at an additional location until the Department approves the application for an additional dispensary location.

To request approval for an additional dispensary location please submit 1) this form, 2) the requested fees 3) a Request Form Cover Page, and 4) all additional documentation as listed below. A request will be deemed incomplete, and not considered, until all required documentation and fees has been submitted.

### Submitting your Request

All documents must be saved as a PDF file with the following file naming format: [name on permit] [name of document]. Files should be submitted in a singular correspondence if via email to [RA-DIIMMRCompliance@pa.gov](mailto:RA-DIIMMRCompliance@pa.gov) OR submitted to the following address on a single USB drive if via mail:

Office of Medical Marijuana - Request Form  
Department of Health  
Room 628 Health and Welfare Building  
625 Forster Street  
Harrisburg, PA 17120

Please ensure the application is properly signed and dated. A signature may be scanned and provided electronically in a PDF file.

### Fees

The following fees must be submitted in the form of certified check or money order made out to "Commonwealth of Pennsylvania", enclosed in two separate envelopes within the request package. The Request for Approval fee is non-refundable. The Permit Fee will be refunded if the request for an additional dispensary location is not approved.

Request for Approval Fee: Additional dispensary location: \$5,000

Permit Fee for the dispensary location: \$30,000

### Proposed Facility Information

Name of Proposed Facility:	
Street Address:	
City:	Zip Code:
Municipality:	County:

### Documentation

Please submit the following:

- A signed statement that the applicant has performed a search of available public records and the proposed dispensary location is not within 1,000 feet of the property line of a public, private or parochial school or a day-care center.
- A copy of the initial application filed with the Department for the permit with updated information provided for the following sections:

<input type="checkbox"/>	Section 1: Application Name, Address and Contact Information	Provide any changes to the applicant's name, address and contact information since the initial application for a permit was filed with the Department.
<input type="checkbox"/>	Section 2: Dispensary Information	Indicate the existing facility location authorized by the permit and provide a description of the proposed location including public access to the dispensary location.
<input type="checkbox"/>	Section 4, Part C: Principals, Financial Backers, Operators and Employees	Attach a list of any principals, financial backers, operators, and employees that have been added to medical marijuana organization since the issuance of the permit by the Department.
<input type="checkbox"/>	Section 8, Part D: Operational Timetable	Attach a timetable for the proposed location indicating the steps that will be taken for the proposed location to become operational within 6-months from the date the proposed location is approved by the Department.
<input type="checkbox"/>	Section 10, Part D: Security and Surveillance	Attach a statement outlining the security and surveillance methods and procedures that will be implemented at the proposed location.
<input type="checkbox"/>	Section 16, Part D: Sanitation and Safety	Attach a statement of the intended sanitation and safety measures that will be implemented at the proposed location.
<input type="checkbox"/>	Section 23 Part F: Community Impact	Attach a statement describing the positive impact the proposed location will have on the community and patients.
<input type="checkbox"/>	Attachment C: Property Title, Lease or Option to Acquire Property Location	Attach copies of any documentation for the proposed location showing an ownership interest in the proposed location.
<input type="checkbox"/>	Attachment D: Site and Facility Plan	Based on the instructions, attach copies of the site plan for the proposed location. Include any documentation provided by the local municipality showing the dispensary location complies with local zoning requirements and can operate at the proposed location as a dispensary.

#### Additional Attestation

I hereby affirm that all other sections of the initial applications remain unchanged and will apply to the proposed location.

Permit ID Number: \_\_\_\_\_

\_\_\_\_\_  
Signature Date

\_\_\_\_\_  
Name Role in MMO

For Internal Use Only

Request ID# \_\_\_\_\_

Date Submitted \_\_\_\_\_

Intake Initials \_\_\_\_\_

## EXHIBIT G

**Office of Medical Marijuana  
Request for Approval: Facility Alteration  
28 Pa. Code § 1141.41**

Pursuant to regulation § 1141.41, a medical marijuana organization shall request approval to make any of the following alterations to the facility for which its permit was issued:

- An increase or decrease in the total square footage of the facility
- The sealing off, creation of or relocation of a common entryway, doorway, passage or other means of public ingress or egress when the common entryway, doorway or passage alters or changes limited access areas
- Any of the following made to enhance activities authorized under the permit:
  - Additional electric fixtures or lighting equipment
  - The lowering of a ceiling
  - Electrical modifications that require inspection by the local municipality

To request approval for a facility alteration, submit 1) this form, 2) the required fee, 3) a Request Form Cover Page, and 4) all additional documentation listed below. A request will be deemed incomplete, and not considered, until all required documentation has been submitted.

**Submitting your Request**

All documents must be saved as a PDF file with the following file naming format: [name on permit]\_[name of document]. Files should be submitted in a singular correspondence if via email to [RA-DIIMMRCompliance@pa.gov](mailto:RA-DIIMMRCompliance@pa.gov) OR submitted to the following address on a single USB drive if via mail:

Office of Medical Marijuana - Request Form  
Department of Health  
Room 628 Health and Welfare Building  
625 Forster Street  
Harrisburg, PA 17120

Please ensure the application is properly signed and dated. A signature may be scanned and provided electronically in a PDF file.

**Fees**

Pursuant to 28 Pa. Code § 1141.28, the following fee must be submitted in the form of certified check or money order made out to "Commonwealth of Pennsylvania", enclosed in an envelope within the application package.

Request for Approval: Facility Alteration Fee: \$250

**Documentation**

Please submit the following:

- A brief explanation of why this alteration is being requested.
- Updated information, provided for the following sections, that differs from the original application filed with the Department (unless otherwise noted):

<input type="checkbox"/>	Section 1: Application Name, Address and Contact Information	Provide any changes to the applicant's name, address and contact information since the initial application for a permit was filed with the Department.
<input type="checkbox"/>	Section 2: Facility Information	Indicate the existing facility location authorized by the permit (the location originally approved for this permit, NOT the new facility location).
<input type="checkbox"/>	Section 8, Part D: Operational Timetable	Attach a timeline defining the steps and duration of the alteration from commencement to completion. Please indicate the steps that will be taken for

		the new location to become operational within 6-months from the date the proposed alterations are approved by the Department.
<input type="checkbox"/>	Section 10, Part D: Security and Surveillance	Attach a statement outlining the security and surveillance methods and procedures that will be implemented following the proposed alterations. Please indicate how they differ from the current security and surveillance methods.
<input type="checkbox"/>	Section 16, Part D <sup>1</sup> : Sanitation and Safety OR Section 20, Part D <sup>2</sup> : Sanitation and Safety	Attach a statement of the intended sanitation and safety measures that will be implemented for the proposed alterations.
<input type="checkbox"/>	Attachment D: Site and Facility Plan	Attach both the current and proposed Site and Facility Plans, illustrating how the proposed plan differs from the current plan. The proposed plan should include the specific proposed changes and any documentation provided by the local municipality showing the facility complies with local zoning requirements and can operate at the proposed location as a grower/processor or a dispensary.
<input type="checkbox"/>	Supplemental Information A: Security Overlay	Attach both the current and proposed Security Overlay. Illustrate the specific proposed changes, including changes to any camera placements, on the proposed Security Overlay.
<input type="checkbox"/>	Supplemental Information B: SOPs	Attach a description of changes to any SOPs prompted by the proposed alteration.

\* Additional documentation associated with this alteration may be requested.

#### Additional Attestation

I hereby affirm that all other sections of the initial applications remain unchanged and will apply to the proposed location.

Permit ID Number: \_\_\_\_\_

\_\_\_\_\_  
Signature Date

\_\_\_\_\_  
Name Role in MMO

<sup>1</sup> For Grower/Processors only.

<sup>2</sup> For Dispensaries only.

## Office of Medical Marijuana Request for Approval: Change of Facility Location 28 Pa. Code § 1141.40

Pursuant to regulation § 1141.40, a medical marijuana organization may request a change in location of a facility. A request for a change in facility location must be accompanied by a completed "Request for Approval: Closure of a Facility". The medical marijuana organization must submit a separate request for each facility that it proposes to move under its permit.

To request approval for a change in location of a facility please submit 1) this form, 2) the required fee 3) a Request Form Cover Page, and 4) all additional documentation as listed below. A request will be deemed incomplete, and not considered, until all required documentation and fees has been submitted.

### Fees

Pursuant to 28 Pa. Code § 1141.28, the following fee must be submitted in the form of certified check or money order made out to "Commonwealth of Pennsylvania", enclosed in an envelope within the application package.

Request for Approval: Change of Facility Location Fee: \$250

### Submitting your Request

All documents must be saved as a PDF file with the following file naming format: [name on permit]\_[name of document]. Files should be submitted in a singular correspondence if via email to [RA-DHMMRCompliance@pa.gov](mailto:RA-DHMMRCompliance@pa.gov) OR submitted to the following address on a single USB drive if via mail:

Office of Medical Marijuana - Request Form  
Department of Health  
Room 628 Health and Welfare Building  
625 Forster Street  
Harrisburg, PA 17120

Please ensure the application is properly signed and dated. A signature may be scanned and provided electronically in a PDF file.

### Facility Information

#### Existing Facility Information

Type of Facility (choose one): <input type="checkbox"/> Grower/processor <input type="checkbox"/> Dispensary	
Name of Existing Facility:	
Street Address:	
City:	Zip Code:
Municipality:	County:

#### Proposed Facility Information

Type of Facility (choose one): <input type="checkbox"/> Grower/processor <input type="checkbox"/> Dispensary	
Name of Existing Facility:	
Street Address:	
City:	Zip Code:
Municipality:	County:

### Documentation

Please submit the following:

- A completed "Request for a Closure of a Facility".
- A statement, with supporting documentation, outlining the reasons the medical marijuana organization is proposing a change in location. If the change of location is based on a waiver granted by the Department,



please attach the letter sent to the Department requesting the waiver and the response letter from Department.

- Updated information for the following sections included in the initial permit application:

<input type="checkbox"/>	Section 1: Application Name, Address and Contact Information	Provide any changes to the applicant's name, address and contact information since the initial application for a permit was filed with the Department.
<input type="checkbox"/>	Section 2: Facility Information	Indicate the existing facility location authorized by the permit and provide a description of the proposed location including public access to the location (dispensaries only).
<input type="checkbox"/>	Section 4, Part C: Principals, Financial Backers, Operators and Employees	Attach a list of any principals, financial backers, operators, and employees that have been added to medical marijuana organization since the issuance of the permit by the Department.
<input type="checkbox"/>	Section 8, Part D: Operational Timetable	Attach a timetable for the proposed location indicating the steps that will be taken for the proposed location to become operational within 6-months from the date the proposed location is approved by the Department.
<input type="checkbox"/>	Section 10, Part D: Security and Surveillance	Attach a statement outlining the security and surveillance methods and procedures that will be implemented at the proposed location.
<input type="checkbox"/>	Section 16, Part D <sup>1</sup> : Sanitation and Safety OR Section 20, Part D <sup>2</sup> : Sanitation and Safety	Attach a statement of the intended sanitation and safety measures that will be implemented at the proposed location.
<input type="checkbox"/>	Section 23 Part F <sup>1</sup> : Community Impact OR Section 28, Part F <sup>2</sup> : Community Impact	Attach a statement describing the positive impact the proposed location will have on the community and patients.
<input type="checkbox"/>	Attachment C: Property Title, Lease or Option to Acquire Property Location	Attach copies of any documentation for the proposed location showing an ownership interest in the proposed location.
<input type="checkbox"/>	Attachment D: Site and Facility Plan	Based on the instructions, attach copies of the site plan for the proposed location. Include any documentation provided by the local municipality showing the facility complies with local zoning requirements and can operate at the proposed location as a grower/processor or dispensary.

#### Additional Attestation

I hereby affirm that all other sections of the initial applications remain unchanged and will apply to the proposed location.

Permit Number: \_\_\_\_\_

\_\_\_\_\_  
Signature Date

\_\_\_\_\_  
Name Role in MMO

<sup>1</sup> For Grower/Processors only.

<sup>2</sup> For Dispensaries only.

For Internal Use Only

Request ID # \_\_\_\_\_

Date Submitted \_\_\_\_\_

Intake Initials \_\_\_\_\_

## EXHIBIT I

## Office of Medical Marijuana Request for Approval: Closure of a Facility 28 Pa. Code § 1141.43

Pursuant to regulation § 1141.43, a medical marijuana organization shall notify the Department in writing immediately, but in no event less than 60 days prior to the projected date of closure, upon making a determination that it intends to close a facility.

A request for approval for closure of a facility may be submitted independently or in conjunction with a "Request for Approval: Change of Facility Location," if the closing facility will be re-opened elsewhere.

To request approval for the closure of a facility please submit 1) this form, 2) a Request Form Cover Page, and 3) all additional documentation listed below. A request will be deemed incomplete, and not considered, until all required documentation has been submitted.

### Submitting your Request

All documents must be saved as a PDF file with the following file naming format: [name on permit]\_[name of document]. Files should be submitted in a singular correspondence via email to [RA-DHMMRCompliance@pa.gov](mailto:RA-DHMMRCompliance@pa.gov).

Please ensure the application is properly signed and dated. A signature may be scanned and provided electronically in a PDF file.

### Documentation

Attach a written plan for closing the facility that includes the following information:

- The process the medical marijuana organization will use, prior to closing, to notify any person that is provided medical marijuana or medical marijuana services.
- The process the medical marijuana organization will use to dispose of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products or other plant matter that will still be in the facility at the time of the projected closure in accordance with § 1151.40 (relating to management and disposal of medical marijuana waste).
- The process the medical marijuana organization will use to dispose of equipment or medical devices or instruments used by the medical marijuana organization in its operations at the facility.

### Affirmations

Affirm each of the following statements by checking the corresponding box and signing the attestation below:

- ☐ As of the date on this form, the medical marijuana organization will no longer accept or purchase seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, other plant matter, medical marijuana products, equipment, or medical devices or instruments.
- ☐ The medical marijuana organization agrees not remove or destroy any seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, other plant matter, medical marijuana products, equipment, or medical devices or instruments until the Department has approved its plan for closure.
- ☐ The medical marijuana organization agrees not to remove or destroy any seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, other plant matter, medical marijuana products, equipment, or medical devices or instruments until the Department has approved its plan for closure.
- ☐ The medical marijuana organization understands that the Department may enter the site and facility and inspect the medical marijuana organization's vehicles to approve the medical marijuana organization's closure plan.
- ☐ If the Department approves the medical marijuana organization's plan to close the facility, the medical marijuana organization shall surrender its permit to the Department on or before the date for closure provided in the plan.

I acknowledge that a false statement made by me in this document, or any accompanying documents, is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation).

Permit ID Number: \_\_\_\_\_

\_\_\_\_\_  
Signature Date

\_\_\_\_\_  
Name Role in MMO

For Internal Use Only

Request ID # \_\_\_\_\_

Date Submitted \_\_\_\_\_

Intake Initials \_\_\_\_\_

CDL-1

**FACE SHEET  
FOR FILING DOCUMENTS  
WITH THE LEGISLATIVE REFERENCE BUREAU**



**(Pursuant to Commonwealth Documents Law)**

**RECEIVED**

**SEP 19 2022**

**Independent Regulatory  
Review Commission**

DO NOT WRITE IN THIS SPACE

<p>Copy below is hereby approved as to form and legality. Attorney General</p> <p>BY: _____ (DEPUTY ATTORNEY GENERAL)</p> <p>_____ DATE OF APPROVAL</p> <p><input type="checkbox"/> Check if applicable Copy not approved. Objections attached.</p>	<p>Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:</p> <p><b>DEPARTMENT OF HEALTH</b> (AGENCY)</p> <p>DOCUMENT/FISCAL NOTE NO. <u>10-219</u></p> <p>DATE OF ADOPTION: _____</p> <p>BY:  _____</p> <p>TITLE: <u>Acting Secretary of Health</u> (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)</p>	<p>Copy below is hereby approved as to form and legality. Executive or Independent Agencies.</p> <p>BY:  _____</p> <p>9/16/2022 _____ DATE OF APPROVAL</p> <p>(Deputy General Counsel) (Chief Counsel, Independent Agency) (Strike inapplicable title)</p> <p><input type="checkbox"/> Check if applicable. No Attorney General approval or objection within 30 days after submission.</p>
---	--	---

**NOTICE OF FINAL RULEMAKING**

**DEPARTMENT OF HEALTH**

**TITLE 28. HEALTH AND SAFETY**

**PARTS IX. and IXa. MEDICAL MARIJUANA**

**28 PA. CODE CHAPTERS 1131—1230; 1141a—1230a**

**MEDICAL MARIJUANA**

# **FINAL RULEMAKING**

## **DEPARTMENT OF HEALTH**

**[ 28 PA. CODE CHS. 1131—1230 AND 1141a—1230a ]**

### **Medical Marijuana**

**[Pa.B. ]**

**II**

The Department of Health (Department) promulgates these final regulations in 28 Pa. Code Part IXa (relating to medical marijuana) by replacing the current temporary regulations at 28 Pa. Code Part IX. The final regulations are set forth in Annex A.

#### *Purpose of the Rulemaking*

Under the authority of section 1107 of the Medical Marijuana Act (“MMA” or “the act”) (35 P.S. § 10231.1107) regarding temporary regulations, the Department promulgated temporary regulations to facilitate the prompt implementation of the Medical Marijuana Act (act) (35 P.S. §§ 10231.101—10231.2110) published at 46 Pa.B. 3254 (June 25, 2016); 46 Pa.B. 6829 (October 29, 2016); 46 Pa.B. 8036 (December 24, 2016); 47 Pa.B. 73 (January 7, 2017); 47 Pa.B. 74 (January 7, 2017); 47 Pa.B. 199 (January 14, 2017); 47 Pa.B. 217 (January 14, 2017); 47 Pa.B. 269 (January 14, 2017); 47 Pa.B. 3096 (June 3, 2017); 47 Pa.B. 6938 (November 11, 2017); and 48 Pa.B. 1508 (March 17, 2018). The content of the temporary regulations resulted from extensive surveying of stakeholder groups and countless working meetings with the Legislature. Under section 1107 of the act, the Department's authority to adopt temporary regulations was to expire May 12, 2018, 2 years after the effective date of section 1107 of the act. Prior to the expiration of its authority to adopt temporary regulations, the Department promulgated a second set of temporary regulations, with an expiration date of May 12, 2020, published at 48 Pa.B. 2767 (May 12, 2018); 48 Pa.B. 2793 (May 12, 2018); 48 Pa.B. 2801 (May 12, 2018); 48 Pa.B. 2806 (May 12, 2018); 48 Pa.B. 2810 (May 12, 2018); 48 Pa.B. 2814 (May 12, 2018); and 48 Pa.B. 2767 (May 12, 2018). Act 10 of 2020, section 1736-A.1, extended the expiration date of the temporary regulations to November 20, 2021.

On June 22, 2018, the General Assembly amended Chapter 20 of the act (35 P.S. §§ 10231.2000—10231.2004) and provided the Department with authority to issue new temporary regulations to implement the revised Chapter 20. Under section 2004 of the act (35 P.S. § 10231.2004), the Department's authority to issue Chapter 20 temporary regulations was to expire 2 years after initial publication of the amended Chapter 20 temporary regulations. The Department rescinded the initial Chapter 20 temporary regulations on July 28, 2018, at 48 Pa. B. 4493 (July 28, 2018), and promulgated revised Chapter 20 temporary regulations at 48 Pa.B. 5072 (August 18, 2018) and 48 Pa.B. 7778 (December 22, 2018). On June 30, 2021, Act 44 of 2021 was enacted, which further extended the Department's authority to promulgate temporary regulations until May 31, 2022. 35 P.S. § 10231.1107(b). As a result, the Department published a notice extending the deadline for expiration of the temporary medical marijuana regulations to January 15, 2024, by republishing and readopting the temporary regulations at 52 Pa.B. 359 (January 15, 2022).

Section 301 of the act authorizes the Department to promulgate all regulations necessary to carry out the act. 35 P.S. § 10231.301(b). Section 301 also directs the Department to: issue permits to

medical marijuana organizations to authorize them to grow, process or dispense medical marijuana and ensure their compliance with the act; register practitioners and ensure their compliance with the act; have regulatory and enforcement authority over the growing, processing, sale and use of medical marijuana; establish and maintain an electronic database to include activities and information relating to medical marijuana organizations, patient certifications and identification cards issued, practitioner registration and electronic tracking of all medical marijuana; monitoring all growth, transfer, possession, processing, testing and dispensing of medical marijuana; maintain a directory of patients and caregivers approved to use or assist in the administration of medical marijuana; develop a four-hour training course for physicians, pharmacists, certified registered nurse practitioners and physician assistants regarding the latest scientific research on medical marijuana, including the risks and benefits of medical marijuana; develop a two-hour course for the principals and employees of a medical marijuana organization who either have direct contact with patients or caregivers or who physically handle medical marijuana; develop enforcement procedures, including announced and unannounced inspections of facilities of the grower/processors and dispensaries and all records of the medical marijuana organizations; establish a program to authorize the use of medical marijuana to conduct medical research relating to the use of medical marijuana to treat serious medical conditions, including the collection of data and the provision of research grants; establish and maintain public outreach programs about the medical marijuana program; collaborate as necessary with other Commonwealth agencies or contract with third parties as necessary to carry out the provisions of the act; determine the minimum number and type of medical marijuana products to be produced by a grower/processor and dispensed by a dispensary; develop recordkeeping requirements for all books, papers, any electronic database or tracking system data and other information of a medical marijuana organization; and restrict the advertising and marketing of medical marijuana.

This rulemaking transforms the current temporary regulations found in Part IX to permanent regulations governing the medical marijuana program in a new Part IXa. These regulations further the purpose of the act by providing access to medical marijuana for patients with serious medical conditions; ensuring a safe and effective method of distribution; and promoting high-quality research into the efficacy of medical marijuana. As a prefatory note, the current temporary regulations include Chapter 1131 (relating to safe harbor letter—temporary regulations). Chapter 1131 has expired, and the chapter is reserved.

The Department has received comments throughout the public comment period and prior to submission of this final-form rulemaking. Further, the Department has continued to meet with stakeholders to hear their concerns. The Department has responded to these comments in this preamble. The comments and responses are included section-by-section. In its comments on the proposed regulation, IRRC requested more explanation, basis, and rationale for each section because the temporary regulation upon which this rulemaking was based was not subject to the Commonwealth Documents Law, the Regulatory Review Act, and the Commonwealth Attorneys Act. In response, the Department has included the explanation, basis, and rationale for each section below, and has also gone into more depth regarding the changes from temporary to proposed to final. As an additional clarifying technique, the preamble will describe the changes from temporary to proposed as though the changes are edits. While the Department recognizes that, technically speaking, the temporary chapters will be reserved and the proposed chapters are new, the easiest way to describe the differences between the temporary and proposed regulations are by describing them as “edits,” “revisions” or “changes” from temporary to proposed.

In addition, IRRC requested the Department address whether the regulated community, in light of the enactment of the Act of June 30, 2021, P.L. No. 44 (Act 44 of 2021), had a chance to review the Act 44 provisions in this final-form rulemaking. Because the Act 44 provisions are self-executing, and the Department is mirroring this language in the final-form rulemaking, additional public comment would be impracticable and unnecessary. Further, the Department has continuously

engaged the regulated community since the enactment of Act 44 to address questions and clarify implementation of certain self-executing provisions where practical. **[Editor's Note: Please retain all of the formatting in this preamble.]**

## *B. Requirements of the Regulation*

### *Chapter 1141a. General Provisions*

This chapter in the final-form rulemaking contains general provisions that apply to all permittees such as: definitions; public and confidential records; permitting regions; requirements and fees for permit applications, including renewal applications; changes in ownership and facility location; alteration of facilities; facility and training requirements; and penalties and sanctions for noncompliance. The provisions of this chapter are promulgated in accordance with chapter 1 (preliminary provisions), chapter 3 (program), chapter 6 (medical marijuana organizations) and chapter 13 (offenses related to medical marijuana) of the act. This chapter is substantially similar to the temporary Chapter 1141 (relating to general provisions— temporary regulations). Differences between the temporary regulations, the proposed, and this final-form rulemaking are discussed more fully as follows.

#### *§ 1141a.21. Definitions*

This section in the final-form rulemaking includes all terms that were contained in the temporary § 1141.21, as well as additional terms. This section also consolidates all definitions for Part IXa into this section instead of defining the terms separately in each chapter as was done with the temporary regulations. Because of the request for clarity, and to make it easier for the regulated community to understand the changes that were made, special formatting is used here. The terms that were included in the temporary § 1141.21 are in regular font; the terms that were included in the temporary regulation in other sections are underlined; the terms that were included for the first time on proposed are **underlined and bolded**; and the terms that were included for the first time on final-form are **CAPITALIZED and bolded**. No changes were made on final-form to definitions included for the first time on proposed.

This final-form rulemaking includes the definitions for ACRC—Academic Clinical Research Center, Accreditation body, Accredited medical school, Acute care hospital, Act, **Added substance**, Adult patient, Adverse event, Adverse loss, Advertising, Applicant, Approved laboratory, **CAS number**, **CBC**, CBD, **CBDA**, **CBDV**, **CBG**, **CBN**, **Cannabinoids**, Caregiver, Certificate of accreditation, Certificate of analysis, Certified medical use, Certified registered nurse practitioner, Chain of custody, Change in control, Change in ownership, Clinical registrant, Continuing care, Controlled substance, Controlling interest, **D8**, **DE-IDENTIFIED DATA**, Department, Device, Disadvantaged business, Dispensary, Dispense, Diverse group, Diverse participants, Diversity plan, Electronic tracking system, Employee, Excipients, Facility, Family or household member, Financial backer, Financial institution, Form of medical marijuana, Fund, Grower/processor, Harvest batch, Harvest lot, **HARVESTED HEMP**, Health care medical marijuana organization, Hydroponic nutrient solution, IRB—Institutional review board, Identification card, Immature medical marijuana plant, Immediate family, Industrial hemp, Initial permit application, Institution of higher education, Laboratory, Legal guardian, Limited access area, Marijuana, Medical Board, Medical marijuana, Medical marijuana cardholder, Medical marijuana container, **Medical marijuana extract**, Medical marijuana organization, Medical marijuana patient authorization letter, Medical marijuana plant, Medical marijuana product, Medical Marijuana Program, **MEDICAL MARIJUANA UNIT**, Medical marijuana waste, Medical professional, Minor patient, Minority-owned business, Municipal waste, Municipality, Nebulization, Nutrient, Nutrient practice, Office, Operational, Operator, Parent, Patient, Patient and caregiver registry, Patient certification, Patient consultation, Permit, Permittee,



Person, Pharmacist, Physician, Physician assistant, **POSTHARVEST PLANT MATERIAL**, Practitioner, Practitioner registry, Prescription Drug Monitoring Program, Principal, Process lot, Processing, Professional disciplinary action, Publicly traded company, RAC—Research approval committee, Research, Research contract, **RESEARCH INITIATIVE**, Research program, Research project or study, Research protocol, Sample, Security, Serious medical condition, Service-disabled, Service-disabled veteran-owned small business, Site, **SPECIES**, Spent hydroponic nutrient solution, **SYNCHRONOUS INTERACTION**, THC, **THCA**, **THCV**, Terminal illness, **Terpenes**, Test sample, Third-party certifying organization, Transport vehicle, Unit, Vaporization, Veteran, Veteran-owned small business, Women-owned business.

Terms that were defined in the temporary regulations at 28 Pa. Code §§ 1171.21, 1211.21, and 1230.22, and not carried over to the proposed or final-form rulemaking are: Approved Clinical Registrant, Certified ACRC, Clerk, Laboratory Applicant. Immediate family as defined in the temporary regulation at 28 Pa. Code § 1141.21 was deleted from proposed to final-form.

The definition of "ACRC" was revised on proposed to mirror the definition of "Academic Clinical Research Center" in the act. The definition of "applicant" was revised on proposed to include persons who apply to become an approved laboratory, an ACRC, or a clinical registrant and to move subsections (ii) and (iii) from subsection (C) to subsection (B), as initial placement in subsection (C) was in error.

One commentator sought revision to the term "added substances" under this section to expressly exclude hemp-derived terpenes. Act 44 of 2021 expressly permits a grower/processor to add hemp or hemp-derived additives if the hemp is obtained from a person holding a permit issued by the Department of Agriculture to grow or cultivate hemp under the 3 Pa.C.S. Ch. 15 (relating to controlled plants and noxious weeds). 35 P.S. § 10231.702(a)(4). Because statute now includes hemp-derived additives, including hemp-derived terpenes, the Department takes no action on this comment.

Another commentator requested that the definition of "added substance" clarify those substances that are safe for inhalation versus those that are safe for consumption. Before approving a product containing added substances, the Department references a multitude of sources, including those outlined in 1151a.27(f), in evaluating appropriateness of each added substance and considers the intended route of administration. Accordingly, the Department will take no action in response to this comment.

The Department received multiple comments regarding the definition of "adverse event," seeking to strike the inclusion of "mental harm" as overly broad. After consideration, the Department retains the proposed definition of adverse event in this final-form rulemaking. In promulgating the act, the General Assembly expressly and repeatedly prioritized patient safety. *See* 35 P.S. §§ 10231.102(2) ("The Commonwealth is committed to patient safety."); 10231.102(3)(ii) ("It is the intent of the General Assembly to: . . . Provide a safe and effective method of delivery of medical marijuana to patients."); 10231.1105(b)(3) (authorizing the Board to make recommendations for amendments to the act "for reasons of patient safety"); and 10231.2000(b)(1)-(2) (declaring dedication to patient safety as part of medical marijuana research program). Considering the General Assembly's clear intent with respect to patient safety, and in recognition of the medical nature of this program, the Department believes that documentation and investigation of any adverse event is necessary to ensure the safety of patients.

On proposed, due to revising the definition of "applicant," the definitions of "approved clinical registrant" and "certified ACRC" were removed as unnecessary. To correspond to these changes, the

definitions of "IRB, " "RAC, " and "Research contract" were revised on proposed to remove the reference to "certified" ACRC.

The definition of "CBD" was revised on proposed to add the substance's Chemical Abstracts Service (CAS) number to conform to scientific standards of substance identification.

The definition of "caregiver" is revised on final-form to reflect statutory changes made by the Act 44 of 2021.

The Department received a comment requesting to retract the Department's definition of Certificate of Accreditation (COA), believing that the addition of this defined term limits the opportunities for grower/processors to conduct testing for the purposes of research and development. In response, while the COA is designed to apply to tests conducted as required under the act, the regulations will allow for additional testing. *See* Chapter 17. As a result, the Department declined to make changes to the definition of certificate of accreditation.

In response to a public comment stating that the "certificate of analysis" should provide a broader range of testing, results, and times, the definition of "certificate of analysis" is revised on final-form to include a sample taken for stability testing, and the definition of "chain of custody" is revised on final-form to clarify that it is not only the written procedures used to collect and move samples, but also the real-time documentation of actions taken from collection to test completion. One commentator requested an example of what the Department's expectations are with the addition of "and the real-time documentation of actions taken" to the definition of "chain of custody." After consideration, the Department takes no action in response to this comment as the definition as a whole illustrates the need to document in real time each action taken to fulfill the written procedures used to record the possession and transfer of samples and test samples.

The definition of "clinical registrant" was revised on proposed to add subsection (iii) as the unnecessary definition of "approved clinical registrant" was removed on proposed. Per comment from IRRC regarding use of the defined term within the definition, the phrase "as a clinical registrant" is removed on final-form from the definition of "clinical registrant" in subsection (iii).

The Department received comments seeking to revise the definition of "continuing care" to remove the requirement that the practitioner conduct an in-person consultation with the patient. IRRC also raised the question of whether temporary measures implemented during the COVID-19 response could be made permanent in these regulations. All of the temporary measures implemented during the COVID-19 response were made permanent by Act 44 of 2021, removal of the "in-person" patient consultation. The definition of "continuing care" had been revised on proposed to reflect the definition in the act by adding "including an in-person consultation with the patient." However, "in-person" is removed on final-form from the definition, pursuant to statutory change made in Act 44 of 2021. 35 P.S. § 10231.103.

The definition of "controlling interest" was changed on proposed to mirror the definition in the act by changing "company" to "entity" in subsection (i).

The definition of "de-identified data" was added on final-form in response to comments from IRRC and other commentators seeking clarification on 1141a.22(f).

One commentator requested that the Department revise the definition of "device" to include that devices may be purchased at a dispensary or another source, to eliminate confusion as to what devices are permitted for use in Pennsylvania's medical marijuana program. Adopting this proposal is not necessary because the definition of "device" is currently not limited to devices purchased from a

permitted dispensary and the Department does not prohibit patients from purchasing devices from sources other than dispensaries. However, devices sold by dispensaries have been evaluated by the Department and approved, under § 1161.27(c), as safe and suitable for use.

One commentator, though not referencing a specific provision, sought to amend the definition of "diverse participant" to remove women, citing that women are equal to men. After consideration, the Department takes no action in response to this comment as the act requires diversity goals and defines "diverse group" as including women-owned businesses. 35 P.S. § 10213.615.

One commentator sought to amend the definition of "electronic tracking system" to allow permittees to utilize the electronic tracking system of their choosing, as opposed to the electronic tracking system prescribed by the Department. The Department, however, is unable to adopt the requested revision, as the requirement to establish a singular electronic tracking system is enshrined in the act. *See* 35 P.S. § 10231.301(a)(4).

Several commentators expressed concern about the Department using one electronic tracking system exclusively, with many commentators suggesting the Department should allow third-party API to connect with the required electronic tracking system. Because Act 44 of 2021 added an application-programming interface of a medical marijuana organization's enterprise resource planning, inventory, accounting and point-of-sale software with the Department's electronic tracking system, these comments have been addressed. 35 P.S. § 10231.701(c.1).

The definition of "harvested hemp" is added on final-form due to Act 44 of 2021 amending section 702 of the act to allow grower/processors to obtain harvested hemp from hemp growers or cultivators holding a permit issued by the Pennsylvania Department of Agriculture.

The definition of "immediate family" is removed on final-form as unnecessary.

The definition of "laboratory applicant" was removed on proposed because the definition of "applicant" was revised to include persons who apply to become an approved laboratory.

The definition of "marijuana" was revised on proposed to exclude synthetic marijuana. Additionally, in response to multiple commentators requesting the inclusion of hemp-derived CBD products, and per Act 44 of 2021, the definition of "marijuana" is amended on final-form to remove the industrial hemp exclusion in subsection (ii), and the now unnecessary definition of "industrial hemp" is removed. Per Act 44 of 2021, grower/processor permittees may now obtain harvested hemp from a person holding a permit issued by the Department of Agriculture to grow or cultivate hemp under 3 Pa.C.S. Ch. 15 (relating to controlled plants and noxious weeds). 35 P.S. § 10231.702(a)(4).

The Department received multiple comments (with some referencing this provision, and others commenting generally) seeking to add "edibles" and to expressly allow for chewable pills to the definition of medical marijuana, expanding on the acceptable forms of medical marijuana as defined in this section. The Department is unable to adopt such revisions, as permissible forms of medical marijuana are prescribed by the act. *See* 35 P.S. § 10231.303(b)(2). Patients, however, retain the right to incorporate medical marijuana into edible form for their own consumption. *Id.* at § 10231.304(c). Additionally, Act 44 of 2021 gave the Board, with the Secretary's concurrence, authority to change the forms of medical marijuana permitted under the act. 35 P.S. § 10231.1201.

The definition of "medical marijuana organization" was revised on proposed to remove the exclusion of a clinical registrant, to comport with section 2002(b)(5) of the act, 35 P.S. § 2002(b)(5). One commentator sought to exclude clinical registrants from the definition of "medical marijuana

organization," reasoning that its inclusion is inappropriate, as a clinical registrant needs to be separated from the commercial market and sector off solely for research markets. The Department, however, is unable to adopt the requested change. The definition mirrors the act. 35 P.S. § 10231.2002(b)(5). As the requested revision requires legislative change, the Department takes no action in response to this request.

One commentator sought an addition to this provision to define "medical marijuana trim" to allow for the transportation of medical marijuana trim between grower/processors. The commentator articulated the benefits that trim's inclusion would provide by increasing patient access to products, as other grower/processors could process the trim into medical marijuana products. Act 44 of 2021 expressly permits a grower/processor to obtain and transport bulk postharvest medical marijuana plant material from another Commonwealth grower/processor to process medical marijuana. 35 P.S. § 10231.702(a)(2.1). Additionally, the Department's final-form rulemaking conforms with this new provision in the act. Accordingly, the Department takes no action in response to this comment.

In response to public comment seeking to define a 30-day supply of medical marijuana, a definition for "medical marijuana unit" is added on final-form, which corresponds to the 90-day supply set at 192 medical marijuana units in § 1161a.24(b). A 90-day supply, rather than a 30-day supply, is used pursuant to statutory change implemented in Act 44 of 2021.

In response to public comments, reiterated by IRRC, the definition of "medical marijuana waste" is revised on final-form to address a specific scenario that resulted in financial loss to the grower/processor. Historically, products erroneously delivered to the wrong dispensary delivered were required to be returned to the grower/processor and destroyed since products returned to grower/processor are included in the definition of medical marijuana waste. This revision creates a limited exclusion from the definition for certain returned products.

One commentator sought revision of the definition of "medical marijuana waste" to remove medical marijuana roots from the definition. This commentator stated that destroying the roots requires extensive efforts, and those efforts provide little benefit when compared to the low utilization for improper purposes. The commentator, providing citations to other states not including medical marijuana roots in the definition of medical marijuana waste, suggested that application of Department-approved organic chemicals would render the roots incapable of growth in a more efficient manner than the methods currently required by the regulations. After consideration, the Department will take no action in response to this request. There are a multitude of products designed to shred medical marijuana waste, including roots. Given these options, grower/processors can ably destroy medical marijuana waste as currently required.

The definition of "municipality" was revised on proposed to add "county" and "or any similar general-purpose unit of government which shall hereafter be created by the General Assembly."

The definition of "patient consultation" is revised on final-form to reflect changes made, by Act 44 of 2021, to the definition of "continuing care" in section 103 of the act, removing the requirement of "in-person" consultations and allowing for telemedicine. 35 P.S. § 10231.103. The definition of "permit" was revised on proposed by changing "applicant" to "medical marijuana organization" to reflect the definition of "permit" in the act.

Per request for revision from IRRC, the Department replaces "and" with "or" in the definitions of "physician" and "physician assistant," in this final-form rulemaking.

The definition of "postharvest plant material" is added on final-form to mirror the definition added to section 702 of the act by Act 44 of 2021. 35 P.S. § 10231.702(a)(2.1).

The definition of "research initiative" is added on final-form to mirror the definition added to section 103 of the act by Act 44 of 2021. 35 P.S. § 10231.103.

IRRC questioned whether the references to a "research program" or "study" within the definition of "research protocol" should be revised to instead reference the defined term "research project" or "study?" The distinctions between the terms "research project" or "study" and "research program" are intentional and should not be revised. Section 2003 of the act, which does not become effective until marijuana is rescheduled at the federal level, pertains only to a "research project" or a "research study." In order to advance other medical marijuana research, the Department added the definition of "research program," consistent with the language used in sections 2000 and 2002 of the act. However, to add clarity, the definition of "research protocol" is revised to include research projects.

The definition of "serious medical condition" was revised on proposed. Act 44 of 2021 amended the statutory definition of "serious medical condition" to include "other conditions that are recommended by the Advisory Board and approved by the Secretary under section 1202" and gave this amendment retroactive effect to May 18, 2016, codifying conditions added by the Board between the act's commencement and Act 44 of 2021's passage. The Medical Marijuana Advisory Board (Board) is charged with issuing a final report making various recommendations. *See* 35 P.S. § 10231.1201(j)(5)(ii). The Board issued its final report and, in accordance with section 1201(j)(6) of the act, adopted the report at a public meeting on April 9, 2018. The Board's final report recommended that a process be established for a subcommittee of the Board to review and approve additional serious medical conditions on a continuous basis; the Secretary approved this recommendation at 48 Pa.B. 2898 (May 12, 2018). Consequently, the definition of "serious medical condition" was removed on final-form as serious medical conditions will be included as a list in Appendix A to allow timely updates to newly approved conditions. The Department will periodically, no less than annually if additional serious medical conditions have been recommended by the Board and approved by the Secretary, publish a notice in the *Pennsylvania Bulletin* updating Appendix A to reflect all approved serious medical conditions and post the updated list on the Department's public website.

IRRC commented that the process for amending the definition of "serious medical condition" should be included in the final-form regulations, with an opportunity for public notice and comment. The process is now statutorily defined and notice of updates to Appendix A will be periodically, no less than annually if additional serious medical conditions have been recommended by the Board and approved by the Secretary, published by the Department. The Department additionally notes that the Advisory Board meetings are public meetings subject to 65 Pa.C.S. §§ 701-716, P.L. 729, No. 93 (the Sunshine Act) and that the public may submit written comments to the Advisory Board for review. *See* 35 P.S. § 10231.1201(j)(3). Implementation of this comment is unnecessary.

The Department received a comment regarding the addition of "anxiety" and "Tourette's Syndrome" to the definition of "serious medical condition." The commentator sought clarity as to whether these additions were proper. As described above, these revisions are proper and follow from Act 44 of 2021 and from section 1201 of the act.

One commentator, commenting generally, wished to add "insomnia" as a serious medical condition. The Department is unable to add a new serious medical condition without a final report issued by the Board authorizing such a condition, and, therefore, cannot take action in response to this comment. However, Act 44 of 2021 provides the Board, with the Secretary's concurrence, the authority to approve additional serious medical conditions. 35 P.S. § 10231.1201.

One commentator, though not referencing a specific provision, objected to the Department's inclusion of post-traumatic stress disorder (PTSD), autism, opioid use disorder, and anxiety as serious medical conditions for which individuals can be certified for medical marijuana use and sought their removal. In response, PTSD and autism are included in the act, and so the removal of those conditions would require legislative change. In addition, opioid use disorder and anxiety were properly added as serious medical conditions using the approval method explained above and as adopted by Act 44 of 2021. Accordingly, the Department takes no action in response to this comment.

Another commentator lamented what they believed to be overlapping or vague serious medical conditions and requested the addition of other conditions to clarify this ambiguity. The Department, however, is unable to adopt the requested revisions. Additions to the serious medical conditions would have to be done through one of two means: (1) legislative change; or (2) recommendation of the medical marijuana advisory board, with concurrence of the Secretary, as explained above. As the Department cannot compel action in either case, the Department takes no action in response to this comment.

The Department adds a definition of "species" on final-form in response to public comments. Several public commentators, including IRRC, questioned the need for "species" on the product label and suggested that, if it is required, a definition should be provided. While the act requires medical marijuana products to identify the species, 35 P.S. § 10231.303(b)(8), the act does not define the term. The Department recognizes that the names and number of marijuana species is a topic of debate. However, patient feedback reveals that consumers are interested in knowing whether the product consists of cannabis sativa, cannabis indica, or both. Accordingly, "species" will be defined as "cannabis sativa, cannabis indica or a hybrid of the two."

A definition for "synchronous interaction" is added, mirroring the definition added in Act 44 of 2021. 35 P.S. § 10231.103. The definition of "THC" is revised to clarify that the term refers to "Delta-9" tetrahydrocannabinol.

Some commentators sought to revise the definition of "THC" to exclude all variations other than delta-9 tetrahydrocannabinol. No change is necessary in response, as the definition of THC is currently limited to delta-9 tetrahydrocannabinol.

#### *§ 1141a.22. Records subject to disclosure; confidentiality*

Consistent with section 302 of the act, 35 P.S. § 10231.302, this section addresses which records are subject to disclosure and which records must remain confidential. This section substantially transitions the temporary § 1141.22 (relating to records subject to disclosure; confidentiality) to a permanent section § 1141a.22. Subsection (b) was revised on proposed and subsections (f) and (g) were added on proposed, as detailed below. In addition, subsections (d) and (e) were modified in the final-form rulemaking, as detailed below.

##### *Subsection (a).*

This subsection lists what records are public records subject to disclosure under the Right-to-Know Law (RTKL) (65 P.S. §§ 67.101—67.3104). No changes were made to this subsection from temporary to proposed to final-form.

##### *Subsection (b).*

This subsection lists what information is considered confidential and not subject to the RTKL. Paragraph (11) of this subsection was revised from temporary to proposed to replace the phrase "The names and any other information relating to..." with "Any information that would identify..." This amendment was made to eliminate any ambiguity relating to the confidentiality of individuals who review permit applications to protect the identities of, and any other information pertaining to, those individuals.

The RTKL contemplates promulgation of regulations protecting the confidential nature of certain information. *See* Section 306 of the RTKL, which provides that "[n]othing in [the RTKL] shall supersede or modify the public or nonpublic nature of a record or document established in . . . regulation." 65 P.S. § 67.306 (emphasis added). To score the permit applications, the Department collaborated with a multitude of Commonwealth agencies. To dissuade applicants from attempting to exert any improper influence—an unfortunate, but realistic, concern when introducing a new billion-dollar industry—the Department protected the confidentiality of individuals who scored the applications by promulgating the temporary regulation, and the Department has determined that such protection remains necessary to carry out the provisions of the act.

No comments were received on this subsection and no changes were made from proposed to final-form.

*Subsection (c).*

This subsection provides that applicants are responsible for marking confidential proprietary information contained in their applications prior to submission. No changes were made to this subsection from temporary to proposed to final-form.

*Subsection (d).*

This subsection provides that an applicant's failure to redact confidential proprietary information contained in the application will result in the disclosure of that information if requested under the RTKL. No changes were made from temporary to proposed. Per comment from IRRC regarding ambiguity about the "version" of the initial permit application requiring redaction in this subsection, the phrase "in its submitted permit application" is replaced in this final-form rulemaking with "in accordance with § 1141a.29(a)(2)" in order to clarify when redactions are required.

*Subsection (e).*

This subsection, as proposed, matched the temporary subsection (e), except that it initially proposed adding language to clarify that an applicant was responsible for defending only those redactions it makes to protect its confidential proprietary or trade secret information and that unsuccessful defense thereof may result in full disclosure of the application in unredacted form. This subsection is revised in final form to reflect the holding of the Pennsylvania Supreme Court in *McKelvey v. DOH*, 255 A.3d 385 (Pa. 2021) that the Department is obligated to make its own determination as to whether records marked as confidential, proprietary or trade secret should be released.

*Subsection (f).*

This subsection was added on proposed and provides that the Department may release de-identified data for research purposes that are subject to approval and oversight by the Department and an IRB. The nascent nature of the medical marijuana program requires not only constant review of

the efficacy of the program for its current purposes, but also research into potential areas of improvement. The addition of this new subsection serves to effectuate those goals.

The Department received a comment seeking explanation regarding subsection (f) of this provision, allowing the Department to release de-identified data for research purposes that are subject to approval and oversight by the Department and an IRB. This commentator believes that this data is not subject to disclosure, as it is not enumerated in section 302 of the act. 35 P.S. § 10231.302. In response, section 302 prohibits the disclosure of individual *identifying* data, in addition to deeming some records as public information. *Id.* This added provision permits the disclosure of *de-identified data for research purposes*. Section 302 of the act is silent as to the non-public disclosure of de-identified data for research purposes. Moreover, in section 2000 of the act, the General Assembly expressly stated its findings that patients deserve the benefit of quality research and that the Commonwealth has an interest in creating a mechanism to allow Commonwealth medical schools and hospitals to develop research programs and studies. 35 P.S. § 10231.2000(a). To facilitate this research and achieve the greatest benefit offered by such research, it is crucial to disclose de-identified data (subject to multiple levels of oversight) to facilitate the highest quality research. As section 302 of the act does not deem this data confidential, and considering the benefits to research into medical marijuana, the Department will take no action in response to this comment.

Additionally, another commentator requested that the Department notify applicable permittees when the Department releases de-identified data in addition to informing the permittee what de-identified data was released. However, the Department will not be releasing any confidential information of a permittee. Rather, the data will pertain to a patient's product usage.

IRRC additionally asked the Department to clarify how it will implement this provision, including providing notice that the data of a grower/processor will be or has been disclosed. The newly-added definition of "de-identified data" explains the release process; and, as explained above, no confidential data of a grower/processor will be released.

No changes were made to this subsection from proposed to final-form.

#### *Subsection (g).*

This subsection was added on proposed and permits the Department to collaborate with other Commonwealth agencies for purposes of investigating and enforcing violations of the act and regulations. This is necessary because other agencies have regulatory authority outside of the act, such as the Department of State in the licensing and professional conduct of practitioners, and collaboration is required by the act. This addition is consistent with section 301 of the act. 35 P.S. § 10231.301(a)(11). No comments were received on this subsection, and no changes were made to this subsection from proposed to final-form.

#### *§ 1141a.23. Limitation on number of permits*

This section sets the limits on the amount of grower/processor and dispensary permits the Department may issue and the limit of permits that may be received by one person consistent with section 616 of the act, 35 P.S. § 10231.616.

The proposed section 1141a.23 mirrored the temporary § 1141.23 (relating to limitation on number of permits), except for changing "Notwithstanding" to "Except as provided in" as the introduction to the section and revising incorrect citations in subsection (3).



On final-form, in response to IRRC's request to remove non-regulatory language in subsection (2)(ii), the phrase "as approved by the Department" is replaced with "as approved in the initial permit application or under § 1161a.40." Subsection (3) is removed on final-form to comport with elimination of this requirement in Act 44 of 2021.

One commentator, though not citing a specific regulatory provision, requested that the Department ban vertical integration of permittees within the medical marijuana program. This commentator cited concerns related to costs and effects on small businesses. The Department, however, is unable to take the requested action, as vertical integration is permitted by the act itself. *See* 35 P.S. § 10231.616(5).

#### *§ 1141a.24. Medical marijuana regions*

This section outlines the geographic areas contained in each of the six medical marijuana regions in this Commonwealth, consistent with section 603(d) of the act, 35 P.S. § 10231.603(d). Further, this section provides factors the Department will consider when issuing a permit and allows the Department to change the number or boundaries of the regions every 2 years, consistent with section 604 of the act, 35 P.S. § 10231.604. This section mirrors the temporary § 1141.24 (relating to medical marijuana regions). No comments were received on this section, and no changes were made to this section from temporary to proposed to final-form.

#### *§ 1141a.25. General requirements for permits*

This section outlines the general guidelines and prohibitions with respect to permits, consistent with section 608 of the act, 35 P.S. § 10231.608. This section mirrors the temporary § 1141.25 (relating to general requirements for permits). No changes were made to this section from temporary to proposed to final-form.

IRRC commented under this section but pertaining to a pathway for pre-operational facilities to select a new location within the same region, despite the specific location identified in the permit application. This comment is addressed below under § 1141a.40.1 (request to change location of a non-operational facility).

#### *§ 1141a.26. Privilege and nontransferability*

This section provides that the issuance or renewal of a permit is a revocable privilege, and that permits are nontransferable, consistent with section 603 of the act, 35 P.S. § 10231.603. This section mirrors the temporary § 1141.26 (relating to privilege and nontransferability). No comments were received on this section, and no changes were made to this section from temporary to proposed to final-form.

#### *§ 1141a.27. General requirements for application*

This section follows from section 606 of the act, 35 P.S. § 10231.606, and outlines the general requirements for an application as further described below. Subsections (a), (c), and (d) were revised on proposed, as detailed below. Changes to subsections (a) and (b) were made from proposed to final-form.

##### *Subsection (a).*

This subsection lists the types of applications to be submitted to the Department. Subsections (a)(3), (a)(4), and (a)(5) were revised on proposed by removing the phrase "as authorized by a

permit." This phrase is unnecessary because the definitions of "medical marijuana organization" and "facility" make clear that a permit has been issued. The temporary subsection (a)(4), which currently provides for "[a]n application for approval of a change of location of a facility," was revised on proposed to add that an application to change location may be submitted only for an "operational" facility. This revision clarifies that the application is not intended to pertain to non-operational facilities. A commentator requested that the Department remove "of an operational facility" from (a)(4), as to allow non-operational facilities to relocate. The Department has a process to allow relocation of non-operational facilities under exceptional circumstances and that process is described in newly added § 1141a.40.1. Finally, in response to a public comment requesting this section to properly reflect that laboratories must submit a renewal application under § 1171a.25, subsection (a)(7) is revised on final-form to add "or renewal of" a laboratory to capture the laboratory renewal application that must be filed every two years. Beyond these revisions, this final subsection mirrors the temporary subsection (a).

#### *Subsection (b).*

As proposed, this subsection mirrored the temporary subsection (b). This subsection provides that, by submitting an application, an applicant consents to investigations to ensure the applicant's ability to meet the requirements under the act. On final-form, in response to IRRC's request to remove non-regulatory language, the phrase "to the extent deemed appropriate by the Department" is removed from this subsection.

#### *Subsection (c).*

This subsection lists the information that is required with the submission of an application. If this required information is not included, the application will be rejected as incomplete. As proposed, this section mirrored the temporary subsection (c), except for changing the citation in subsection (c)(1) to refer to this new chapter and adding "for an initial permit or for a permit renewal" after "application" to clarify that this provision applies to medical marijuana permit applications. No comments were received on this section and no changes were made to this section proposed to final-form.

#### *Subsection (d).*

This subsection provides that an incomplete application will be rejected. As proposed, this subsection revised the language in the temporary subsection (d), which provided that "[a]n application that is rejected by the Department as incomplete will be returned to the applicant without further consideration by the Department and the initial permit fee will be refunded." At proposed stage, this subsection removed the requirement on the Department to return an incomplete application, making for a more efficient and cost-effective operation. Additionally, the language regarding refunding the initial permit fee was relocated to final-form §§ 1141a.28(a)(2) and (b)(2), and "for an initial permit" was added after "application" to clarify that this provision applies only to initial permit applications. No comments were received on this section and no changes were made to this section from proposed to final-form.

#### *§ 1141a.28. Fees*

This section tracks section 607 of the act, 35 P.S. § 10231.607. Subsections (a), (b), and (c) were revised, as detailed below.

#### *Subsection (a).*

This subsection provides the fee amounts for initial and renewal grower/processor permits, and to whom initial permit fees will be refunded. The temporary subsection (a) provides that the fee for these permits must be paid by "certified check or money order." This subsection was revised on proposed to expand the acceptable forms of payment to include cashier's checks. This revision provides applicants greater flexibility in their choice of payment. Subsection (a)(2) was also revised to clarify that the permit fee will be refunded if the application is rejected, as well as if the permit is not granted. No comments were received on this subsection and no additional revisions were made to this subsection from proposed to final-form.

*Subsection (b).*

This subsection provides the fee amounts for initial and renewal dispensary permits, and to whom initial permit fees will be refunded. The temporary subsection (b) provides that the fee for these permits must be paid by "certified check or money order." This subsection was revised on proposed to expand the acceptable forms of payment to include cashier's checks. This revision provides applicants greater flexibility in their choice of payment. Subsection (b)(1) was also revised to match the language in subsection (a)(1) and subsection (b)(2) was revised to clarify that the permit fee will be refunded if the application is rejected, as well as if the permit is not granted. No comments were received on this subsection and no additional revisions were made to this subsection from proposed to final-form.

*Subsection (c).*

This subsection provides that a medical marijuana organization shall pay a \$250 fee for: (1) "an application for approval of a change in ownership;" (2) an application for approval of a change of location of a facility; and (3) an application for approval of alteration of a facility. The subsection makes three changes to the temporary subsection. Subsection (c) was revised on proposed to add "cashier's check" as an acceptable form of payment, consistent with the revisions to subsections (a) and (b). Additionally, the unnecessary phrase "authorized by permit" in temporary subsections (a)(2) and (a)(3) was removed. Finally, subsection (c)(2) was revised to add the word "operational" before "facility," consistent with the revision to § 1141a.27(a)(4) (relating to general requirements for "facility,") to clarify that the application and fee only applies to an operational facility. No comments were received on this subsection and no additional revisions were made to this subsection from proposed to final-form.

*§ 1141a.29. Initial permit application*

This section details permit application requirements, consistent with section 602 of the act, 35 P.S. § 10231.602. Revisions to subsections (a) and (b) are detailed below.

*Subsection (a).*

This subsection provides that the Department will publish notice of initial application availability in the *Pennsylvania Bulletin*; that the applicant may only use the application form prescribed by the Department; that applicants are required to redact their applications; and that untimely submissions will not be accepted. This subsection mirrors the temporary subsection (a), except that the citation in subsection (a)(2) was changed on proposed to refer to this new chapter. No comments were received on this subsection and no additional revisions were made to this subsection from proposed to final-form.

*Subsection (b).*

This subsection requires certain information from an applicant in addition to that required by § 1141a.27 (relating to general requirements for application).

Per comments from IRRC directing removal of non-regulatory language, the phrase "at a minimum" is removed in final-form from subsections (b)(3)(ii), (iii) and (b)(12).

The citations in subsections (b), (b)(6)(iii), (b)(9)(iv), (b)(12)(xii), and (b)(13) were revised on proposed to refer to this new chapter. Subsection (b)(6)(ii) is removed on final-form to comport with elimination of this requirement in Act 44 of 2021. Also on final-form, subsections (b)(6)(iii) and (iv) are renumbered due to the removal of subsection (ii) and are revised to effectuate statutory changes made by Act 44 of 2021.

Former subsection (b)(6)(iii), now subsection (b)(6)(ii), was revised on final-form to effectuate the statutory changes made by Act 44 of 2021 on the persons not required to receive a background check.

Former subsection (b)(6)(iv), now subsection (b)(6)(iii), was revised on proposed by adding "financial backer" to the introductory phrase for consistency throughout the subsection.

Subsection (b)(6)(iv)(B) in the temporary regulations requires an affidavit from each principal or operator of the applicant indicating whether the principal, operator, or financial backer has been convicted of a criminal offense graded higher than a summary offense. This language had been revised at the proposed stage to reflect that applicants must disclose if they had previously been convicted of a criminal offense graded higher than a summary offense "in this Commonwealth or the lowest-graded criminal offense in another State or country." However, this subsection, now subsection (b)(6)(iii)(B) in final form, is further revised to reflect changes made by Act 44 of 2021, which now requires reporting of only felony drug convictions less than ten years old. 35 P.S. § 10231.614. Subsection (b)(6)(iv) also added subsections (C) and (D) on proposed. These subsections were reworded and relocated from temporary subsections 1141.29(b)(9)(vi) and (vii), because those subsections were more appropriately located in the section of the application requiring disclosures via affidavit.

Temporary subsection (b)(9) outlines the types of evidence that would factor into the Department's determination of an applicant's ability to establish and operate a facility. At the proposed stage, subsection (v) was deleted as duplicative of background check requirements in subsection (b)(6). Subsections (vi) and (vii) were reworded and moved to 1141a.29(b)(6)(iii) because they are more appropriately located in the section of the application requiring disclosures via affidavit.

In response to IRRC's request to remove the non-regulatory language, subsection (b)(12) was revised on final-form to specifically detail other requirements to be included in the plan of operation regarding packaging, additives, processing and extraction, and sanitation and safety.

Subsection (b)(14)(i) was removed on final-form to comport with elimination of this requirement in Act 44 of 2021. 35 P.S. § 10231.602(a)(7)(i).

In response to IRRC's request to remove the non-regulatory language, subsection (b)(16) was revised on final-form to list the specific requirement for inclusion of a diversity plan in an application and a new subsection (b)(17) is added to require inclusion of a community impact statement in an application.

*Subsection (c).*

This section provides that if the Department determines that an initial permit application is complete but lacking information, the Department may, but is not obligated to, request the additional information from the applicant. Once contacted, an applicant has 30 days to provide the additional documentation. No comments were received on this subsection and no changes were made to this subsection from temporary to proposed to final-form.

*Subsection (d).*

This section provides that the Department may, in its discretion, extend the deadline in subsection (c) for up to an additional 15 days. No comments were received on this subsection and no changes were made to this subsection from temporary to proposed to final-form.

*Subsection (e).*

This section specifies the Department's investigatory authority to inspect different facets of an applicant's proposed site and compliance with the act and regulations, in addition to potentially interviewing individuals affiliated with the applicant's facility. No comments were received on this subsection and no changes were made to this subsection from temporary to proposed to final-form.

*§ 1141a.30. Capital requirements*

This section provides that a medical marijuana organization applicant must provide an affidavit, confirming that the applicant has the necessary amount of funds on deposit with one or more financial institutions, consistent with section 607 of the act, 35 P.S. § 10231.607. No comments were received on this subsection and no changes were made to this subsection from temporary to proposed to final-form.

*§ 1141a.31. Background checks*

This section details background check requirements, consistent with section 602 of the act, 35 P.S. § 10231.602, and replaces the temporary § 1141.31 (relating to background checks). While this section largely tracks the temporary § 1141.31, this section includes revisions to subsections (a) and (c), as detailed below.

*Subsection (a).*

This subsection provides the way the Department will conduct criminal background checks on applicants and their affiliates. This subsection was revised at proposed to change the citation to refer to this new chapter. No comments were received on this subsection and no changes were made to this subsection from proposed to final-form.

*Subsection (b).*

This subsection provides that the Department will only use the criminal background check for the limited purpose of determining character, fitness, and suitability to serve in the individual's designated capacity. No comments were received on this subsection and no changes were made to this subsection from temporary to proposed to final-form.

*Subsection (b.1).*

This subsection is added on final-form to comport with new language from Act 44 of 2021. 35 P.S. § 10231.602(a)(4). This subsection provides that after submitting proof to the Department that

fingerprints have been obtained, an individual may begin employment at a medical marijuana organization in a supervised capacity. If the Department does not approve the individual to affiliate with the medical marijuana organization, the individual shall be immediately terminated from the medical marijuana organization.

*Subsection (c).*

This subsection, in temporary form, exempted from the background check requirement an owner of a publicly traded company if the Department determined that the owner was not substantially involved in the activities of the medical marijuana organization. This subsection was revised at proposed stage to exempt from the background check requirement an owner of a publicly traded company holds 5% or more of the company's securities or the owner has voting rights to elect or appoint one or more members of the board of directors or other governing board. In final-form, this section is further revised, pursuant to Act 44 of 2021, 35 P.S. § 10231.602(a)(4), to exempt owners of securities in a publicly traded corporation or owners of 5% or less in privately held business entities and who do not have voting rights to elect or appoint one or more members of the board of directors or other governing board.

Some commentators, though not specifically referencing this regulatory provision, criticized the processing time of affiliation of new employees, and sought the addition of a provision to ensure that affiliations be completed within a two-week period. The Department understands these commentators' frustration. Recent changes implemented by Act 44 of 2021 will streamline this process. Act 44 enables the Department to receive background checks electronically from the FBI and state police instead of by paper, which often took 6-12 weeks. 35 P.S. § 10231.602(a)(4). Additionally, Act 44 of 2021 permits an individual to begin employment at a medical marijuana organization in a supervised capacity while awaiting background check results. 35 P.S. § 10231.602(a)(4). Accordingly, the Department will not implement this comment.

*Subsection (d)*

Subsection (d) details prohibitions on financial backers, principals, or employees from holding positions with medical marijuana organizations. No changes were made to this subsection at proposed stage. This subsection is revised on final-form to reflect changes made by Act 44 of 2021, limiting the prohibition to felony convictions relating to the manufacture, delivery, or possession with intent to manufacture or deliver a controlled substance in violation of the Act of April 14, 1972 (P.L. 233, No. 64), known as the Controlled Substance, Drug, Device and Cosmetic Act, or similar law in any other jurisdiction, that are less than 10 years old.

IRRC questioned the reasonableness of a lifetime ban on individuals with certain criminal histories. As indicated above, Act 44 of 2021 eliminated the lifetime ban and narrowed the disqualifying convictions.

One commentator proposed to extend this subsection (d) to allow financial backers, principals, and employees to begin work pending the results and processing of the background checks. The Department incorporated the changes made by Act 44 of 2021 and provisional employment is now permitted as reflected in final form subsection (b.1).

*§ 1141a.32. Diversity goals*

This section outlines the Department's intent that medical marijuana organizations establish practices and procedures for promoting and ensuring diversity, consistent with section 615 of the act, 35 P.S. § 10231.615. Under this section, applicants are required to include in their application a

diversity plan, including contracts with diverse vendors, efforts to recruit diverse participants, and the diversity in the applicant's workforce. The Department will review the diversity plans submitted by applicants for viability. Applicants must also include in the renewal applications information of their efforts to meet their diversity goals and the effectiveness of their diversity plans. The only change made to this section from temporary to proposed was revision of the citation in subsection (g) to refer to this new chapter.

On final-form, the phrase "are reasonable and represent a good faith effort to" in subsection (c) is removed, per comment from IRRC, as it constitutes non-regulatory language and is unnecessary. Also, in response to IRRC's comment, the word "advice" in subsection (h) is replaced with the word "information" and the word "should" is replaced with "may" as the Department provides information to the applicant in the application instructions and in the scoring matrix as to how the applicant may demonstrate compliance with the act's diversity goals.

#### *§ 1141a.33. Review of initial permit applications*

This section provides that the Department will review initial permit applications in accordance with section 603(a.1) of the act and the factors in § 1141a.24(b) (relating to medical marijuana regions). Further, the Department will publish the number of permits to be issued and the locations thereof in the *Pennsylvania Bulletin* before the initial permit applications are made available for submission. The only change to this section from temporary proposed was revision of the citation in subsection (a) to refer to this new chapter. No comments were received on this section and no changes were made to this section from proposed to final-form.

#### *§ 1141a.34. Denial of permit*

This section delineates the grounds upon which the Department will deny the issuance of a permit to an applicant, and is consistent with section 603 of the act, 35 P.S. § 10231.603. The only changes to this section from temporary to proposed were revision of the citations in subsections (3) and (8) to refer to this new chapter. On final-form, revisions are made to subsection (3) to address statutory changes made in Act 44 of 2021. No comments were received on this section and no additional changes were made to this section from proposed to final-form.

#### *§ 1141a.35. Notice of denial*

Under this section, the Department will provide written notice of denial to an applicant, and the applicant may then appeal a notice of denial. The only change made to this section from temporary to proposed was revision of a citation to refer to the new Chapter 1230a (relating to practice and procedure). No comments were received on this section and no additional changes were made to this section from proposed to final-form.

#### *§ 1141a.36. Permit renewal applications*

This section provides the procedure for medical marijuana organizations applying for a permit renewal, in addition to specifying the information that must be included in the application, consistent with section 612 of the act, 35 P.S. § 10231.612. The only change made to this section from temporary to proposed was revision of the citation in subsection (b) to refer to this new chapter.

The Department received a comment from IRRC seeking clarification of the information sought by subsection (c)(3). To clarify, the subsection is revised on final-form to add: "including a summary of any noncompliance and corrective action taken or a statement indicating that the medical

marijuana organization has not violated the act or regulations as of the date the renewal application is submitted." No additional changes were made to this section from proposed to final-form.

One commentator objected to the requirement under this provision that a medical marijuana organization submit a permit renewal application no less than four months prior to the expiration of the current permit. This commentator asserted that medical marijuana organizations should be permitted to submit a permit renewal application any time prior to thirty days of the expiration of the current permit because having to submit a permit renewal application eight months into the active permit term deprives the medical marijuana organization from providing accurate information in some instances. Reviewing and processing permit renewal applications is a time-intensive process, and this laborious process must be repeated for a multitude of permittees submitting permit renewal applications prior to the expiration of the respective permittee's current permit. This minimum four-month review time is necessary to ensure all necessary permit renewal applications can be reviewed and processed in a timely manner. Moreover, the commentator's fears regarding an inability to provide accurate information are misplaced. Some of the required information does not solely contemplate the timeframe of the active permit. Instead, the renewal application seeks information based on timeframes that will have already passed by the time the permittee submits the permit renewal application. *See* 28 Pa. Code § 1141a.36(c)(1) (seeking information from the prior renewal period) and § 1141.36(c)(2) (seeking information from the twelve-month period prior to the date the renewal permit application was submitted). Accordingly, the Department declines to implement a change in response to this comment.

#### *§ 1141a.37. Denial of renewal of a permit*

This section provides the grounds upon which the Department will deny the renewal of a medical marijuana organization's permit, consistent with section 612 of the act, 35 P.S. § 10231.612, and outlines the obligations of a medical marijuana organization should it fail to file a permit renewal application or should the Department deny its application for a renewal permit. The only changes made to this section from temporary to proposed were revision of the citations in subsections (b), (d), and (e) to refer to this new chapter. No comments were received on this section and no additional changes were made to this section from proposed to final-form.

#### *§ 1141a.38. Duty to report*

This section outlines the circumstances under which an applicant must report changes of information during the application process, as well as during the permit period, to the Department, and is consistent with section 606 of the act, 35 P.S. § 10231.606.

At proposed stage, consistent with the revisions to § 1141a.39 (relating to application for change in ownership of a medical marijuana organization), subsection (b) was amended to reflect that medical marijuana organizations only need to submit an application for a change in ownership, as opposed to an application for approval of a change of ownership. This revision intended to reflect the fact that the Department does not approve equity transactions of medical marijuana organizations. Instead, the Department only approves the suitability of the individuals affiliating with medical marijuana organizations. Also, on proposed, the citations in subsections (b) and (c) were revised to refer to this new chapter.

On final-form, references to submitting an application for change in ownership are removed, as the process currently utilized by the Department, as detailed in § 1141a.39, does not require submission of an application. Additionally, per comments from IRRC regarding the use of non-regulatory language, the phrase "at least" in subsection (a)(2) is replaced with "no less than." Subsection (a)(3) includes a nonsubstantive edit to make clear when to notify the Department of an adverse loss.



*§ 1141a.39. Change in ownership of a medical marijuana organization*

This section replaces the temporary § 1141.39 (relating to application for approval of a change in ownership of a medical marijuana organization). This section substantially amends the provisions in temporary § 1141.39, as detailed below.

*Title.*

This section omits the words "approval of a" from the title of temporary § 1141.39, consistent with the amendments to § 1141a.38 discussed above. The Department received a comment from IRRC requesting provision of the form required to comply with this section. The Department did supply, with the proposed rulemaking packet, two forms entitled "MM Form – Reporting Individuals Affiliated with the Organization" and "MM Form – Reporting Individuals No Longer Affiliated with the Organization." These two forms are used to comply with this section. To provide additional clarity, the phrase "application for" is removed from the title of this section on final-form and additional clarifying revisions are made as detailed below.

*Subsection (a).*

This subsection provides that medical marijuana organizations are required to inform the Department in the event of an impending change in ownership involving a change in control. At proposed stage, the words "approval of a" were omitted when discussing the application for a change in ownership, for the same reasons as discussed above. Also on proposed, the citation was revised to refer to this new chapter. On final form, consistent with IRRC's proposal to provide clarity on the process, the phrase "an application for change in ownership, on a form prescribed by the Department," is removed and language is added clarifying that the process involves supplying the Department with the name of each individual affiliating, and each individual no longer affiliating, with the medical marijuana organization.

*Subsection (b).*

This subsection provides that a change of ownership will not be considered complete until the applicant pays the necessary fees. Temporary subsection (b) was omitted in its entirety on proposed, as it did not reflect the internal process used to evaluate affiliation of individuals with a medical marijuana organization. Proposed subsection (b) tracked the substantive requirements of the temporary subsection (c), but omitted the words "approval of a" when discussing the application for a change in ownership, for the same reasons discussed above; revised the citation to refer to this new chapter; and removed "the Department may reject an incomplete application" as this language did not reflect actual practice. On final form, consistent with changes to the title and subsection (a), this subsection is further revised to remove reference to an application and to add language clarifying that a change in ownership will not be considered complete until the names of all incoming and outgoing affiliates have been submitted to the Department.

*Subsection (c).*

Under this subsection, medical marijuana organizations will be required to provide all information required by § 1141a.29 (relating to initial permit application) for each individual involved in the change of ownership. This subsection mirrors the temporary subsection (d), except for revising the citation to refer to this new chapter. No comments were received on this subsection and no additional changes were made to this section from proposed to final-form.

*Subsection (d).*

This subsection, as proposed, was modeled after the temporary subsection (f), which provides that a change in ownership occurring without the Department's "prior written approval of the change as provided in this section" is a violation of the act and this part. As proposed, this subsection provided that a medical marijuana organization's change in ownership occurring without the Department's knowledge of all individuals affiliated with the medical marijuana organization is a violation of the act and this part. This revision reinforced the fact that the Department only determines the suitability of the individuals affiliating with a medical marijuana organization and does not approve a medical marijuana organization's equity transaction. As a result of a public comment received reflecting on the length of time needed to clear background checks and obtain written approval to affiliate with a medical marijuana organization, the phrase "and written approval" is removed from this subsection in final-form. The Department currently does not require completion of all affiliation approvals before a medical marijuana organization may complete an equity transaction. Denial of an individual's affiliation will not void the equity transaction. Rather, the medical marijuana organization will simply be required to remove the individual from the organization.

IRRC also requested the Department to explain the need for written approval of all individuals affiliating with the medical marijuana organization, or to delete the requirement. As indicated above, the Department has eliminated the requirement.

*Subsection (e)*

Temporary subsection (e) was removed in its entirety at proposed stage to eliminate a process that was not utilized.

The Department received a comment regarding who approves equity transactions. The participating entities approve their own equity transactions, although the Department may ask to review a completed transaction to ensure that the permit has not been transferred in violation of the act. 35 P.S. § 10231.603(b).

*§ 1141a.40. Application for approval of a change in location of an operational facility*

This section provides the procedure in which an operational facility may apply to relocate, consistent with section 609 of the act, 35 P.S. § 10231.609. This section outlines the applicant's responsibilities with respect to the content of the application, duties after receiving approval, and grounds for denial of an application. At proposed stage, the following revisions were made to the temporary provisions: the word "operational" was added to the title and to subsections (a) and (b), consistent with the revisions to §§ 1141a.27-.28 (relating to general requirements for applications; fees); the phrase "authorized under a permit" was removed from subsections (a) and (b), as the language was unnecessary; and subsection (a) was revised to refer to this new chapter.

IRRC requested the Department to explain how the Department will evaluate whether to approve a relocation request for an operational facility. In response, subsection (h) is added.

The Department received numerous comments either opposing the limitation of this section to operational facilities or suggesting the addition of a provision for relocation of non-operational facilities. In response, the Department adds § 1141a.40.1.

*§ 1141a.40.1. Request to change location of a non-operational facility*

This new section is added in response to public comments and provides that the Department will review a request to change the location of a non-operational facility based upon individual circumstances and in consideration of the following factors: (1) inability to operationalize the location due to circumstances beyond the permittee's control and the permittee knew, or should have known, of the circumstances prior to selecting the site location; (2) viability of the permittee or the ability to sustain the permitted location, or both, is at risk; and (3) impact on patient access to medical marijuana or resulting acquisition costs of medical marijuana in this market, or both, may be excessive. This section further provides that the Department will not approve a change of location that is outside the boundaries of the region for which the initial permit was issued and may require relocation within the same municipality or county as the originally designated location. The addition of this subsection memorializes the procedure the Department has consistently used to consider requests to relocate non-operational facilities. The Department considers the burden for a request to relocate a non-operational facility to be high because permit applications are scored based upon the location provided within the application itself, and a successful applicant's attempt to relocate before operationalizing the location provided in the application undercuts the application and scoring processes.

*§ 1141a.41. Application for approval of alteration of a facility*

This section provides that, generally, a medical marijuana organization may not alter its facility after the issuance of a permit. This section further provides that a medical marijuana organization wishing to make such an alteration must submit an application to do so if the proposed alteration involves one or more of the scenarios delineated in subsections (b)(1)-(3). The only change to this section from temporary to proposed was revision of the citation in subsection (b) to refer to this new chapter. No comments were received on this section and no changes were made to this section from proposed to final-form.

*§ 1141a.42. Failure to be operational*

This section requires a medical marijuana organization to notify the Department that it is operational within six months from the date the Department issues the permit. The Department will then conduct an inspection to determine whether the medical marijuana organization is operational. Failure to adhere to its operational timeline will require the medical marijuana organization to create a plan of correction to become operational. If the medical marijuana organization fails to comply with its plan of correction within 90 days of the Department approving the plan, the Department may take disciplinary action. The only change to this section from proposed to temporary was revision of the citation in subsection (d) to refer to this new chapter.

The Department received a comment from IRRC requesting clarification of how the Department will know when notice is received under subsection (c), which requires submittal of a plan of correction within 30 days of receiving the Department's notice of deficiency. To clarify on final-form, the Department replaces "receiving" with "the mailing date on" the Department's notice.

One public commentator requested that the Department amend the language of this section to allow for the operationalization of a facility to be extended beyond six months as permitted by the Department. After consideration, the Department will not adopt the requested revision. The regulations as written allow for extensions of the six-month operational timeline, which multiple permittees have utilized in operationalizing their respective facilities. As the regulations currently allow for the requested revision, the Department will not adopt a duplicative provision.

*§ 1141a.43. Closure of a facility*

This section outlines the procedure for a medical marijuana facility to close a facility. A medical marijuana organization that intends to close a facility must provide proper notice and a closure plan to the Department, which must be approved by the Department. This section also lists activities in which a medical marijuana organization is prohibited from engaging after providing notice of its intention to close a facility. This section mirrors the temporary § 1141.43 (relating to closure of a facility), except for changing the citations in subsections (c)(3) and (d) to refer to this new chapter. No comments were received on this section and no changes were made to this section from proposed to final-form.

#### *§ 1141a.44. Insurance requirements*

This section requires a medical marijuana organization to obtain and maintain an adequate amount of insurance coverage for its activities, facilities, and equipment. This section further provides that a medical marijuana organization must obtain and maintain adequate workers' compensation insurance coverage. This section mirrors the temporary § 1141.44 (relating to insurance requirements). No comments were received on this section and no changes were made to this section from proposed to final-form.

#### *§ 1141a.45. Inspection and investigation*

This section provides that the Department may conduct announced or unannounced inspections to ensure a medical marijuana organization's compliance with its permit, the act, and this part, and specifies the elements of the inspections. This section further provides the extent to which the Department and its authorized agents may inspect a facility. The section also outlines the penalty for a medical marijuana organization's failure to provide immediate access to its facility. This section mirrors the temporary § 1141.45 (relating to inspection and investigation). No comments were received on this section and no changes were made to this section from proposed to final-form.

#### *§ 1141a.46. Reports*

This section details reports required to be submitted by medical marijuana organizations and largely mirrors the temporary § 1141.46 (relating to reports), except for revisions to subsection (a), as detailed below.

##### *Subsection (a).*

This subsection outlines the ongoing reports medical marijuana organizations must provide to the Department and details the required contents of the reports. As proposed, revisions were made to subsections (a)(1) and (a)(2) to require dispensaries and growers/processors to report the "average price per unit of medical marijuana products sold" rather than the "per-dose price." These revisions are necessary because a "dose" varies from one patient to another and from one product to another. Per comments from IRRC regarding the use of non-regulatory language and public commentators regarding units of measurement, subsection (a)(2)(iii) is further revised in final-form to delete "and in a unit of measurement as determined by the Department".

##### *Subsection (b).*

This subsection mirrors the temporary subsection (b), which provides that the Department will aggregate the information submitted through these reports and publish it on the Department's website. No comments were received on this subsection and no changes were made from proposed to final-form.

#### *Subsection (c).*

As proposed, this subsection mirrored the temporary subsection (c), which provides that the Department may require ongoing reporting of operational and financial information. Per comments from IRRC regarding the use of non-regulatory language, the phrase "in a form and manner prescribed by the Department" is removed from this subsection in final-form.

#### *Subsection (d)*

As proposed, this subsection mirrored the temporary subsection (d), which provides that the Department may require any reports necessary to carry out its responsibilities under the Act and this part. No comments were received on this subsection and no changes were made from proposed to final-form.

#### *§ 1141a.47. General penalties and sanctions*

This section outlines the penalties and sanctions the Department may impose for violations of the act and this part, which range from a written warning to revocation of a permit. This section further provides that individuals who assist in the violation of the act or this part are subject to civil penalties.

At proposed stage, two changes were made from the temporary provisions. Subsection (v), falsification of information on any application submitted to the Department, was added to the list of reasons for which the Department may suspend or revoke a medical marijuana organization's permit. This addition serves to underscore the Department's expectation that applicants be truthful in all submissions to the Department. The words "temporary regulations" were deleted from subsection (d). As this rulemaking promulgates Chapter 1230a as permanent regulations, this deletion was a necessary byproduct.

In response to numerous comments, including legislator comments, the Department added, on final form, two examples of falsification - the failure to comply with a labor peace agreement submitted with an application and the failure to follow through on any commitment made in the Community Impact section of the application. IRRC also requested the Department to explain how it will ensure that a permit holder is implementing the initiatives included in the organization's permit application. The addition of falsification of information in the application as a reason for imposing penalties and sanctions, as well as these two non-exclusive examples of falsification, ensures that the Department will have authority to enforce commitments made in a permit application.

Additionally, per comment from IRRC, the phrases "or suspects" and "will likely create" in subsection (a)(5)(ii) are removed as they constitute non-regulatory language. Additionally, the remainder of the subsection is revised to require observation of an operational failure or evidence of diversion or contamination of seeds, plants or products.

#### *§ 1141a.48. Training*

This section outlines who must undergo a two-hour training course developed by the Department, in addition to the information that must be included in the training. This section further provides that the Department will make its training course available at no cost to medical marijuana organizations, and medical marijuana organizations must retain the attendance records for the training and make them available to the Department upon request. As proposed, this section mirrored the temporary § 1141.48 (relating to training), except that the content was reorganized to clarify that principals, as

well as employees, who have direct contact with patients or caregivers or who physically handle medical marijuana plants, seeds, and products must complete the training.

One public commentator described the training materials they reviewed during their original training (in 2019) as outdated. The training materials, however, have been updated since that time. Another commentator also requested that the Department update its training materials. The Department will continue to review and update its training materials as appropriate. As the concerns raised by the former commentator have already been addressed, and the Department will review to address the latter commentator, the Department takes no regulatory action.

IRRC posed several questions regarding this section: First, who administers the training? The Department administers the training through its online trainer provider. Second, what is the rationale for allowing an employee to start working at a facility before the training is complete? To allow employees time to complete new employment onboarding activities. Third, if an employee leaves one medical marijuana organization and starts working for a different organization, will that employee need to take the course again? The Department does not require completed training to be repeated; however, some employers may require repeat training. Fourth, Subsection (c) requires the medical marijuana organization to retain the attendance records of its principals and employees. Does the medical marijuana organization have ownership of the records that need to be kept? Yes. The principal or employee prints a certificate of completion and provides it to the medical marijuana organization. Finally, must records be kept for individuals that are no longer employed by the organization? No. The regulation requires retention of records for the medical marijuana organization's principals and employees. Once separated, they are no longer principals or employees of the medical marijuana organization and there is no obligation to retain the records.

One commentator sought clarification as to whether approved laboratories, including principals and employees, are subject to this section. Approved laboratories, including principals and employees, are not subject to this section because it applies to "the principals and employees of a medical marijuana organization," and approved laboratories are not a medical marijuana organization under the act or this regulatory rulemaking. *See* the definition of "medical marijuana organization" at 35 P.S. § 10231.103 and 28 Pa. Code § 1141a.21.

#### *§ 1141a.49. Zoning*

This section provides that medical marijuana organizations must meet the same municipal zoning and land use requirements as other similar facilities located in the same zoning district. As proposed, this section mirrored the temporary § 1141.49 (relating to zoning).

Several commentators, including a legislator and IRRC, raised concerns related to community impact statements as it relates to zoning issues in applications. The commentators sought the inclusion of community impact statements and letters of support or opposition from the municipality in the permit applications. Community impact statements are a required part of all permittee applications. Moreover, the regulations already require a medical marijuana organization to meet the identical municipal zoning and land use requirements as other manufacturing or commercial facilities located in the same zoning district. Accordingly, letters of support or opposition are not necessary. Further, requiring a medical marijuana organization to meet the identical municipal zoning and land use requirements as other manufacturing or commercial facilities located in the same zoning district, ensures that these facilities will not be permitted to situate in residential areas. No changes were made to this section from proposed to final-form.

#### *§ 1141a.50. Advertising by a medical marijuana organization*

This section provides that medical marijuana organizations must be consistent with applicable federal regulations when advertising or marketing medical marijuana products, and before use, these materials must first be approved by the Department. This section further provides that it does not apply to information provided by a grower/processor to a dispensary listing various medical marijuana products, instruments, and devices that the grower/processor is offering for sale to the dispensary. As proposed, this section mirrored the temporary § 1141.50 (relating to advertising by a medical marijuana organization).

One commentator sought clarification as to whether this provision prohibits grower/processor permittees from taking photographs of the interior of the facility for advertising and marketing purposes. It was this commentator's understanding that the Department prohibited this practice and suggested that it should be provided expressly within this provision. After careful consideration, the Department will take no action in response to this comment. The commentator correctly observes that the Department does not and has not allowed this practice, as interior photographs present a security risk to the facility by potentially revealing the layout and compromising the location and type of security measures implemented. Section 1141a.22(b)(9) provides that "[i]nformation regarding the physical features of, and security measures installed in, a facility" is considered confidential and not subject to the RTKL. *Id.* § 1141a.22(b)(9). As permitting photographs of the interior of a grower/processor facility threatens to undermine the efforts expended to maintain the confidentiality of building and security features, no revision is warranted.

Another commentator sought removal of the term "promotional" in subsection (b) of this provision. This commentator asserts that all promotional material should be permitted and not subject to Department approval. The Department, however, is required to restrict advertising and marketing of medical marijuana under the act. *See* 35 P.S. § 10231.301(a)(14). Accordingly, the Department is unable to implement this comment.

Another commentator sought to strike subsection (b)'s requirement that the Department review all promotional, marketing, and advertising materials prior to their use. The Department, however, is unable to adopt the requested revision. Section 301(a)(14) of the act requires that the Department restrict the advertising and marketing of medical marijuana to be consistent with federal standards. *See* 35 P.S. § 10231.301(a)(14). It is unquestionable that the Department is unable to enforce these restrictions without first reviewing the material. As the requested revision requires legislative change, the Department is unable to implement this comment. No changes were made to this section from proposed to final-form.

IRRC requested information regarding the Department's process for implementing this provision. The Department requires permittees to submit for approval all planned promotional, marketing and advertising activity using the Request for Approval: Promotional, Advertising or Marketing Materials form included with this regulatory packet. IRRC also questioned the Department's statutory authority to review promotional materials. As indicated above, the act requires the Department to restrict the advertising and marketing of medical marijuana, which would include promotional material. IRRC further asked the Department to clarify whether educational material from growers/processors used to educate patients is considered promotional material. Yes. Educational material includes the publishing permittee's name and any information that includes the permittee's name is considered promotional material.

#### *§ 1141a.51. Technical advisories*

This section provides that the Department may publish technical advisories in the *Pennsylvania Bulletin* to provide guidance with respect to the Department's interpretation of the act and this part,

but that the advisories would not have the force of law or regulation. No changes were made to this section from temporary to proposed to final-form.

### *Chapter 1151a. Growers/Processors*

This chapter pertains to grower/processors of medical marijuana and details: facility requirements; plans of operation; access to facilities; security and surveillance; permissible forms of medical marijuana; requirements for growing, processing, inventory, storage, equipment and maintenance, sanitation and safety, packaging and labeling, transportation, electronic tracking system use, disposal of waste, and pesticide use; recall of medical marijuana products and quarantine orders. This chapter tracks chapter 7 of the act, 35 P.S. § 10231.701 *et seq.* This chapter replaces the temporary Chapter 1151 (relating to growers/processors -- temporary regulations). New sections and amendments to sections of the temporary regulations are discussed more fully below.

#### *§ 1151a.21. Growers/processors generally*

This section provides that a grower/processor is under a continuing obligation to meet the qualifications necessary to receive a permit. This section further provides that a grower/processor may not engage in growing/processing operations prior to being deemed operational by the Department; nor may a grower/processor employ someone under the age of 18 to work at its facility. The only change to this section from temporary to proposed was revision to the citation in subsection (b)(1) to refer to this new chapter.

Some commentators, though not referencing a specific regulatory provision, requested that the Department allow patients to grow medical marijuana in their homes, citing prospective benefits related to cost and pricing. The Department, however, is unable to implement the requested action, as the act provides that it is unlawful to grow medical marijuana without a permit issued by the Department. *See* 35 P.S. § 10231.304(b)(3). Accordingly, the Department is unable to implement these comments.

#### *§ 1151a.22. Plans of operation*

This section provides that at the time the Department determines a grower/processor to be operational, the grower/processor must provide the Department a full and complete plan of operation for review. This section also delineates the required components of this plan of operation and provides that a grower/processor shall make the plan of operation available to the Department upon request.

Subsection (c) was added at proposed stage, requiring a grower/processor to comply with its plan of operation. This addition will ensure that growers/processors comply with the plans of operation submitted to the Department, which provide guidance as to how a grower/processor will handle specific events. Further, the language in paragraph (a)(2)(ii) was revised as proposed by replacing the word "visitors" with the phrase "individuals requiring access to the facility." This revision emphasizes that grower/processor facilities are not open to the public and are not permitted to have non-essential visitors. Finally, the citation in subsection (a)(12) was revised as proposed to refer to this new chapter. No comments were received on this section and no changes were made from proposed to final-form.

#### *§ 1151a.23. Grower/processor facilities*

This section provides that growing/processing operations must occur in a secure facility, that certain areas must be marked with specific signage, and that the facility must have an enclosed,



secure area out of public sight for loading and unloading. At proposed stage, the word "visitor" in subsection (b)(3) was replaced with "individual." Replacement of the term "visitor" accentuates the fact that grower/processor facilities are not open to the public and are not permitted to have non-essential visitors.

A comment from IRRC indicated that the phrase "as approved" by the Department in subsection (a) constituted non-regulatory language. Therefore, in final-form, the phrase is replaced with "that has been inspected and deemed operational" by the Department. No additional changes were made to this section from temporary to proposed to final-form.

The Department received numerous comments, including from IRRC, regarding the Department replacing the word "visitors" with "individuals" in subsection (b)(3) of this provision. Commentators objected on the basis that this change would require grower/processors to purchase and implement new signage to comply, asserting that the new signage would cost thousands of dollars. Some commentators sought adequate time to order and hang the new signage if the Department were to retain the usage of "individuals." The revision provides necessary clarity to this provision. Moreover, the commentators' concerns related to cost are dependent largely on the permittee, not the Department. Although this provision contains specifications related to size and content of the signage, it does not require a specific type of signage—*i.e.* paper vs. metal. Any exorbitant costs related to acquisition of new signage would be a result of a permittee's preference, not regulatory requirement. Lastly, given the relative ease and expedience of installing a paper sign during the pendency of any potential custom signage, the Department finds no need for a grace period.

Commenters also asserted that the revision restricts disability accommodation for those requiring physical assistance into a dispensary unless the patient uses a caregiver, which is a time-intensive and costly process. Since the Medical Marijuana Assistance Program is now implemented, background check fees have been eliminated for caregivers. Additionally, there are no card fees for patients and caregivers participating in financial hardship programs such as CHIP, Medicaid, PACE, PACENET, SNAP, and WIC, so cost is not a barrier. Finally, the Department can assign a caregiver to those who are unable to wait for the background check completion, so time delay is also not a barrier.

#### *§ 1151a.24. Growing and processing inventory*

This section details inventory requirements, consistent with section 702 of the act, 35 P.S. § 10231.702, and replaces the current § 1151.24 (previously relating to start-up inventory). This section contains multiple changes from the temporary provisions, as detailed below.

##### *Title.*

The title of the subsection is changed on final-form to replace "start-up" with "growing and processing" as revisions to the section resulting from statutory change are not limited to start-up inventory.

##### *Subsection (a).*

The temporary subsection provided that, within 30 days of being deemed operational, a grower/processor may obtain seeds or immature medical marijuana plants from outside this Commonwealth to secure its start-up inventory. This subsection as proposed removed references to "immature medical marijuana plants" as § 702(a) of the act, at the time of initial drafting, only permitted the importation of seeds from outside the Commonwealth. This subsection, as proposed, also added that a grower/processor could obtain seeds from outside the Commonwealth during any 30-day window established by the Department if the Department deemed it necessary.

IRRC asked why “immature medical marijuana plants” were included in the temporary regulations if not authorized by statute and asked the Department to explain the reasonableness and the fiscal impact of removing “immature medical marijuana plants” from this provision if the provision remained unchanged in final-form. No explanation is necessary since Act 44 of 2021 amended the act to include this language, 35 P.S. § 10231.702, which specifically says a grower/processor may “obtain and transport seed and immature plant material from outside this Commonwealth during at least one 30-day period per year as designated by the Department to grow and process medical marijuana.” final subsection (a) is revised pursuant to statutory changes made in Act 44 of 2021. 35 P.S. § 10231.702. In accordance with amended § 702 of the act, grower/processors may also import immature medical marijuana plants. Additionally, because Act 44 of 2021 amended the act to require at least one additional 30-day period per year for the importation of seeds and immature plants, this subsection is further revised to establish one annual 30-day period as December 1 to December 30, and to establish a process for a grower/processor to request additional windows for importation.

The Department received numerous comments regarding the 30-day windows established in subsection (a). Most commentators sought the establishment of many more 30-day windows, whether they be periodic or *ad hoc*. Others, however, commented seeking clarity as to when the Department would establish a 30-day window. Additionally, IRRC commented on this subsection, raising various questions, some of which are now moot in light of Act 44 of 2021 and the resulting regulatory revisions explained above. In response to IRRC’s questioning how the process would be implemented, subsections (a)(1)-(5) are added. These subsections outline the process for a grower/processor to request another 30-day window (in addition to the December 30-day window) to import seeds and immature plants – i.e., by written request submitted at least 60 days in advance of the proposed start date, with justification including, but not limited to, the need to refresh or improve genetics, patient demand, and the need to ensure ample supply of product. The Department will provide written notice, no later than 30 days prior to the proposed start date, approving or denying the request based on sufficiency of the justification presented. These additions are consistent with section 702 of the act, which requires “at least” one additional 30-day window. 35 P.S. § 10231.702(a)(1). Additionally, these provisions were requested by the regulated community and any fiscal impact would be voluntarily carried by the grower/processor.

#### *Subsection (b).*

This subsection provides that a grower/processor may not obtain medical marijuana plants, as opposed to seeds or immature medical marijuana plants, from outside this Commonwealth at any time. This subsection mirrors the temporary subsection (b).

One commentator objected to subsection (b) of this provision and requested that grower/processors be permitted to obtain immature medical marijuana plants from outside of this Commonwealth, citing the benefit of greater variety of medicine available to patients and the burden of competitive disadvantages related to not being able to receive clones of other strains of medical marijuana. As indicated above, this change has been implemented pursuant to statutory change.

#### *Subsection (c)*

Subsection (c) requires that a grower/processor record in the electronic tracking system each seed or immature medical marijuana plant that it receives during a 30-day period under subsection (a) within 24 hours of receiving the seed or plant. This subsection, as proposed, removed “and immature medical marijuana plant” as section 702(a) of the act, at the time of initial drafting, only permitted the importation of seeds from outside the Commonwealth. The final subsection is further revised to allow

for the importation of immature medical marijuana plants during multiple importation windows pursuant to statutory change made in Act 44 of 2021. 35 P.S. § 10231.702(a)(1).

One commentator objected to the removal of "immature medical marijuana plant[s]" from this subsection, raising concerns regarding time needed for harvest and getting a grow operation ready to be harvested for processing in an expedient fashion. As explained above, this initial revision has been reversed due to Act 44 of 2021.

*Subsection (d).*

The temporary subsection (d) provides that "[a]fter the 30-day period in subsection (a), a grower/processor shall only grow medical marijuana plants from seeds or immature medical marijuana plants located physically in its facility, or purchase seeds, immature medical marijuana plants or medical marijuana plants from another grower/processor." Necessitated by the change to subsection (a), this subsection was revised at proposed stage to incorporate any additional 30-day window that may be provided for the importation of seeds or immature medical marijuana plants. No additional changes were made from proposed to final-form.

*Subsection (e)*

This subsection is added on final-form pursuant to Act 44 of 2021, which provides that a grower/processor may obtain and transport bulk postharvest plant material from another grower/processor within this Commonwealth to process. 35 P.S. § 10231.702(a)(2.1).

*Subsection (f)*

This subsection is added on final-form pursuant to Act 44 of 2021, which provides that a grower/processor may obtain harvested hemp from a person holding a permit issued by the Department of Agriculture to grow or cultivate hemp under the 3 Pa.C.S. Ch. 15 (relating to controlled plants and noxious weeds) if the hemp received by a grower/processor is subject to the laboratory testing requirements of section 704 of the act. 35 P.S. § 10231.702(a)(4).

*Subsection (g)*

This subsection is added on final-form pursuant to Act 44 of 2021, which provides that a grower/processor may add hemp or hemp-derived additives obtained or cultivated in accordance with subsection (f). 35 P.S. § 10231.702(a)(5).

*§ 1151a.25. Access to grower/processor facilities*

This subsection limits access to grower/processor facilities. Several substantive changes have been made to the temporary § 1151.25 (relating to visitor access to grower/processor facilities).

*Title*

Temporary § 1151.25 is entitled: "Visitor access to grower/processor facilities." The title to this section was amended at proposed stage to: "Access to grower/processor facilities." Removing the term "visitor" accentuates the fact that grower/processor facilities are not open to the public.

*Subsection (a).*

This subsection provides that grower/processor facilities may not be open to the general public. This subsection was revised at proposed stage to clarify that if someone who is not approved to enter a facility requires access to that facility for purposes related to the work of the facility, the individual will be required to sign a log detailing the need for entry and will also be required to wear a temporary identification badge while on site and in the facility. This subsection clarifies who may have access to a facility, and for what purpose. No changes were made from proposed to final-form.

One commentator objected to the proposed changes in this provision, though not specifically referencing this regulatory subsection, and requested that grower/processors be permitted to allow visitors subject to the existing identification, log, and escort protocols, citing the need of media, government officials, researchers, consultants, investors, and academic institutions to see and appreciate the sophistication of grower/processor facilities for the continued evolution and betterment of medical marijuana operations. IRRC requested amendment of this provision to address the issue of access for individuals such as prospective principals, financial backers, operators or employees of the organization, local first responders, local law enforcement, lawmakers, and others who may need to enter grower/processor facilities for legitimate purposes such as information gathering, training, or orientation. In response, subsection (a) is revised to include "potential investment or employment" as reasons to allow entry. The remaining classes of individuals are already permitted entry under subsection (g).

*Subsection (b).*

This subsection requires individuals to present a government-issued photo identification to enter a grower/processor facility. The temporary subsection (b) provides that "visitors" must present proper identification; this subsection, as proposed, replaced "visitors" with "individuals," consistent with the Department's removal of the term "visitor" from the final regulations. No changes were made from proposed to final-form.

*Subsections (c) and (d).*

Subsection (c) provides that individuals under the age of 18 are not permitted in a grower/processor facility. Subsection (d) provides that a grower/processor must post proper signage at its facility. No comments were received on these subsections and no changes were made from temporary to proposed to final-form.

*Subsection (e).*

This subsection provides the requirements for a grower/processor to admit an individual into its facility. The changes from the temporary to proposed include: replacing the word "visitor" with "individual" and requiring that the individual detail the need for entry in the log. These changes are consistent with the Department's intent to remove the word "visitor" from the regulations, and to ensure that individuals entering grower/processor facilities are entering for the proper reasons. No changes were made to this subsection from proposed to final-form.

The Department received comments objecting to the requirement under subsection (e)(5) that, when admitting an individual to a site or facility, grower/processors ensure that the individual does not touch any medical marijuana seeds, immature medical marijuana plants, medical marijuana, or medical marijuana products. *See* 28 Pa. Code § 1151a.25(e)(5). Those commentators saw this as a hindrance for employees of laboratories collecting samples for testing. These concerns, however, are misplaced, as laboratory personnel are authorized to enter and collect samples under § 1171a.28. *See* 28 Pa. Code § 1171a.28.

One commentator objected to this subsection's requirements that an individual's name and company name be listed on a temporary identification badge. All the requirements under this subsection—including those to which the commentator objects—are in place to ensure that individuals with appropriate business purposes are permitted to enter and traverse through a facility, while maintaining safety and security. Not obtaining this information could threaten facility safety and security; accordingly, the Department will not adopt the requested change.

*Subsection (f).*

This subsection provides the content and retention requirements for the log that individuals must sign upon entry to a grower/processor facility. Consistent with the rest of this section, this subsection was revised at proposed stage to replace the word "visitor" with words or phrases corresponding to revisions made in other subsections within this section. Additionally, the date is added in final-form as a required entry on the log.

The Department received a comment from IRRC regarding the need to require maintenance of logs for four years and questioned whether the log could be maintained electronically. In response, the Department reduces the storage requirement in final-form subsection (1) to 180 days, unless otherwise required for investigative or litigation purposes, which aligns with the timeframe required by Act 44 of 2021 for grower/processors to retain security surveillance records. This timeframe is reasonable given that entry records may need to be reviewed in conjunction with security surveillance video. The Department additionally clarifies that the log may be maintained electronically.

*Subsection (g).*

This subsection provides that nothing in § 1151a.25 will limit the right of the Department or its authorized agents, State or local law enforcement, or other Federal, State or local government officials, from entering any area of a grower/processor site or facility, if entrance is necessary to perform their functions and duties. At proposed stage, the phrase "that pertain to the act or this part" was added to the end to clarify that the official governmental duties must be related to the act or regulations.

One commentator and IRRC requested revision of this subsection to allow prospective principals, financial backers, operators/employees, local first responders, lawmakers, and others to enter grower/processor facilities for the purposes of information gathering, training, or orientation. As it relates to employees/affiliates of the grower/processor, those individuals are permitted to enter the facility once they are affiliated and Act 44 of 2021 eliminated the prior delay in the affiliation process caused by the background check requirement. The remaining classes of individuals, as provided by this subsection, are permitted entry for governmental official functions as authorized by the act and these regulations. Any unauthorized purpose is not a legitimate reason for entry, and the Department will not compromise facility security to accommodate these purposes.

*Subsection (h).*

This subsection provides that grower/processor employees or other affiliated persons may not be compensated for granting access to a limited access area. The only change to the language of the temporary subsection (h) was replacement of the word "visitor" with "individual" at proposed stage, consistent with the rationale explained above. No changes were made from proposed to final-form.

*§ 1151a.26. Security and surveillance*

This section details the requirements of a grower/processor's security and surveillance systems and the inspection and servicing requirements, consistent with section 702 of the act, 35 P.S. § 10231.702. This section further provides requirements for accessing rooms containing security and surveillance monitoring equipment. This section largely mirrors the temporary § 1151.26 (relating to security and surveillance), except for the changes detailed below.

The following changes were made on final-form: Per comments from IRRC regarding the use of non-regulatory language, the phrase "at least" in subsection (a)(1)(viii) and (a)(2)(i)(E)(ii) is replaced with "no less than." Subsection (a)(2) is revised to require "continuous" surveillance per the statutory change made in Act 44 of 2021. 35 P.S. § 10231.702(b)(2). The Department received numerous comments, including from IRRC, regarding the cost imposed by subsection (a)(4) requiring storage of all video surveillance for two years. The storage requirement is reduced to 180 days, unless otherwise required for investigative or litigation purposes, per Act 44 of 2021. 35 P.S. § 10231.702(b)(2). Due to the statutory amendment, the Department is unable to reduce the storage requirement to ninety days as suggested by multiple commentors. The phrase "at least" in subsection (b)(3) is removed, per comment from IRRC, as it constitutes non-regulatory language and is unnecessary. Subsection (b)(3) is further revised on final-form, in response to a comment from IRRC, to clarify that the records may be maintained in paper or electronic form. In light of the clarification that records may be retained electronically, no change is made to the time frame, as fiscal impact for retaining electronic records, even for four years, will be minimal.

One commentator sought to implement motion-activated security and surveillance systems instead of 24/7 continuous recording security and surveillance system, claiming an increased failure rate in systems related to burn out that results in ongoing maintenance costs. The Department is unable to implement this comment, as Act 44 of 2021 requires a grower/processor to maintain continuous video surveillance. 35 P.S. § 10231.702(b)(2).

Subsection (b)(5) was revised at proposed stage to permit more than one employee to be assigned to monitor the security system, whereas the temporary subsection only allowed one employee to be assigned. Additionally, subsection (d) was revised to require that all entrances to and exits from a grower/processor facility must be securely locked "at all times," as opposed to only during nonworking hours, as provided by the temporary subsection. These changes ensure the safety and security of a grower/processor facility.

The Department received a comment seeking to remove subsection (b)(5)'s requirement that a grower/processor designate employees to continually monitor the security and surveillance system at the facility. This commentator finds this monitoring provision to be duplicative of the requirement, under subsection (a), that the security system be professionally monitored—*i.e.*, monitored by a third party. *See* 28 Pa. Code § 1151a.26(a). IRRC also questions the need for this requirement. This requirement is needed because employees monitoring the system at the facility will be able to respond immediately to issues without delay caused by a third-party offsite vendor needing to contact the facility. Immediate response to a security breach is in the best interest of facility safety and security, and the Department will not take any action that lessens the safety and security of these facilities.

Another commentator suggested revision to subsection (d)'s requirement that facility doors be securely locked at all times. This commentator suggested that doors being securely locked at all times is harmful to conducting business, in addition to presenting a safety issue in the event of a fire. The Department disagrees. The regulated community has ably operated under this requirement, and the Department sees no benefit to removing this requirement. Moreover, the locked-door requirement does not present a safety issue in the event of a fire. Locked doors serve as an impediment from *entry*

into a facility, not exit from a facility. Accordingly, the Department will take no action in response to this comment.

IRRC asked the Department to explain how implementation of the final-form regulation will protect the public health, safety, and welfare. Requiring locked doors at these facilities will help to prevent unauthorized entry, theft and diversion of product into the black market.

*§ 1151a.27. Requirements for growing and processing medical marijuana*

This section establishes growing and processing requirements. At proposed stage, the language largely mirrored the temporary provisions except for the following: the phrase "additional active ingredients or materials" in temporary subsection (f) was replaced with the newly defined term "added substance" for the purposes of clarity; paragraphs (i) through (iv) were added to subsection (f) to provide criteria on what the Department will consider when determining whether to approve an added substance. Subparagraphs (i) and (ii) are identical to language added to the act by Act 44 of 2021. 35 P.S. § 10231.702(a)(5). Subparagraphs (iii) and (iv) require consideration of the United States Food and Drug Administration approval for added substances, considering the route of administration and dosage, as well as known drug interactions; and subsection (h)(3) was revised to more clearly read that a grower/processor may only process parts of the medical marijuana plant that "[d]o not contain levels of mold, rot or other fungus or bacterial diseases above the minimum levels acceptable to the Department."

IRRC asked what are the acceptable minimum levels, what criteria will be used to determine the minimal levels, and how this standard will be implemented? In response, subsection (h)(3) is revised on final-form to replace "acceptable to the Department" with "contained in the standards for testing under § 1171a.30 (relating to standards for testing)."

IRRC also noted that mold and mildew are not anomalies and asked the Department to explain the reasonableness of not permitting the option for remediation in order for growers/processors to achieve acceptable levels by processing into medical marijuana infused products. The Pennsylvania Cannabis Coalition (PCC) frequently advocates for the ability of its members to remediate product. However, PCC has yet to respond to the Department's request for scientific evidence that the processes used will remediate contaminants to acceptable levels. The Department's own research reveals that mold prevention is the best method. <https://cannabisindustryjournal.com/column/the-best-way-to-remediate-moldy-cannabis-is-no-remediation-at-all/>. Further, Act 44 of 2021, added language allowing for processing of lots failing for yeast and mold to be processed into topical forms only, provided that the product is labelled as remediated. 35 P.S. § 10231.702(a)(3)

This final-form section is revised to mirror the language in Act 44 of 2021 and provides that a grower/processor may use a pesticide that is registered by the Department of Agriculture under the act of March 1, 1974 (P.L.90, No.24), known as the Pennsylvania Pesticide Control Act of 1973, and designated by the Secretary of Agriculture in consultation with the Secretary for use by a grower/processor. 35 P.S. § 10231.702(c). This section also requires a grower/processor to use approved pesticides in a manner approved by the Department of Agriculture based on Federal law and regulations. A grower/processor must also log all actions taken to detect pests or pathogens and the measures taken for control. This section requires a grower/processor to use appropriate nutrient practices, use fertilizer as appropriate to support healthy plant growth, and maintain records of fertilizer and growth additives used.

Per comments from IRRC regarding the use of non-regulatory language, proposed subsection (e) is revised in to delete "that is greater than an acceptable level as determined by the Department."

One commentator requested that the "Comments" section be removed from Appendix A (the list of approved pesticides), citing greater ease of use than that proscribed in Appendix A. Appendix A, as a list of approved pesticides, is removed per the changes made in section 1151.27(a), which were necessitated by Act 44 of 2021, and is replaced with a new Appendix A (relating to Serious Medical Conditions).

One commentator requested that the Department, in conjunction with the Pennsylvania Department of Agriculture, review the list of approved pesticides at least annually to ensure they remain accurate and applicable. Another commentator requested that the Department expand the list of pesticides acceptable for use on medical marijuana. IRRC also asked the Department to clarify how this provision will be implemented, and to address the reasonableness of the provision in the final-form regulation. Substantial changes have been made, as explained above, in response to Act 44 of 2021, expanding permissible pesticides and allowing for regular updating of the list. This provision is reasonable, as it directly aligns with the new statutory language.

One commentator sought to include food grade excipients as an added substance. Food grade excipients are permitted if approved by the Department.

One commentator sought to remove subsection (h)(1) to allow grower/processors to process seeds and stems. After consideration, the Department will take no action in response to this comment. The Department will not compromise the quality of medical marijuana by allowing unusable parts that are not medicine. Furthermore, seeds should not be provided to patients as possible abuse can result in home growing, which is not permissible under the act.

#### *§ 1151a.28. Forms of medical marijuana*

This section lists the six acceptable forms of medical marijuana that a grower/processor may process, consistent with section 303 of the act, 35 P.S. § 10231.303, in addition to providing that a grower/processor may not manufacture, produce, or assemble any medical marijuana product, instrument or device without the prior written approval of the Department. No changes were made to this section from temporary to proposed to final-form.

The Department received comments seeking to add edibles to subsection (a), as to allow grower/processors to process medical marijuana into edible or drink form. For several reasons, the Department is unable to make such a revision. First, the acceptable forms for processing under this subsection mirror the forms of medical marijuana provided under the act. *See* 35 P.S. § 10231.303. Additionally, the act further deems those forms to be the exclusive forms for the lawful dispensing of medical marijuana. *Id.* at § 10231.303(b)(2). Patients, however, retain the right to incorporate medical marijuana into edible form for their own consumption. *Id.* at § 10231.304(c). Additionally, Act 44 of 2021 gave the Board, with the Secretary's concurrence, authority to change the forms of medical marijuana permitted under the act. 35 P.S. § 10231.1201.

#### *§ 1151a.29. Limit on medical marijuana processing*

This section provides that medical marijuana or medical marijuana products must have a specific concentration of total THC and total CBD, in addition to reporting the concentrations of delineated cannabinoids and listing them on the product's label, consistent with section 801 of the act, 35 P.S. § 10231.801. Further, this section provides that within six months after the Department deems a grower/processor to be operational, a grower/processor must provide the Department a forecast of its medical marijuana production and form and notify the Department of potential increases or decreases within the following six months. This section mirrors the temporary § 1151.29 (relating to limit on medical marijuana processing), excepting the revisions noted below.



Subsection (a) was revised at proposed stage to replace the full name of each cannabinoid on the product label with the abbreviation—as each is a defined term—in addition to requiring that the amount of Delta-9 THC be disclosed on the product label. These revisions are aimed at providing transparency with respect to the cannabinoids in medical marijuana products, while maximizing label space. Some commentors, including IRRC, asserted that this information does not readily fit on a label, and would require the print to be very small, possibly unreadable. IRRC asked the Department to explain the reasonableness of this requirement and to address the fiscal impact and implementation timeframe. The Department is requiring labeling of these additional cannabinoids at the request of patients, who understand the significance of different cannabinoids and how they work on the endocannabinoid system. It is reasonable for patients to know which products contain their preferred cannabinoid, and in what amount. Labeling space is not constraining, as many permittees are already making use of accordion-style labels that are common in the pharmaceutical industry. Since many permittees are already using accordion-style labels, the fiscal impact should be negligible, and no additional time needed for implementation. However, the Department will allow a transition period to deplete existing supply.

Per comments from IRRC regarding the use of non-regulatory language, the phrase "at a minimum" is removed from final-form subsection (a). In response to public comments, reiterated by IRRC, opposing the necessity of listing each cannabinoid on the label even if it is 0.0%, subsections (a)(2), (3), and (5)-(7) are revised in final-form to require listing of these cannabinoids only if greater than 0.0%. The Department is unable to implement this proposed revision for THC and CBD because the act requires listing the percentage of these cannabinoids on the label. 35 P.S. §§ 10231.303(b)(8) and 10231.801(i)(5). In addition to the above reasoning, the Department will not act on one commentator's suggestion that subsections (1)-(5) only be listed if the cannabinoid profiles are greater than 0.1% and subsections (6)-(10) should be provided via an electronic link as the Department seeks a comprehensive listing of all relevant information on the label for patient transparency and safety and not all patients have means to utilize an electronic link.

Temporary subsection (b) required a grower/processor to "immediately" notify the Department of anticipated increases or decreases in production. At proposed stage, subsection (b), as proposed, required the grower/processor to notify the Department "promptly." Upon receipt and consideration of comments from the regulated community requesting that a window of time to report anticipated variations be provided, especially for those initial operational phase grower/processors still growing accustomed to the market, and from IRRC requesting clarification on the notification timeframe, this requirement is further revised on final-form to "within 48 hours." This amendment provides clarity and a slightly expanded time frame for a grower/processor to notify the Department of a potential increase or decrease in production of medical marijuana or medical marijuana products.

The Department received public comments which, though not referencing a specific regulatory provision, sought to impose a cap of 10% on the percentage of THC in medical marijuana products. These commentators cited to risks of harm associated with high-potency medical marijuana products and their suitability within a medical program. After consideration, the Department will take no action in response to these comments. Medical marijuana products are to be administered as part of a patient's course of treatment while under the continuing care of a practitioner for the patient's serious medical condition. While research continues to develop in this area, the efficacy of different forms/potencies/strains of medical marijuana will differ from one patient to another. While the Department is sensitive to the commentators' concerns, it will not implement a cap at this time.

#### *§ 1151a.30. Inventory data*

This section, consistent with section 701 of the act, 35 P.S. § 10231.701, specifies the data elements to be included in a grower/processor's inventory and requires a grower/processor to maintain the listed data in its electronic tracking system, in addition to requiring that a grower/processor establish inventory controls, and that the inventory information be maintained in an electronic record. This section mirrored the temporary § 1151.30 (relating to inventory data) at proposed stage. Only one change was made in final-form subsection (b)(2), per comment from IRRC, to remove the non-regulatory phrase "at least."

#### *§ 1151a.31. Storage requirements*

This section, consistent with section 703 of the act, 35 P.S. § 10231.703, requires a grower/processor to ensure that its facility maintains a locked storage area for its products, and that these areas are kept in a clean and orderly condition. This section mirrors the temporary § 1151.31 (relating to storage requirements), except for amending a citation in proposed subsection (a) to refer to this new chapter. No comments were received on this section and no changes were made from proposed to final-form.

#### *§ 1151a.32. Equipment, operation and maintenance*

This section requires a grower/processor to have a written process in place to maintain the sanitation and operation of its equipment, which must be provided to the Department upon request; to routinely calibrate equipment used in operations; and to maintain a log regarding the maintenance, cleaning, and calibration of its equipment. This section mirrored the temporary § 1151.32 (relating to equipment, operation and maintenance) at proposed stage. Per comment from IRRC, regarding the use of vague non-regulatory language, the word "routinely" in final-form subsection (b)(1) is replaced with "annually, or more frequently if recommended by the manufacturer,".

#### *§ 1151a.33. Sanitation and safety in a facility*

This section requires that a grower/processor maintain sanitary conditions to limit potential for contamination, in accordance with the requirements listed in subsection (a), including, for example, frequent cleaning and sanitizing, proper removal of trash, and protection against pests. Further, this section states that any employee coming into direct contact with medical marijuana is subject to restrictions in 28 Pa. Code § 27.153 (relating to restrictions on food handlers). This section also requires a grower/processor to provide potable water, cleansers, and handwashing facilities, as well as clean restroom facilities. Finally, this section requires a grower/processor to comply with state and local building codes. This section mirrored the temporary § 1151.33 (relating to sanitation and safety in a facility) at proposed stage, except that "28 Pa. Code" was added to correct the incomplete citation in subsection (b). No comments were received on this section and no changes were made from proposed to final-form.

#### *§ 1151a.34. Packaging and labeling of medical marijuana products*

This section details packaging and labeling requirements and makes several substantive changes to the temporary § 1151.34 (relating to packaging and labeling of medical marijuana products) as described below.

##### *Subsection (a).*

This subsection provides that a grower/processor must package and label its products at its facility, and that the original seal may not be broken except for testing purposes at an approved laboratory. No comments were received on this subsection and no changes were made from temporary to proposed to final-form.

#### *Subsection (b).*

This subsection lists the general requirements for medical marijuana product packaging. The temporary subsection (b)(3) provides that packaging must be "[l]ight resistant or opaque, or both." This subsection was revised at proposed stage to remove the "light resistant" packaging option. This revision effectuates the Department's intent for non-transparent packaging.

The Department received multiple public comments opposing the opaque requirement, asserting that patients desire the ability to see dry leaf forms before purchasing and that greater transparency to view the medical marijuana products would reduce potential product returns. In response, further revision is made to subsection (b)(3) to exempt packages containing dry leaf from the opaque requirement. In response to several public comments directed at minimizing dispensing errors caused by similarities in packaging between different products, which are a patient safety concern and could lead to serious adverse events, the Department also added final-form subsection (b)(5), requiring packaging to clearly distinguish the contents of the package from the contents of any other package of similar appearance. The Department also received several public comments requesting the listing of all ingredients on product packaging for patient knowledge, particularly for those with allergies, to provide greater transparency for patient safety. The Department agrees that requiring this information will enhance patient safety and, therefore, added final-form subsection (b)(6) requiring the product package to list all product ingredients and include a warning for known allergens, such as tree nuts.

#### *Subsection (c).*

This subsection, which mirrors the temporary subsection (c), requires a grower/processor to identify each process lot of medical marijuana with a unique identifier.

One commentator suggested this provision should include language to "allow the Department to access a record of the employee identification number of the employee preparing the package and packaging the medical marijuana product, and the employee identification number of the employee shipping the package." As these suggestions are already required in subsections (d)(9) and (10), the Department will take no action in response to this comment.

#### *Subsection (d).*

This subsection requires that all packaging and labeling be approved by the Department and sets out the information that must be included on each label. The requirements in the temporary subsection (d) were expanded, on proposed, to require: (1) that all packaging receive prior written approval of the Department; (2) labels to list the species and percentages of all cannabinoids and individual terpenes; (3) that labels be firmly affixed to the container directly holding medical marijuana as well as outer packaging; and (4) that THC be the first number in a THC:CBD ratio, when the labeling includes a ratio. These revisions minimize patient confusion caused by medical marijuana packaging and ensure that individuals and law enforcement officials can readily determine if a medical marijuana product was purchased at a dispensary. Subsection (d)(2) also contained a technical revision at proposed stage to correct syntax.

IIRC asked the Department to clarify how a grower/processor obtains packaging and labeling approval, including how a request is made, the timeframe for the Department to respond, and the criteria that the Department will use to approve or disapprove packaging and labels. Permittees submit packaging and labeling approval requests to the medical marijuana compliance resource account using the packaging and labeling approval request form attached to this regulatory packet. The Department reviews each submission to ensure compliance with section 801(i) of the act, 35 P.S.

§ 10231.801(i) and this section. Submissions are reviewed on a first in, first out basis, with response time averaging several weeks.

In response to public comments, reiterated by IRRC, opposing the necessity of listing each terpene on the label even if it is 0.0%, subsection (d)(6) is further revised in final form to require listing of terpenes only if greater than 0.0%.

Subsection (d)(11), which requires the grower/processor to list on the label the dispensary to which the product is to be sold, is revised in final form to accommodate a clinical registrant selling medical marijuana products to another grower/processor and the dispensary destination is unknown. In such cases, the receiving grower/processor will be required to affix a label to the outer packaging listing the dispensary to whom the product is ultimately sold.

In response to public comments, subsection (d)(17) is revised on final-form to clarify that the label needs to be affixed to the container holding the medical marijuana product and to create an exception for directly labelling the container holding medical marijuana to allow for blinded research programs, such as placebo trials, wherein the research requires to blind the medical marijuana product. In such cases, the outer packaging must still be labelled. The Department received a comment objecting to the labeling requirements as many medical marijuana products, like vape cartridges, do not have enough space to affix a label to it. The addition of “product” to this subsection clarifies that the label needs to be affixed to the container holding the medical marijuana product, not for example, the vape cartridge itself which is considered the product. The Department received multiple comments, reiterated by IRRC, objecting to the labeling requirements found in subsection (d) of this provision, citing concerns related to costs associated with creating new packaging and logistics of listing the full array of cannabinoids present within the medical marijuana product. As indicated above, the Department is adding labeling requirements at the request of patients, who want to know the specific cannabinoids and terpenes contained in each product. While the Department understands the commentators' and IRRC's concerns with the additional criteria required on the label, the regulated community has ably utilized accordion-style labels affixed to the container, containing large amounts of information. Since many permittees are already using accordion-style labels, the fiscal impact should be negligible, and no additional time needed for implementation. However, the Department will allow a transition period to deplete existing supply. These labeling requirements are in the best interests of patient safety, as some patients may be sensitive to certain terpenes, and those patients have a right to know if the product they are intending to consume may potentially cause them to experience an adverse event. Moreover, some commentators, including IRRC, sought removal or explanation of the requirement to include plant species on the label. One commentator even suggested that the label should instead have the full cannabinoid and terpene profile as these should be used to accurately predict the effects of a medical marijuana product on the human body. The requirement to include “species” on the label is found in the act and would require legislative change to remove. *See* 35 P.S. § 10231.303(b)(8). As indicated above, a clarifying definition of “species” has been added. As it relates to including the cannabinoid and terpene profile on the label, this is already a requirement found under section 1161a.28(b)(6). Although permittees may experience incremental cost increases related to complying with these requirements, the Department must prioritize the express intent of the legislature: patient safety.

IRRC questioned the necessity of listing the receiving dispensary on the label. This information is important to law enforcement who has been trained on lawfully dispensed packaging and expects to see the selling dispensary name displayed on the package.

IRRC further reiterated other commentator concerns over being required to affix large amounts of information directly to a small container. As previously indicated, permittees are already successfully

using accordion-style labels that can accommodate all required information on a very small space. It is reasonable for patients to know the cannabinoids and terpenes contained in each product, and in what amounts. Further, law enforcement expressed concern for unlabeled containers once removed from outer packaging. Additionally, patients relayed inability to distinguish products once removed from outer packaging, such as identical syringes containing identical appearing, yet distinct, oils. Requiring labels to be affixed directly to the container holding medical marijuana will assist law enforcement and patients alike. The Department will allow a transition period to deplete existing supply or previously packaged products.

One commentator wanted to add "resistant to moisture and contain acrylic adhesive" to subsection (d), claiming that it would provide specificity. After consideration, the Department will not act in response to this comment. "Moisture resistant" is a lower standard than "weather resistant" and as such, the "clarification" would mean lowering the standard. The higher weather resistant standard ensures the labeling will remain legible on the products as required by the act and regulations and speaks to patient safety.

Some commentators requested that the Department remove the requirement that labels include the number of individual doses or, instead, list mg/mL, citing lack of uniformity in dosing standards. The Department, however, is unable to facilitate the requested revision. The requirement that labels reflect the number of individual doses is found in the act itself. *See* 35 P.S. § 10231.801(i)(5). Accordingly, the Department will take no action in response to these comments.

One commentator requested that the Department require the labels to contain the number of individual doses contained within the package for ingestible medical marijuana products, which would be satisfied by including directions to an electronic link. After consideration, the Department will take no action in response to this comment. This information can be provided to patients via a medication information sheet to allow for sufficient clarity and readability of all the current label requirements.

#### *Subsection (e).*

This subsection specifies the design and other elements that may not be included on a label. This subsection mirrors the temporary subsection (e). No comments were received on this subsection and no changes were made from temporary to proposed to final-form.

#### *§ 1151a.35. Transportation of medical marijuana*

This section details transportation requirements, consistent with section 703 of the act, 35 P.S. § 10231.703. Deviations from the temporary § 1151.35 (relating to transportation of medical marijuana) are noted below.

Some commentators sought an addition to this provision to allow for the transportation of medical marijuana trim between grower/processors. The commentators asserted that trim would classify as "plant material," which may be transferred between grower/processors under section 702(a)(2) of the act. *See* 35 P.S. § 10231.702(a)(2). Further, the commentators articulated the benefits that trim's inclusion would provide in the form of increasing patient access to products, as other grower/processors could process the trim into medical marijuana products. This comment has been adopted by the addition of "postharvest plant material," which was added to section 702 of the act by Act 44 of 2021. 35 P.S. § 10231.702(a)(2.1). All references to transporting "medical marijuana" in final-form subsections (a) through (f) are eliminated to clarify that only seeds, plants, postharvest plant material, and medical marijuana products may be transported. This clarification is necessary as

the act, even as amended by Act 44 of 2021, does not allow for the transportation of finished but unpackaged pills, oils, gels, creams, ointments, tinctures, or liquids.

One commentator requested that the Department add a provision to require that deliveries be scheduled in advance, as to avoid multiple deliveries arriving at the same time. After careful consideration, the Department will take no action in response to this comment. The timing of deliveries is a policy decision for each permittee to make. In the same vein, permittees can create standard operating procedures to ensure the timing and orderliness of deliveries.

*Subsection (a).*

This subsection provides the guidelines for the transportation of medical marijuana seeds, plants, plant material, and medical marijuana products – transporting only between specified hours; allowing for third-party contracting; prohibiting transport outside the Commonwealth; and requiring use of GPS tracking. This subsection mirrors the temporary provision, except for replacing medical marijuana with postharvest plant material as explained above.

*Subsection (b).*

This subsection requires the vehicles used to transport medical marijuana to be insured, unmarked, and temperature controlled with secure cargo areas.

A commentor pointed out that subsection (b)(1) was inconsistent with the Department's revision to § 1161.35(b)(1) to require that vehicles transporting medical marijuana products be "equipped with a secure lockbox located within a locking cargo area." Given that the Department reverted § 1161.35(b)(1) to its original form, in response to multiple public comments, the two provisions now mirror each other. IRRC reiterated comments indicating that the requirement of having a secure lockbox or locking cargo area adds cost. However, all vehicles are already equipped with locking cargo or trunk areas.

The temporary subsection (b)(4) requires that vehicles engaged in the transportation of medical marijuana "[d]isplay current State inspection stickers and maintain a current State vehicle registration." This subsection was revised as proposed to read that transportation vehicles must "[m]aintain current State inspection and vehicle registrations." This revision allows for the possible elimination of inspection stickers in the future, as has been done with registration stickers.

This subsection otherwise mirrors the temporary provision, except for replacing medical marijuana with postharvest plant material as explained above.

One commentator requested that the Department increase the permissible size of 1'x1'x1' to accommodate more medical marijuana products when transporting products between grower/processor facilities. As such a requirement is not present in this provision or any other provision in these final regulations, the Department will take no action in response to this request.

*Subsection (c).*

This subsection, as proposed, required medical marijuana transport vehicles to be staffed with at least two individuals, one of whom must always remain with the vehicle, who: are licensed drivers, wear plain clothing, carry identification, and have access to communication. Per comments from IRRC regarding the use of non-regulatory language, the phrase "at least two" is replaced with "two or more" in final-form. For the same reason, the phrase "at least" is removed from final-form subsection (c)(1).

This subsection otherwise mirrors the temporary provision, except for replacing medical marijuana with postharvest plant material as explained above.

The Department received multiple comments, reiterated by IRRC, objecting to the requirement under this subsection of staffing two or more individuals performing transportation of medical marijuana. These comments largely focused on the financial burden of additional staffing, and one comment suggested that only trips over five hours should have additional staffing. After consideration, the Department will take no action in response to these comments. This requirement is reasonable and serves the dual purposes of safety and diversion prevention. Reducing the current standards would undermine those purposes. Further, permittees have been successfully operating under these requirements for the last five years.

*Subsections (d)-(h).*

These subsections provide that transportation vehicles are subject to inspection and require: products in transport must be concealed from outside view; direct transportation from a grower/processor facility to a medical marijuana dispensary or laboratory where unloading must promptly occur; a grower/processor must immediately report to the Department any accidents, losses, or diversions of product that occur during transport; and a grower/processor must daily notify the Department of its delivery schedule.

Subsection (d) is revised on final form, in response to comments, to state that products in transport "must be placed inside a secure lockbox or locking cargo area." This change clarifies that transport vehicles must be equipped with a lockbox or locking cargo area, and that these security devices must be utilized for transporting product to minimize opportunity for diversion. Per comments from IRRC regarding the use of non-regulatory language, the phrase "in a form and manner prescribed by the Department" is removed from subsections (f) and (g).

These subsections otherwise mirror the temporary provisions, except for replacing medical marijuana with postharvest plant material as explained above.

One commentator requested that the Department revise subsection (d) as to allow for both delivery and pickup within the same trip. This practice, however, is not prohibited by these regulations. Accordingly, the Department will take no action in response to this comment.

Some commentators, reiterated by IRRC, objected to what they believe to be excessive consequences of informing the Department of a reportable event under subsection (f). Specifically, the commentators cited to an instance wherein a grower/processor delivered medical marijuana products to an improper dispensary. After reporting this delivery error, the grower/processor was directed to recover and destroy the medical marijuana products as products returned to grower/processor are included in the definition of medical marijuana waste. The commentators object to what they believe to be severe and expensive consequences for delivering product to the wrong facility. In response, the definition of "medical marijuana waste" has been revised, as indicated above, to exclude this scenario from the definition and eliminate the destruction requirement.

*§ 1151a.36. Transport manifest*

This section, consistent with section 703 of the act, 35 P.S. § 10231.703, requires a grower/processor to generate and maintain an electronic transport manifest, documenting all deliveries. This transport manifest is subject to inspection by the Department upon request. Subsection (a) details the information that must be contained in the manifest. Subsection (b) details

specific chain of custody requirements for the transportation of seeds, plants, and other medical marijuana products. Subsection (c) specifies the transportation requirements for seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, and medical marijuana products. Subsection (d) requires a grower/processor to provide a copy of the manifest to the delivery recipient. Subsection (e) requires a grower/processor to provide a copy of the manifest to the Department and other governmental officials if requested. As proposed, this section mirrored the temporary § 1151.36 (relating to transport manifest) except for revising the citation in subsection (c) to refer to this new chapter. In final-form, all references to transporting "medical marijuana" are replaced with "postharvest plant material" consistent with Act 44 of 2021 and § 1151a.35.

The Department received multiple comments, reiterated by IRRC, questioning whether the term "shipping container" as used in this section, means the medical marijuana packaging. When the subsection is read in its entirety to include reference to seeds and plants needing to be packaged in shipping containers, the subsection refers to an appropriately sized shipping container other than the medical marijuana product packaging. Accordingly, the Department will take no action in response to these comments.

One commentator suggested to replace "shipping container" with "for shipment" to eliminate vagueness. The Department believes it has sufficiently addressed the vagueness issue and does not believe that the requested change would accurately reflect the requirement of a container in addition to medical marijuana product packaging. Accordingly, the Department will take no further action in response to this comment.

One commentator requested that medical marijuana organizations be permitted to manually override erroneous entries in the transport manifest. After consideration, the Department will not adopt the requested revision. To allow for medical marijuana organizations to manually tamper with the information in the transport manifest allows for possible diversion and/or unaccounted for medical marijuana products. Accordingly, the Department will take no action in response to this comment.

One commentator requested that the Department revise subsection (d) to require that a grower/processor must send the transport manifest to the dispensary in an appropriate amount of time prior to delivery. After careful consideration, the Department will take no action in response to this comment. The timing of deliveries (and sending of the transport manifest) is a policy decision for each permittee to make. In the same vein, permittees can create standard operating procedures to ensure the timing and orderliness of deliveries.

*§ 1151a.37. Transportation of seeds, immature medical marijuana plants, medical marijuana plants and postharvest plant material*

This section, consistent with section 702 of the act, 35 P.S. § 10231.702, provides that a grower/processor may only transport seeds, immature medical marijuana plants, medical marijuana plants, and postharvest plant material within this Commonwealth. As proposed, this section mirrored the temporary § 1151.37 (relating to transportation of seeds, immature medical marijuana plants and medical marijuana plants), except for revising three cross-references in subsection (c) to refer to this new chapter. In final-form, references to transporting "postharvest plant material" are added to be consistent with Act 44 of 2021 and § 1151.35.

The Department received a public comment, reiterated by IRRC, objecting to the Department not permitting grower/processors to transport final-form medical marijuana products or biomass to another grower/processor. This comment has been partially adopted by the addition of § 1151.24(e), allowing grower/processors to obtain and transport "postharvest plant material" from another



grower/processor, which was added pursuant to Act 44 of 2021. 35 P.S. § 10231.702(a)(2.1). The Department is unable to incorporate the remainder of the comment as section 702(a) of the act does not permit a grower/processor to transport final form medical marijuana products unless it is a clinical registrant. Compare 35 P.S. § 10231.702 and 35 P.S. § 10231.2002(b)(8).

*§ 1151a.38. Evidence of adverse loss during transport*

This section outlines a grower/processor's duties in the event of a discrepancy in the transport manifest upon delivery. This section also requires a grower/processor to report suspected theft or diversion of seeds, plants, or product to the Department; to investigate a discrepancy in the transport manifest; to amend its plan of operation if necessary to prevent future discrepancies; and to submit a report of the investigation to the Department. As proposed, this section mirrored the temporary § 1151.38 (relating to evidence of adverse loss during transport) except for adding "unresolved" to subsection (a). This change was made to eliminate required refusal of a delivery if the discrepancy is resolved. This revision eliminates unnecessary delay in grower/processors obtaining inventory, which will ultimately affect delivery of products to dispensaries and patients.

In final-form, all references to transporting "medical marijuana" are replaced with "postharvest plant material" consistent with Act 44 of 2021 and § 1151.35. Additionally, per comments from IRRC regarding the use of non-regulatory language, the phrase "in a form and manner prescribed by the Department" is removed from subsections (a) and (b).

*§ 1151a.39. Electronic Tracking System*

This section, consistent with section 701 of the act, 35 P.S. § 10231.701, provides that a grower/processor must use an electronic tracking system prescribed by the Department. As proposed, this section mirrored the temporary § 1151.39 (relating to electronic tracking system), except for omitting the obsolete language that the Department will provide notice of the electronic tracking system to be used by growers/processors, as the Department published this information in the *Pennsylvania Bulletin* at the time the system was implemented.

This section is revised in final-form to add language from Act 44 of 2021, providing that the system shall allow for two-way communication, automation and secure application-programming interface of a medical marijuana organization's enterprise resource planning, inventory, accounting and point-of-sale software, and allow for access to all data required to be transmitted to the Department to ensure compliance with the operational reporting requirements of the act and these regulations. 35 P.S. § 10231.701(c.1) (effective December 31, 2021).

One commentator, referencing an email sent to permittees wherein the Department stated that MJ Freeway would be the electronic tracking system of record for the medical marijuana program in the Commonwealth, asserted that regulations were being promulgated via email. This commentator, however, is mistaken. While the Department did send an email to that effect, it did so after publishing the same in the *Pennsylvania Bulletin*. 47 Pa.B. 2835 (May 13, 2017). <http://www.pacodeandbulletin.gov/Display/pabull?file=/secure/pabulletin/data/vol47/47-19/827.html>). As the commentator's concerns are misplaced, the Department will take no action in response to this comment.

IRRC asked the Department to explain how it administers the electronic tracking system required by the Act; whether a medical marijuana organization can use an API of its choosing to connect to the database; and to consider the suggestions of commenters as their concerns relate to the use of an API and the potential benefits of safety and efficiency that commenters contend can be realized. As indicated above, the Department's vendor, MJ Freeway, administers the electronic tracking system.

The system developed by MJ Freeway is compliant with all requirements of the act. Additionally, this section is revised, as described above, to allow the use of API integration pursuant to Act 44 of 2021.

*§ 1151a.40. Management and disposal of medical marijuana waste*

This section provides the obligations of a grower/processor with respect to the collection, storage, and disposal of medical marijuana waste. Specifically, all unused, surplus, returned, contaminated, or expired medical marijuana waste must be rendered unusable, unrecognizable, and incapable of ingestion and composted or disposed of according to municipal waste procedures or according to laws pertaining to hazardous waste. No changes were made to this section from temporary to proposed to final-form.

One commentator suggested revising this section to allow for the reprocessing of any unopened returned medical marijuana products. If the tamper evident seal is intact, the commentator believes the product is safe for reprocessing. IRRC also asked the Department to explain the need to destroy unopened, returned medical marijuana, and to address the fiscal impacts of this provision if it is retained in the final-form. As indicated above, the definition of “medical marijuana waste” has been revised to exclude unopened, briefly misdirected to the wrong dispensary, medical marijuana products from the definition, eliminating the destruction requirement and majority of fiscal impact to permittees. However, the Department will not allow further exception for products that have been dispensed and later returned. Like what one might expect in the pharmaceutical field, prescription medications that are returned cannot simply be repackaged and resold—they are destroyed. The Department maintains the same position in administering the medical marijuana program—*i.e.*, products dispensed and later returned to a grower/processor are considered waste and must be destroyed.

One commentator requested that the Department revise subsection (e)(3) to allow dispensaries to dispose of medical marijuana waste. After consideration, the Department will take no action in response to this comment. As described in subsection (c) of this section, grower/processors are responsible for the management and disposal of medical marijuana waste. Dispensaries do not have this responsibility, and the Department will maintain this current standard.

*§ 1151a.42. Complaints about or recall of medical marijuana products*

This section provides that in the event of a complaint of an adverse event from using medical marijuana, a dispensary must notify the Department and the grower/processor from which it purchased the medical marijuana and outlines the grower/processor's subsequent investigatory and reporting obligations. Further, this section addresses processes and procedures in the event of a voluntary or mandatory recall of medical marijuana or medical marijuana products, subject to penalties for noncompliance; specifies the information that must be entered into the electronic tracking system; and specifies the requirements of a recall plan.

Several changes were made at the proposed stage – adding a requirement to subsection (a)(1) that growers/processors must “immediately” investigate complaints and adding subsection (h) authorizing the Department to initiate a mandatory recall upon receipt of information that any medical marijuana product poses a risk to public health and safety. These amendments underscore the Department's goals of product quality and patient safety.

In final-form, references to “postharvest plant material” are added to be consistent with Act 44 of 2021. Per comments from IRRC regarding the use of non-regulatory language, the phrase “any other

information required by the Department" is removed from subsection (g)(10) as unnecessary, as all required reporting elements are listed in subsections (g)(1) through (g)(9).

One commentator, reiterated by IRRC, sought clarification as to what is contemplated using "condition" in subsection (h), asserting that the term is vague. The common, dictionary definition of the term is intended – i.e., the state of something with regard to its appearance, quality, or working order. Further, the term is qualified as meaning those conditions that "pose[] a risk to public health and safety." 28 Pa. Code § 1151a.42(h). While the Department declines to enumerate or otherwise identify the universe of conditions that would be considered to pose a risk to public health or safety, the Department will discharge its duties in making those determinations with patient safety as its primary consideration.

Some commentators, reiterated by IRRC, requested that the Department add a procedure to allow patients to report problematic products—i.e., seeds, fungus, other problems with products—to the Department. Such a procedure is already in place. Patients may report information to the Department via email or phone, as well as requesting a complaint form that may be submitted directly to the Department. As this procedure currently exists, the Department will take no action in response to these comments.

One commentator sought clarification as to when adverse events need to be reported, querying as to whether only "serious" adverse events need to be reported. In response, the regulations require reporting an "adverse event" as that term is defined in this regulatory packet.

One commentator requested that the Department revise subsection (a) to require a dispensary to notify the Department and a grower/processor of a product complaint "in a reasonable time" as opposed to the temporary regulatory requirement of providing notification "immediately." After consideration, the Department will take no action in response to this comment. If a dispensary receives a product complaint, it could be indicative of a serious issue, threatening patient safety. Thus, immediate notification is appropriate, to avoid any potential harm to patients.

#### *§ 1151a.43. Pesticides*

This section, consistent with section 702 of the act, 35 P.S. § 10231.702, requires that the use of pesticides by a grower/processor be in accordance with the applicable laws in this Commonwealth, subject to oversight by the Department and the Pennsylvania Department of Agriculture. Further, this section outlines the recordkeeping, record retention, and record production requirements associated with pesticide application, prescribes the pesticide active ingredients that a grower/processor may use, and defines terms relevant to this section, including select terms used in the statutes cited in this section. As proposed, this section mirrored the temporary § 1151.43, except that language was added in subsection (d) to clarify that the Department of Agriculture, which enforces the Pesticide Control Act, coordinates with the Department. In final-form, references to "postharvest plant material" are added to be consistent with Act 44 of 2021. In final-form, per comments from IRRC regarding the use of non-regulatory language, the phrase "at least" is removed from subsection (c)(2).

One commentator requested that the Department expand the list of pesticides acceptable for use on medical marijuana. This change was implemented per Act 44 of 2021 and will be continually reviewed as detailed in § 1151.27(a).

One commentator requested that the Department, in conjunction with the Pennsylvania Department of Agriculture, review the list of approved pesticides at least annually to ensure they remain accurate and applicable. Another commentator requested that the Department expand the list of pesticides acceptable for use on medical marijuana. IRRC also asked the Department to clarify

how this provision will be implemented, and to address the reasonableness of the provision in the final-form regulation. Substantial changes have been made, as explained above, in response to Act 44 of 2021, expanding permissible pesticides and allowing for regular updating of the list. This provision is reasonable, as it directly aligns with the new statutory language.

#### *§ 1151a.44. Treatment and quarantine orders*

This section provides that the Department, in conjunction with the Pennsylvania Department of Agriculture, may issue and carry out a treatment order against a grower/processor if the grower/processor fails or refuses to eradicate a plant pest found at its facility. Further, this section permits the Department of Agriculture, acting with the cooperation of the Department, to establish a quarantine, if necessary, to prevent the dissemination of plant pests and outlines the requirements in the event a quarantine is established. No comments were received on this section and no changes were made from temporary to proposed to final-form.

#### *Chapter 1161a. Dispensaries*

This chapter pertains to medical marijuana dispensaries and details: facility requirements; dispensing requirements and restrictions; licensed medical professionals at dispensary facilities; items and services provided; label verification and safety insert requirements; plans of operation; access to facilities; security and surveillance; requirements for inventory, storage, sanitation and safety, transportation, and electronic tracking system use; recall of medical marijuana products and applications for additional locations. This chapter, which tracks chapter 8 of the act, replaces the temporary Chapter 1161 (relating to dispensaries -- temporary regulations). New sections and amendments to sections of the temporary regulations are discussed more fully below.

#### *§ 1161a.22. Dispensaries generally*

This section provides that a dispensary is under a continuing obligation to meet the qualifications necessary to receive a permit. This section further provides that a dispensary may not engage in dispensing operations prior to being inspected and deemed operational by the Department, may not employ someone under the age of 18, and may not allow a patient to administer medical marijuana in the facility unless the patient is also an employee. As proposed, this section mirrored the temporary § 1161.22 (relating to dispensaries generally), except for revising a citation in subsection (b)(1) to refer to the new Chapter 1141a. No comments were received on this section and no changes were made from proposed to final-form,

#### *§ 1161a.23. Dispensing medical marijuana products*

This section details dispensing requirements, consistent with section 801 of the act, 35 P.S. § 10231.801. As proposed, this section mirrored the temporary § 1161.23 (relating to dispensing medical marijuana products). Subsection (a) is revised, on final form, to comport with Act 44 of 2021, which allows for curbside delivery. 35 P.S. § 10231.802(a)(1). This section further specifies the necessary prerequisites the dispensary must complete before dispensing medical marijuana products and before completing a transaction, including information that must be listed on a receipt and recordkeeping requirements. Subsection (b) is revised on final-form in response to a public comment requesting clarification that the dispensary's medical professional shall review the patient certification prior to dispensing, as only the medical professional has access to the patient certification and this obligation cannot be delegated to a non-medical professional.

One commentator sought the removal of subsection (b)(2)'s requirement that a dispensary review a patient's most recent certification prior to dispensing medical marijuana products to that individual.

This commentator asserted that the review is unnecessary, as it requires the dispensary's medical professional to review this certification and causes disruptions to other patient consultations. The Department, however, is unable to take any action in response to this comment. This regulatory provision is also found in the act itself and would require legislative change to remove. *See* 35 P.S. § 10231.801(f).

One commentator requested that the Department revise subsection (b)(2)(ii) to allow for patients to deny consultation with a dispensary's medical professional if no limitations are present on the patient certification. After consideration, the Department will take no action in response to this comment. Regardless of limitations present on the patient certification, the Department believes all patients can benefit from consulting with a medical professional before engaging in the purchase of medical marijuana products.

Another commentator queried as to whether a medical marijuana identification card qualifies as a valid identification to enter a dispensary—the answer is yes; medical marijuana identification cards are valid for purposes of entering a dispensary facility. *See* 35 P.S. § 10231.801(a).

One commentator requested that the Department revise subsection (c)(4) to remove the requirement that limitations on a patient certification be listed on the receipt, questioning the rationale behind its inclusion. The act itself requires that this information be included on the receipt and, accordingly, the Department cannot revise that requirement. *See* 35 P.S. § 10231.801(a). As the request requires legislative change, the Department is unable to take action in response to this comment.

#### *§ 1161a.24. Limitations on dispensing*

This section, consistent with section 801 of the act, 35 P.S. § 10231.801, provides that a dispensary may only dispense medical marijuana or medical marijuana products in a quantity or form provided for on the patient's certification and permitted by the act or these regulations. As proposed, this section mirrored the temporary § 1161.24 (relating to limitations on dispensing). Subsection (a)(3) is revised in final-form to incorporate changes made to sections 1201 and 1202 of the act by Act 44 of 2021, empowering the Board to change the forms of medical marijuana, with approval of the secretary and publication in the *Pennsylvania Bulletin*. 35 P.S. §§ 10231.1201 and 1202.

Subsection (b) is revised in final-form to reflect statutory amendment in Act 44 of 2021 to a 90-day supply. 35 P.S. § 10231.801(e). Additionally, in response to a public comment requesting to define a 30-day supply of medical marijuana, subsection (b) is further revised and provides that a 90-day supply is 192 medical marijuana units. The definition for "medical marijuana unit" is added in § 1141a.21.

One commentator sought clarification as to whether the certifying practitioner is the one providing limitations on forms of medical marijuana for patients. The answer is yes; the certifying practitioner may list certain limitations on a patient certification, and a dispensary may only dispense medical marijuana to a patient in the forms permitted under the patient certification. 35 P.S. § 10231.801(d)(1).

One commentator sought to remove (a)(1)'s requirement that a patient not be dispensed more than provided on the patient certification. This requirement is present in the act itself. *See* 35 P.S. § 10231.801(d). Accordingly, the Department is unable to take action in response to this request.

#### *§ 1161a.25. Licensed medical professionals at facility*

This section, consistent with section 801 of the act, 35 P.S. § 10231.801, details requirements for medical professional staffing at dispensaries. Further, this section provides training requirements and continuing education standards for physicians, pharmacists, physician assistants, and certified registered nurse practitioners. This section also prohibits a practitioner or physician from issuing patient certifications while at the facility.

Subsections (a) and (b), as proposed, provided that a physician or pharmacist must be present at the facility during operating hours and, if a permittee operates more than one facility under the same permit, a physician assistant or certified registered nurse practitioner may cover the other sites. These subsections are revised in final-form to reflect changes made in Act 44 of 2021, allowing a physician, pharmacist, physician assistant or certified nurse practitioner to be available either in person or by synchronous interaction. 35 P.S. § 10231.801(b).

Subsection (b) was revised at proposed stage to provide that a facility's "physician, pharmacist, physician assistant and certified registered nurse practitioner may rotate coverage of facilities as long as a physician or pharmacist is always either in person or by synchronous interaction, at one of the facilities." This addition clarifies that a dispensary authorized to operate more than one facility may allow the physician and pharmacist to rotate coverage to the secondary and tertiary dispensaries, as opposed to being limited to covering only the primary location.

One commentator sought to revise this section to allow a physician or pharmacist to be physically present at one facility location and be "virtually" present at the remaining locations with no need for other staffing at those other locations. Conversely, the Department received numerous comments from certifying practitioners, pharmacists, medical professionals, patients, and caregivers requesting the Department clearly define a 1:1 ratio of medical professionals at each dispensary site, because medical professionals cannot provide adequate care if they are constantly covering multiple dispensary locations and it is not in the best interest of the patients. That minimum ratio is enshrined in Act 44 of 2021, which provides that a physician or pharmacist shall be available at all times while a dispensary is open, and if a dispensary has more than one location, a physician assistant or certified registered nurse practitioner may be available, either in person or by synchronous interaction, at the other dispensary locations *in lieu of* the physician or pharmacist. *See* 35 P.S. § 10231.801(b). Some of these commentators even requested that the synchronous interactions be eliminated or limited to emergency situations. In response to these comments, subsection (b) is revised on final-form to include language specifying that one medical professional cannot cover more than one dispensary location regardless of whether in-person coverage or synchronous interaction. As it relates to the elimination or limitation of synchronous interactions, the Department takes no action in response to this request as the requested revision requires legislative change.

One commentator sought clarification as to the requirements under subsection (b) of this provision. Specifically, whether a pharmacist or physician must be present at each dispensary facility (assuming the dispensary permittee is approved to operate at more than one location). As the Department explained at the proposed stage, subsection (b) clarifies that a dispensary authorized to operate more than one facility may allow the physician and pharmacist to rotate coverage to the secondary and tertiary dispensaries, as opposed to being limited to covering only the primary location. The remaining locations may utilize the services of a physician assistant or a certified registered nurse practitioner.

One commentator sought to amend subsection (c) to require training every two years that includes relevant yearly updates of any amendments, announcements, etc. These medical professionals are required to meet continuing education requirements to maintain their licenses. As this training could be covered through continuing education requirements, the Department declines to implement this suggestion.

*§ 1161a.26. Dispensary facilities*

This section imposes restrictions with respect to dispensary facilities and amenities, consistent with section 802 of the act, 35 P.S. § 10231.802. It also provides that individuals under the age of 18 may not enter a dispensary unless the individual is a patient or accompanied by a parent, guardian, or caregiver. This section further provides signage requirements for specific areas of the facility.

No changes were made to subsection (a) from temporary to proposed. A comment from IRRC indicated that the phrase "as approved" by the Department in subsection (a) constituted non-regulatory language. Therefore, on final-form, the phrase is replaced with "that has been inspected and deemed operational" by the Department. Subsection (a) is further revised in final form to comport with Act 44 of 2021, which allows for curbside delivery. 35 P.S. § 10231.802(a)(1).

As proposed, subsection (b)(1) was revised to provide that a dispensary may not be located within 1,000 feet of "a public, private or parochial school, or a day-care center providing services to children under the age of 18, measured from the property line of a public, private or parochial school nearest to the dispensary to the nearest physical wall of the dispensary." This change clarifies that "school" is not intended to mean post-secondary schools and further defines how the 1,000-foot setback will be measured. This section retains the authority of the Department to waive this requirement per the act. 35 P.S. § 10231.802(b).

The Department received a comment of general opposition to the regulatory packet, raising myriad questions regarding safety. One such question, though not aimed at this provision specifically, queried as to protections for schools. This provision aims to accomplish protection for schools, as subsection (b)(1) requires that dispensary facilities be located more than 1,000 feet away from public, private, or parochial schools, as well as day care centers providing services to minors. Additionally, similar protections and other provisions germane to schools can be found in the act itself. *See* 35 P.S. §§ 10231.802(a)(3), 10231.2104. As protections are already provided in the act and final regulations, the Department takes no action in response to this request.

Subsection (e)(1) was revised as proposed to replace the word "visitors" with "individuals." This change is to remove references to "visitors," as discussed elsewhere in this Preamble.

No changes were made to subsections (c), (d) and (f) from temporary to proposed to final-form.

The Department received numerous comments regarding the Department replacing the word "visitors" with "individuals" in subsection (e) of this provision. Commentators objected on the basis that this change would require dispensaries to purchase and implement new signage to comply, asserting that the new signage would cost thousands of dollars. If the Department were to retain the usage of "individuals," commentators sought adequate time to order and hang the new signage. After consideration, the Department takes no action in response to this comment. The commentators' concerns related to cost are dependent largely on the permittee, not the Department. Although this provision contains specifications related to size and content of the signage, it does not require a specific type of signage—*i.e. paper vs. metal*. Any exorbitant costs related to acquisition of new signage would be a result of a permittee's preference, not regulatory requirement.

Some commentators suggested that the Department revise this section to allow patients to be assisted into dispensaries and with transactions by an individual who cares for the patient but who is not an approved caregiver within this program. These commentators requested allowing a family member to help a patient who needs such assistance without having to undergo approval as a caregiver. After consideration, the Department takes no action in response to these comments.

Allowing unknown third parties to enter dispensaries with patients undercuts the secure nature of dispensary facilities. Patients needing assistance are best served: (1) through an approved caregiver under this program, or (2) dispensary staff.

*§ 1161a.27. Items and services provided at a dispensary*

This section details restrictions on sales of products and devices at dispensaries and substantially revises the temporary § 1161.27 (relating to items and services provided at a dispensary), as detailed below.

*Subsection (a).*

This subsection provides that a dispensary may only dispense medical marijuana in forms prescribed in § 1161a.23(b)(2) (relating to dispensing medical marijuana products). This subsection mirrors the temporary provision, except for amending the regulatory citation to refer to this new chapter.

*Subsections (b) and (c).*

These subsections respectively provide that a dispensary may only purchase medical marijuana products from a grower/processor and that, with prior written approval from the Department, a dispensary may sell instruments, devices, and services related to the use of medical marijuana products. No changes were made to these subsections from temporary to proposed to final-form.

Some commentators requested that the Department create a procedure to allow patients to request that dispensaries be permitted to sell certain medical marijuana devices, as opposed to only dispensaries being able to make the request. Patients may already engage in such a practice by asking their dispensary of choice to seek approval from the Department to sell certain medical marijuana devices. As the dispensary ultimately determines the products and devices it sells after Department approval, patients seeking the addition of specific devices are better suited to convey this to the dispensary who may then request approval under subsection (b). This, too, alleviates one commentator's concern that patients would have to make stops at different stores to buy different products/items.

*Subsection (d).*

This subsection provides that a dispensary may dispense a medical marijuana product with a THC concentration of 0.3% or less so long as the dispensary purchases it from a grower/processor. This subsection, at proposed stage, provided that dispensaries may dispense a medical marijuana product with a THC concentration of less than 0.3% if purchased from a grower/processor that has obtained prior Department approval. Consistent with the changes made in response to public comments to remove the industrial hemp exclusion from the definition of marijuana, this subsection is revised in final form to remove the requirement for a grower/processor to obtain Department approval to sell to a dispensary a medical marijuana product with a THC concentration of 0.3 % or less.

The Department received a comment seeking clarification on whether subsection (d) allows grower/processors to offer hemp-based CBD products to be sold in dispensaries. In accordance with the statutory changes implemented by Act 44 of 2021, grower/processors may obtain harvested hemp that passes the testing requirements from a person holding a permit issued by the Department of Agriculture to grow or cultivate hemp and may produce hemp-based medical marijuana products to be sold in dispensaries.



*Subsection (e).*

This subsection proscribes certain actions for dispensaries. Specifically, dispensaries may not (1) provide medical marijuana product at no cost unless the patient is approved for financial assistance by the Department; (2) make purchases conditional upon the patient purchasing a medical device at the facility or a separate facility; (3) deliver, or contract with a third party, to deliver medical marijuana; and (4) sell items and services unrelated to the use of medical marijuana products. As proposed, this subsection removed the prohibition on advertising activities, as that provision caused confusion. The removal of this subsection does not, however, negate the general requirement in § 1141a.50(b) (relating to advertising by a medical marijuana organization) that all promotional, advertising, and marketing materials must be approved by the Department prior to use. Further, the prohibition on delivering medical marijuana products was revised, as proposed, to prohibit a dispensary from contracting delivery to third parties, in addition to prohibiting a dispensary from delivering to a patient or caregiver. Finally, an additional prohibition on the sale of items unrelated to the use of medical marijuana was added at the proposed stage. These revisions seek to limit the services a dispensary may provide to a patient or caregiver that are unrelated to the sale of medical marijuana products. No changes were made to this subsection from proposed to final-form.

One commentator objected to subsection (e)(2)'s prohibition on providing patients medical marijuana products at no cost or free unless the patient is approved by the Department for financial assistance. This commentator believed that patients who are participating in a research study should receive products at no cost. After consideration, the Department takes no action in response to this request. While the Department maintains its position that no-cost or free products may not be dispensed, the permittee is free to set its own pricing models for certain classes of patients—*i.e.*, low-cost medical marijuana products to those individuals participating in research studies. As permittees retain broad authority to reduce patient expenses as they see fit, the Department will make no revision in response to this comment.

Another commentator requested that the Department allow percentage and dollar amount of discounts to be disclosed to patients to provide more transparent notice to patients and reduce patient costs, in addition to wishing to sell non-medical marijuana related promotional items to patients, subject to Department approval. The prohibition on advertising of discounts has been removed. However, the prohibition of sales of items unrelated to the use of medical marijuana remains, as dispensaries should be limited to sale of only medical marijuana-related products.

The Department received comments in opposition to 1161a.27(e)(3)'s prohibition on dispensaries delivering, or contracting with a third party to deliver, medical marijuana to patients. These commentators believe in allowing for delivery under the medical marijuana program. After consideration, the Department takes no action in response to these comments. Currently, the act allows for patients to designate caregivers for themselves, and those caregivers are permitted to deliver medical marijuana to a patient's residence. *See* 35 P.S. § 10231.103. As the act currently allows for a means of delivery through caregivers, the Department declines to extend delivery services.

One commentator sought clarification as to whether dispensary employees are permitted to become caregivers under the medical marijuana program. The answer is yes; there is no provision in the act or these regulations that would prohibit a dispensary employee from becoming a caregiver, provided the individual passes the background check requirement.

*§ 1161a.28. Labels and safety inserts*

This section sets forth the requirements of what must, and what may not, be listed on a label, in subsections (c) and (d), respectively, in addition to requiring, in subsection (b), that any product sold to a patient be fully sealed and labeled. Further, subsection (c) requires a dispensary to inspect labels to ensure that the label contains all required information and is firmly affixed to the container holding medical marijuana, and subsection (e) prescribes standards for safety inserts. This section tracks section 801 of the act, 35 P.S. § 10231.801(i). This section mirrors the temporary § 1161.28 (relating to labels and safety inserts) with two exceptions, as detailed below.

Subsections (c)(6) and (15) were revised at proposed stage to add the requirements that all cannabinoids and terpenes and corresponding percentages be listed on the label and that a label be firmly affixed to a container directly holding medical marijuana. These revisions seek to ensure that law enforcement may readily discern the difference between packaging containing legitimate medical marijuana and illegal substances, in the event of a patient's interaction with law enforcement. In addition, the changes provide patients and caregivers with more information regarding the products they seek to purchase. In response to a comment regarding subsection (c)(15), pointing out that a dispensary may not open a sealed outer package to inspect the inner label, this subsection is further amended on final-form by changing "and" to "or."

Further, per comments from IRRC regarding the use of non-regulatory language, the phrase "any other information required by the Department" is removed from subsection (c)(14) and is replaced with "a process lot identification number." This additional information is the only other labelling requirement under § 1151.34 that does not currently appear in subsection (c). Subsection (e)(6) is removed on final-form as unnecessary since all patient safety requirements are listed.

The Department received numerous comments regarding this provision's requirement that safety inserts be provided with every dispensing event. These commentators assert that this requirement is wasteful, leading to unnecessary costs for the permittee. The Department, however, is unable to take any action in response to these comments, as the regulatory requirement is contained in the act. *See* 35 P.S. § 10231.801(h).

Another commentator, though not referencing a specific regulatory provision, requested that the Department require patients to be informed about risks of harm associated with medical marijuana. The Department believes this provision, in conjunction with others, provides patients with sufficient notice of potential risks. Beyond receiving a safety insert under this provision during every dispensing event, patients are informed of these risks prior to receiving a patient certification from a practitioner. *See* 28 Pa. Code § 1181a.27(c)(11). As patients are informed prior to using medical marijuana and every time they are dispensed medical marijuana, the Department takes no action in response to this comment.

Other commentators requested that the Department remove the requirement that labels include the number of individual doses, citing lack of uniformity in dosing standards. The Department, however, is unable to incorporate the requested revision. The requirement that labels reflect the amount of individual doses is found in the act itself. *See* 35 P.S. § 10231.801(i)(5). Accordingly, the Department is unable to take action in response to these comments. Similarly, another commentator objected to the inclusion of *all* terpenes on the label. This, however, is required for the sake of patient safety, as patients need to know what they are about to consume, as to avoid any form of an adverse reaction. Accordingly, the Department takes no action in response to this comment.

One commentator requested that labels include allergy warnings. This change was incorporated in § 1151.34(b).

Some commentators, including IRRC, sought removal or explanation of the requirement to include plant species on the label. This requirement is found in the act and would require legislative change to remove. *See* 35 P.S. § 10231.303(b)(8). As indicated above, a clarifying definition of “species” has been added. Although permittees may experience incremental cost increases related to complying with these requirements, the Department must prioritize the express intent of the legislature: patient safety.

Some commentators, including IRRC, asserted that the information required will not readily fit on a label, and will require very small, possibly unreadable, print. IRRC asked the Department to explain the reasonableness of this requirement and to address the fiscal impact and implementation timeframe. The Department is requiring labeling of these additional cannabinoids at the request of patients, who understand the significance of different cannabinoids and how they work on the endocannabinoid system. It is reasonable for patients to know which products contain their preferred cannabinoid, and in what amount. Labeling space is not constraining, as many permittees are already making use of accordion-style labels that are common in the pharmaceutical industry. Since many permittees are already using accordion-style labels, the fiscal impact should be negligible, and no additional time needed for implementation. However, the Department will allow a transition period to deplete existing supply.

#### *§ 1161a.29. Plans of operation*

This section provides that upon the Department determining a dispensary to be operational, the dispensary must provide the Department with its plan of operation. This section outlines what must be included in a plan of operation and requires that a dispensary provide its plan of operation to the Department during inspections of the site and facility and at any time upon request. This section mirrors the temporary § 1161.29 (relating to plans of operation) with two exceptions, as detailed below.

As proposed, subsection (a)(2)(ii) replaced the word “visitors” with “individuals requiring access to the facility.” This change is to remove references to “visitors” wherever possible, as discussed elsewhere in this Preamble. Additionally, subsection (c) was added at proposed stage to require a dispensary to comply with its plan of operation. This addition ensures that a dispensary adheres to the plan of operation submitted to the Department, in addition to informing the Department as to how a dispensary would handle specific events. No comments were received on this section and no changes were made from proposed to final-form.

#### *§ 1161a.30. Access to dispensary facilities*

This section restricts access to dispensary facilities. Several substantive changes are made to the temporary § 1161.30 (relating to visitor access to dispensary facilities), as detailed below.

##### *Title*

Temporary § 1161.30 is entitled: “Visitor access to dispensary facilities.” As proposed, the title was changed to: “Access to dispensary facilities.” This change removes the term “visitor” to emphasize that dispensaries are not open for general visitation.

##### *Subsection (a).*

The temporary subsection (a) provides that a dispensary must post a sign at each entrance indicating that the premises are under continuous video surveillance and that no one under the age of 18 is permitted to enter unless the individual is a patient or accompanied by a parent, guardian, or

caregiver. The proposed amendments added language to the sign indicating that only employees, patients, and caregivers may enter, and that anyone under the age of 18 entering the dispensary must be a patient and accompanied by a parent, guardian or caregiver. The Department received numerous public comments regarding this change, from the regulated and patient communities and from IRRC. The regulated community opposed the change due to the costs associated with having to print new signage. The patient community opposed the inability to bring minor children into the dispensary, which created the need for childcare to obtain medication, especially for single parents. After careful consideration, the Department agrees to abandon this proposed revision and to continue allowing minor children to accompany parents or guardians in the dispensary. Accordingly, subsection (a) is revised in final-form to revert to the language contained in the temporary provision.

*Subsection (b).*

Subsection (b) originally mirrored the temporary subsection (b) and provided that only authorized employees may enter limited access areas in a dispensary. Based on public comments received as noted above, this subsection is revised in final-form to provide that only patients, caregivers, and authorized employees of a dispensary may enter a limited access area, except as provided in subsections (a), (c) or in section 1161a.26(d). This revision clarifies the Department's intent that only employees and cardholders may enter the dispensary unless specifically authorized elsewhere in the regulations.

*Subsection (c).*

The temporary subsection (c) provides that "visitors" must present a government-issued photo identification to enter a dispensary. As proposed, this subsection eliminated the word "visitor" consistent with the Department's removal of the term "visitor" from the regulations. The new language clarifies that the subsection applies to any individual who is not approved to enter the facility who requires access to provide goods and services to the facility and requires the individual to sign a log and detail the need for entry to the facility. The Department received a public comment suggesting that certifying practitioners should be permitted to accompany patients to dispensaries to assist with product selection. In response, this subsection is further amended on final-form to add: "to assist a patient with product selection as the certifying practitioner" as a valid reason to enter a dispensary. Additionally, the identification of a certifying practitioner must match the name and medical credentials documented on the accompanied patient's certification.

One commentator objected to the proposed changes in this provision, though not specifically referencing this regulatory subsection, and requested that dispensaries be permitted to allow visitors subject to the existing identification, log, and escort protocols, citing the need of media, government officials, researchers, consultants, investors, and academic institutions to see and appreciate the sophistication of dispensing floors for the continued evolution and betterment of medical marijuana operations. To remain consistent with IRRC's requested amendment of section 1151a.25 to address the issue of access for individuals such as prospective principals, financial backers, operators or employees of the organization, local first responders, local law enforcement, lawmakers, and others who may need to enter a medical marijuana organization for legitimate purposes such as information gathering, training, or orientation, subsection (c) is revised on final-form to include "or for potential investment or employment when patients and caregivers are not at the dispensary" as reasons to allow entry. The Department understands the business necessity to allow potential investors or potential employees to be on site, however, it must protect the confidentiality of the patients and caregivers accessing these dispensaries, and therefore, limits access to these individuals at times when patients and caregivers are not present. The remaining classes of individuals are already permitted entry under subsection (f).

#### *Subsection (d).*

Subsection (d) details a dispensary's obligations when admitting an individual to its facility, such as requiring the entrant to sign a log detailing the need for entry and to wear a temporary identification badge while in the facility. Like § 1151a.25 (relating to access to grower/processor facilities), proposed subsection (d) revised the temporary subsection (d) to replace the term "visitor" with "individual." No additional changes were made from proposed to final-form.

One commentator objected to this subsection's requirements that an individual's name and company name be listed on a temporary identification badge. After consideration, the Department declines to adopt the requested revision. All requirements under this subsection—including those to which the commentator objects—are in place to ensure that individuals with an appropriate business purpose are permitted to enter and traverse through a facility. As this requested revision threatens facility safety and security, the Department declines to implement the suggestion.

#### *Subsection (e).*

This subsection provides the content and retention requirements for the log that individuals must sign upon entry to a dispensary. Consistent with the rest of this section, proposed subsection (e) replaced the word "visitor" with words or phrases like corresponding revisions to other subsections in this section.

The Department received a comment from IRRC regarding the need to require maintenance of logs for four years and questioned whether the log could be maintained electronically. In response, the Department reduces the storage requirement on final-form to one year and clarifies that the log may be maintained electronically. Additionally, the date is added as a required entry on the log.

#### *Subsection (f).*

This subsection provides that nothing in § 1161a.30 will limit the right of the Department or its authorized agents, State or local law enforcement, or other Federal, State or local government officials from entering any area of a dispensary site or facility, if entrance is necessary to perform their functions and duties that pertain to the act or this part. At proposed stage, the phrase "that pertain to the act or this part" was added to the end to clarify that the official governmental duties must be related to the act or regulations. No changes were made from proposed to final-form.

One commentator queried as to whether firefighters are included in "government officials" for the purposes of this section—the answer is yes, and they are permitted to enter if necessary to perform their duties.

#### *Subsection (g).*

Subsection (g) provides that dispensary employees or other affiliated persons may not be compensated for granting access to a limited access area. As proposed, the only change to the language of the temporary subsection (d) was the replacement of the word "visitor" with "individual," consistent with the rationale explained above. No comments were received on this subsection and no changes were made from proposed to final-form.

#### *§ 1161a.31. Security and surveillance*

This section requires that a dispensary establish and maintain security and surveillance systems to the specifications provided within this section. Further, this section prescribes lighting requirements

and limits access to rooms containing surveillance monitoring equipment. Changes to this section are detailed below.

On final-form, per comments from IRRC regarding the use of non-regulatory language, the phrase "at least" in subsections (a)(1)(viii) and (a)(2)(ii) is replaced with "no less than." For the same reason, the phrase "at least" is removed from subsections (b)(3) and (c). Subsection (b)(3) is further revised on final-form, in response to a comment from IRRC, to clarify that the records may be maintained in paper or electronic form. In light of the clarification that records may be retained electronically, no change is made to the time frame, as fiscal impact for retaining electronic records, even for four years, will be minimal.

Subsection (a)(2) is revised on final-form to require "continuous" surveillance per the statutory change made in Act 44 of 2021. 35 P.S. § 10231.802(a)(1.1). The Department received numerous comments, including from IRRC, regarding the cost imposed by subsection (a)(4) requiring storage of all video surveillance for two years. The storage requirement is reduced to 180 days, unless otherwise required for investigative or litigation purposes, per Act 44 of 2021. 35 P.S. § 10231.802(a)(1.1). Due to the statutory amendment, the Department is unable to reduce the storage requirement to 90 days as suggested by multiple commentors.

The Department received a comment seeking to remove subsection (b)(5)'s requirement that a grower/processor designate employees to continually monitor the security and surveillance system at the facility. This commentator finds this monitoring provision to be duplicative of the requirement, under subsection (a), that the security system be professionally monitored—*i.e.*, monitored by a third party. *See* 28 Pa. Code § 1161a.31(a)(1). IRRC also questions the need for this requirement. This requirement is needed because employees monitoring the system at the facility will be able to respond immediately to issues without delay caused by a third-party offsite vendor needing to contact the facility. Immediate response to a security breach is in the best interest of facility safety and security, and the Department will not take any action that lessens the safety and security of these facilities.

Subsection (c) was revised at proposed stage to allow dispensaries to designate multiple employees to continuously monitor the security and safety of a facility, whereas the temporary provision only permits the designation of one employee. This revision provides dispensaries greater flexibility in ensuring the efficacy of their security systems while also not requiring the monitoring of these systems by a single person. Subsection (c) was also revised at proposed stage to require that a dispensary install "commercial grade, nonresidential doors and door locks" on all external doors of the facility. This change ensures the safety and security of each facility.

Subsection (d) was revised at proposed stage to require that entrances to, and exits from, a dispensary be locked at all times as opposed to just during non-working hours. This change ensures the safety and security of facilities.

The Department received comments seeking to remove 1161a.31(d)'s requirement that all entrances and exits for a dispensary facility remain securely locked at all times. These commentators cited difficulty of access to a facility as burdens caused by the provision. After consideration, the Department takes no action in response to these comments. The requirement under 1161a.31(d) is aimed towards maintaining the safety and security of dispensary facilities. The Department will not make concessions that compromise facility safety and security.

Another commentator suggested revision to subsection (d)'s requirement that facility doors be securely locked at all times. This commentator suggested that doors being securely locked at all times is harmful to conducting business, in addition to presenting a safety issue in the event of a fire. The

Department disagrees. The regulated community has ably operated under this requirement, and the Department sees no benefit to removing this requirement. Moreover, the Department also does not believe the locked-door requirement presents a safety issue in the event of a fire. Locked doors serve as an impediment from *entry* into a facility, not exit from a facility. Accordingly, the Department takes no action in response to this comment.

IRRC asked the Department to explain how implementation of the final-form regulation will protect the public health, safety, and welfare. Requiring locked doors at these facilities will help to prevent unauthorized entry, theft and diversion of product into the black market.

#### *§ 1161a.32. Inventory data*

This section lists the inventory information that must be maintained in the electronic tracking system. In addition, this section requires a dispensary to establish inventory controls, conduct monthly reviews and annual comprehensive inventories and specifies what information must be recorded as a result of inventory reviews. This section mirrors the temporary § 1161.32 (relating to inventory data). No comments were received on this subsection and no changes were made from temporary to proposed to final-form.

#### *§ 1161a.33. Storage requirements*

This section provides that dispensaries must have separate and locked limited access areas for the storage of defective medical marijuana products, as described in this section. This section also provides that all storage areas must be maintained in a clean and orderly condition. As proposed, this section mirrored the temporary § 1161.33 (relating to storage requirements), except for revising a citation in subsection (a) to refer to the new Chapter 1151a. No comments were received on this subsection and no changes were made from proposed to final-form.

#### *§ 1161a.34. Sanitation and safety in a facility*

Subsections (a) and (b) prescribe sanitation requirements and expectations for a dispensary facility and employees therein; subsections (c) and (d) require adequate bathroom and hand-washing facilities; and subsection (e) requires a dispensary to comply with all State and local building codes. As proposed, this section mirrored the temporary § 1161.34 (relating to sanitation and safety in a facility), except that "28 Pa. Code" was added to correct the incomplete citation in subsection (b) and the word "visitor" was deleted from subsections (c) and (d) for the reasons explained elsewhere in this Preamble. No comments were received on this subsection and no changes were made from proposed to final-form.

#### *§ 1161a.35. Transportation of medical marijuana products*

This section provides that a dispensary may deliver medical marijuana products to medical marijuana organizations, subject to requirements delineated in subsection (a). This section also outlines the requirements with respect to the storage of medical marijuana products during transportation in subsection (b); delivery drivers in subsection (c); and transportation in subsections (d) and (e). Further, subsections (f) and (g) impose reporting requirements for specified events, and subsection (h) subjects transport vehicles to inspection at the Department's request.

As proposed, subsection (b)(1) was amended to require vehicles transporting medical marijuana products to be "equipped with a secure lockbox located within a locking cargo area," rather than the requirement in temporary subsection (b) that such vehicles be "equipped with a secure lockbox or locking cargo area." Multiple public comments were received regarding the unnecessary cost

associated with this new requirement. Upon careful consideration, the Department agrees to revert to the original language contained in the temporary regulation. Accordingly, subsection (b)(1) is revised in final-form to mirror the temporary provision. However, subsection (d) is revised on final-form to state that products in transport "must be placed inside a secure lockbox or locking cargo area." This change clarifies that not only must transport vehicles be equipped with a lockbox or locking cargo area, but that these security devices must be utilized for transporting product to minimize opportunity for diversion. IRRC reiterated comments indicating that the requirement of having a secure lockbox or locking cargo area adds cost. However, all vehicles are already equipped with locking cargo or trunk areas. Further, subsection (b)(4) was revised at proposed stage to require transport vehicles to maintain current state inspection and vehicle registrations, whereas the temporary regulation requires current vehicle registration and the display of a state inspection sticker. This revision allows for the possible elimination of inspection stickers in the future, as has been done with registration stickers.

The Department received multiple comments, reiterated by IRRC, objecting to the requirement under subsection (c) of staffing two or more individuals performing transportation of medical marijuana. These comments largely focused on the financial burden of additional staffing, and one comment suggested that only trips over five hours should have additional staffing. After consideration, the Department will take no action in response to these comments. This requirement is reasonable and serves the dual purposes of safety and diversion prevention. Reducing the current standards would undermine those purposes. Further, permittees have been successfully operating under these requirements for the last five years.

Per comments from IRRC regarding the use of non-regulatory language, the phrase "at least two" in final-form subsection (c) is replaced with "two or more." For the same reason, the phrase "at least" is removed from final-form subsection (c)(1) and the phrase "in a form and manner prescribed by the Department" is removed from final-form subsections (f) and (g).

#### *§ 1161a.36. Transport manifest*

Subsections (a) and (b) provide that every transport vehicle shall generate a transport manifest; specifies the information that must be contained in the manifest; and details requirements for delivery to multiple facilities. As proposed, subsection (c) requires all medical marijuana products be transported in a secure lockbox located within a locked cargo area, whereas the temporary regulation requires that the product be packaged in a shipping container. As indicated above, multiple public comments were received regarding the unnecessary cost associated with this new requirement. Upon careful consideration, the Department agrees to further revise the language on final-form to mirror § 1161.35(b)(1).

Subsection (d) requires a dispensary to provide a copy of the manifest to the delivery recipient. Subsection (e) requires a dispensary to provide a copy of the manifest to the Department and other governmental officials if requested. No changes were made to these subsections from temporary to proposed to final-form.

One commentator requested that medical marijuana organizations be permitted to manually override erroneous entries in the transport manifest. After consideration, the Department will not adopt the requested revision. To allow for medical marijuana organizations to manually tamper with the information in the transport manifest allows for possible diversion and/or unaccounted for medical marijuana products. As the requested change threatens product safety, the Department takes no action in response to this comment.

#### *§ 1161a.37. Evidence of adverse loss during transport*



This section outlines a dispensary's duties in the event of an unresolved discrepancy in the transport manifest upon delivery. This section also requires a dispensary to report suspected theft or diversion of product to the Department; to investigate a discrepancy in the transport manifest; to amend its plan of operation, if necessary, to prevent future discrepancies; and to submit a report of the investigation to the Department.

The temporary subsection (a) provides that a dispensary must refuse acceptance of a delivery in the event of any discrepancy in the transport manifest. As proposed, subsection (a) requires a dispensary to refuse delivery only when the discrepancy has not been resolved. This revision eliminates unnecessary delay in product delivery to dispensaries and, ultimately, to patients. Per comments from IRRC regarding the use of non-regulatory language, the phrase "in a form and manner prescribed by the Department" is removed from final-form subsections (a) and (b). No other changes were made from proposed to final-form.

#### *§ 1161a.38. Complaints about or recall of medical marijuana products*

This section provides that dispensaries must notify the Department and the grower/processor from which it purchased the medical marijuana product immediately upon becoming aware of a complaint made to the dispensary by an individual who experienced an adverse event resulting from use of a medical marijuana product. If the grower/processor were to recall the product, the dispensary is required to cease dispensing the item in question and coordinate a return of the recalled product. No changes were made to this section from temporary to proposed to final-form.

Some commentators, reiterated by IRRC, requested that the Department add a procedure to allow patients to report problematic products—*i.e.*, seeds, fungus, other problems with products—to the Department. Such a procedure is already in place. Patients may report information to the Department via email or phone, as well as requesting a complaint form that may be submitted directly to the Department. As this procedure currently exists, the Department takes no action in response to these comments.

Another commentator requested that we define what adverse events require immediate reporting under this section. All adverse events must be immediately reported, and "adverse event" is a defined term. *See* 28 Pa. Code § 1141a.21.

#### *§ 1161a.39. Electronic tracking system*

This section, consistent with section 701 of the act, 35 P.S. § 10231.701, provides that a dispensary must use an electronic tracking system prescribed by the Department. As proposed, this section mirrored the temporary § 1161.39 (relating to electronic tracking system), except for omitting the obsolete language that the Department will provide notice of the electronic tracking system to be used by dispensaries, as the Department published this information in the *Pennsylvania Bulletin* at the time the system was implemented. This section is revised in final-form to add language from Act 44 of 2021, providing that the system shall allow for two-way communication, automation and secure application-programming interface of a medical marijuana organization's enterprise resource planning, inventory, and accounting and point-of-sale software, and allow for access to all data required to be transmitted to the Department to ensure compliance with the operational reporting requirements of the act and these regulations. 35 P.S. § 10231.701(c.1) (effective December 31, 2021). This revision addresses several comments received regarding the use of API integration.

Another commentator requested that medical marijuana be included within Pennsylvania's Prescription Drug Monitoring Program (PDMP), so practitioners may consult its database to review a patient's controlled substance history prior to beginning treatment involving the use of medical

marijuana. While the Department takes no action towards adding medical marijuana to the PDMP database, it notes that the practice of reviewing the patient's history of controlled substance treatments is already required. Specifically, section 403(c.1) of the act allows for practitioners to access the PDMP to review a patient's controlled substance history during a consultation. 35 P.S. § 10231.403(c.1). Adding medical marijuana to the PDMP, however, is prohibited, as cardholder information is deemed confidential under the act. 35 P.S. § 10231.302(a).

One commentator, though not citing a specific regulatory provision, requested that patients have access to lab analyses from medical marijuana testing. The Department, however, is unable to adopt the requested revision. The lab analyses are contained within the electronic tracking system, and that information is deemed confidential by the act. *See* 35 P.S. § 10231.701(c). As the requested revision requires legislative change, the Department will take no action in response to this comment.

IRRC asked the Department to explain how it administers the electronic tracking system required by the Act; whether a medical marijuana organization can use an API of its choosing to connect to the database; and to consider the suggestions of commenters as their concerns relate to the use of an API and the potential benefits of safety and efficiency that commenters contend can be realized. As indicated above, the Department's vendor, MJ Freeway, administers the electronic tracking system. The system developed by MJ Freeway is compliant with all requirements of the act. Additionally, this section is revised, as described above, to allow the use of API integration pursuant to Act 44 of 2021.

One commentator requested guidance on how an approved laboratory is able to establish an API connection to MJ Freeway. Act 44 allows medical marijuana organization permittees, not laboratories, to establish that gateway. As the requested revision requires legislative change, the Department will take no action in response to this comment. *See* 35 P.S. § 10231.701(c.1).

#### *§ 1161a.40. Additional dispensary locations*

This section provides that an applicant for a dispensary permit may identify a primary location and up to two additional dispensary locations in its application, or at a later date, using a form prescribed by the Department and following the initial permitting requirements set forth in § 1114a.29 (relating to initial permit application), subject to the payment of fees specified in subsection (c) and the Department's approval. No changes were made to this section from temporary to proposed. In final-form, subsection (f), allowing a dispensary to interchange the designation of a primary, secondary or tertiary location, was added and the title of this section revised, to effectuate changes made to § 609 of the act by Act 44 of 2021. 35 P.S. § 10231.609(b).

#### *Chapter 1171a. Laboratories*

This chapter pertains to laboratories and details the approval process; suspension, revocation and renewal of approval; testing requirements; sampling procedures; selection protocols; test results and reporting requirements; transportation of samples; advertising restrictions; and ownership prohibitions. This chapter is consistent with section 704 of the act, 35 P.S. § 10231.704, and replaces the temporary Chapter 1171 (relating to laboratories -- temporary regulations). New sections and amendments to sections of the temporary regulations are discussed more fully below.

#### *§ 1171a.22. Laboratories generally*

This section prohibits a laboratory from collecting or testing medical marijuana samples unless the laboratory has been approved by the Department under § 1171a.23 (relating to approval of laboratories) and has a written contract with the grower/processor under § 1171a.29 (relating to

testing requirements). This section requires the Department to post a list of approved laboratories on its website and provides general requirements with respect to: (1) laboratory duties; (2) director responsibilities and employee qualifications; (3) prohibitions on ownership; (4) duration of the Department's approval; and (5) nontransferability of the Department's approval. As proposed, this section mirrored the temporary § 1171.22 (relating to laboratories generally), except for revising citations in subsection (a) to refer to this new chapter. Subsection (g) is added on final-form to reflect that laboratory testing requirements also apply to harvested hemp pursuant to Act 44 of 2021. See 35 P.S. §§ 10231.702(a)(4) and (704).

In final-form, per comments from IRRC regarding the use of non-regulatory language, the first phrase "at least one" in subsection (c) is replaced with "a" and the second is replaced with "one or more."

One commentator sought clarification to the contractual requirement under this section. Specifically, the commentator noted that, on some occasions, grower/processors do not have a formal contract with a specific laboratory, but instead bill for goods and services on a case-by-case basis. To the extent those practices exist, they are in violation of the act, as section 704 requires that grower/processors and laboratories enter into a contract. 35 P.S. § 10231.704. While the commentator suggests that a non-contractual relationship may allow for better business relationships, legislative change would be required to remove the requirement. As the request requires legislative change, the Department will take no action in response to this comment.

#### *§ 1171a.23. Approval of laboratories*

This section provides that a laboratory wishing to become an approved laboratory must submit a completed application to the Department, including the information required in subsections (b) and (d), the submission of which amounts to consent to an investigation of any person, information, or location the Department deems appropriate to approve or deny the application. The subsection adds that the application is available on the Department's public website. Under this section, the Department may grant approval based upon its determination that the applicant is financially and professionally suitable to conduct the required testing.

As proposed, this section mirrored the temporary § 1171.23 (relating to approval of laboratories), except for revising a citation in subsection (b)(8) to refer to this new chapter. Per comments from IRRC regarding the use of non-regulatory language, the phrase "in a form and manner prescribed by the Department" is removed from final-form subsection (a) and new language is added advising that the application may be found on the Department's web site. No other changes were made from proposed to final-form.

One commentator sought clarity as to what qualifies as "professionally suitable," as used in this provision. The Department views ISO 17025 Certification as sufficient for determining professional suitability under this section.

#### *§ 1171a.24. Suspension or revocation of an approval issued to a laboratory*

This section provides that the Department may suspend or revoke a laboratory's approval if the laboratory engages in unethical practices, fails to maintain proper standards for reporting accuracy, or fails to comply with the act or this part. Further, this section delineates other conduct for which the Department may revoke a laboratory's approval. No comments were received on this section and no changes were made from temporary to proposed to final-form.

#### *§ 1171a.25. Renewal of an approval issued to a laboratory.*

This section provides the timeframe in which an approved laboratory must submit an application for renewal. As proposed, this section mirrored the temporary § 1171.25 (relating to renewal of an approval issued to a laboratory), except for revising a citation to refer to this new chapter. No changes were made on final-form.

One commentator asked how often laboratories need to submit for renewal, as well as with how many labs a grower/processor will contract. As to the first question, labs must renew every two years. *See* 28 Pa. Code § 1171a.22. As to the second question, grower/processors must contract with a minimum of two laboratories to comply with the testing requirements required by these regulations.

#### *§ 1171a.26. Stability testing and retention of samples*

As proposed, this section mirrored the temporary § 1171.26 (relating to stability testing and retention of samples) and provided that an approved laboratory must conduct required stability testing of samples collected from growers/processors to ensure product potency and purity and accurate expiration dating, and that the laboratory must properly store those tested samples for one year.

Revisions are made on final-form to reflect changes made to section 704 of the act by Act 44 of 2021. 35 P.S. § 10231.704(b). Subsection (a) is revised to provide that a grower/processor shall retain a sample from each process lot to ensure product potency and purity and accurate expiration dating. Subsection (b) is revised to reflect that stability testing will be done at six-month intervals if the product remains in inventory at a dispensary. Subsection (c) is revised to require the grower/processor, rather than the laboratory, to store a sample from each process lot for subsequent stability testing for the duration of the expiration period.

One commentator requested that the Department modify the retention requirements for harvest batches, suggesting that laboratories should only be required to maintain a sample of only one harvest batch, as opposed to the temporary regulatory requirement of maintaining a sample from *each* harvest batch. This commentator noted that the revision would align with the current pharmaceutical practice of sample retention. Due to the statutory change, which now requires stability testing only on process lots, implementation of this comment is unnecessary.

Other commentators requested revision of the required stability testing under this section. These commentators requested that stability testing be required at one year only if there is product left in inventory (or removed entirely), citing unnecessary expenses related to testing if no product remains in inventory. IRRC also asked the Department to explain the rationale for and reasonableness of testing requirement at six- and twelve-month intervals and the need to perform stability testing under subsection (c) if a product is no longer in inventory. As explained above, the act has been amended to require stability testing at six-month intervals as long as unexpired product remains in inventory. 35 P.S. § 10231.704(b).

With the above reasoning provided, the Department is unable to remove the entire provision as requested by one commentator. In addition to the changes implemented in Act 44 of 2021, these requirements are in the best interest of patient safety, as they ensure high-quality consumer standards.

In addition to requesting clarification on whether grower/processors are required to retain every stability sample for all medical marijuana products, or only those that are currently in their inventory, one commentator expressed concerns on where a grower/processor was to store these samples as well as how to track them when delivered to third-party dispensaries. After consideration, the Department takes no action in response to this comment. As it relates to the first question, grower/processors are

required to retain a sample from each process lot for the duration of the expiration period listed on the medical marijuana product. As it relates to storage and tracking, notwithstanding any enumerated regulatory requirements, these types of internal business decisions are better left to each grower/processor to determine what meets the individual needs of the facility.

*§ 1171a.27. Sampling procedures for testing*

Subsection (a) requires a laboratory to ensure its employees follow established sample preparation procedures. Subsections (b) and (c) outline the elements that a laboratory's policies and sampling procedures must include. As proposed, this section mirrored the temporary § 1171.27 (relating to sampling procedures for testing).

On final-form, per comments from IRRC regarding the use of non-regulatory language, the phrase "at a minimum" is removed from subsection (b). Per concern from IRRC regarding the incorporation of the laboratory guidance into the regulations as an Appendix to be updated by publication of periodic notices in the *Pennsylvania Bulletin*, the Department on final-form incorporated testing methods and standards into this rulemaking. Subsection (b)(2) is revised on final-form to reflect that samples must be representative of the harvest batch, harvest lot or process lot. Subsection (b)(3) is added on final-form to address that the amount being removed from a sample must be based on applicable statistical criteria established under the standards in § 1171a.29.

One commentator suggested that the sampling procedures provided by the Department under subsection (b)(2) do not actually exist as a requirement under testing in § 1171a.29, rendering the "Guidance for Quality Testing and Sampling by Approved Laboratories" moot. The Department revises the previous subsection (b)(2) to require the samples be representative of the harvest batch, harvest lot or process lot as established under the standards in the revised final-form § 1171a.29.

One commentator, though not referencing a specific provision, also sought clarification on the sample preparation "test portion," "analytical unit," or "analytical portion" for microbial samples. The Department has incorporated the testing methods established under the American Herbal Pharmacopoeia's "Cannabis Inflorescence Standards of Identity, Analysis and Quality Control", 2014 Revision Edition. Laboratories must meet or exceed the minimum standards found within this resource.

*§ 1171a.28. Selection protocol for samples*

This section provides that an employee of an approved laboratory may enter a grower/processor facility for the purpose of identifying and collecting samples, subject to procedures regarding chain of custody and permitting access to limited access areas for these purposes. This section also specifies the samples that a laboratory employee must identify and collect from a grower/processor facility. As proposed, this section mirrored the temporary § 1171.28 (relating to selection protocol for samples). Subsection (c)(4) is added on final-form pursuant to Act 44 of 2021. 35 P.S. § 10231.704(b).

In response to one commentator requesting clarification on whether employees of an approved laboratory are permitted to collect research and development samples and are permitted to visit a grower/process facility as part of ongoing account management and/or business development purposes, without collecting compliance samples, subsection (a) is revised on final-form by moving "only" to clarify that approved laboratories may access a grower/processor facility under this subsection as well as § 1151a.25(a). An employee of an approved laboratory is permitted to enter a grower/process facility under § 1151a.25(a) for purposes regarding "testing," which may include

aspects of the contractual relationship of the approved laboratory. The final-form regulations also permit approved laboratories to collect samples for research and development. *See* § 1171a.29(c)(3).

One commentator requested clarification to multiple sections found within tables of the previously proposed laboratory guidance attached in the appendix of the originally submitted final-form rulemaking. The Department takes no action in response to these comments as the tables are no longer included as part of the annex and the standards to be followed are incorporated into this chapter.

Commentators, reiterated by IRRC, opposed as unnecessary and more stringent than other states, the requirement for testing of medical marijuana at the time of harvest and before the product is sold to a dispensary. However, the act specifically requires the two tests. 35 P.S. § 10231.704(a).

#### *§ 1171a.29. Testing requirements*

This section details testing requirements. Several changes are made to the temporary § 1171.29 (relating to testing requirements), as detailed below.

##### *Subsections (a) and (b).*

These subsections provide that an approved laboratory must have a written contract with a growers/processor prior to conducting testing and submit a request for testing through the electronic tracking system. No changes were made to these subsections from temporary to proposed to final-form.

##### *Subsection (c).*

The temporary subsection (c) specifies that an approved laboratory must minimally test two samples at harvest and at process stages. Subsection (c) was amended at proposed stage to provide that one approved laboratory must conduct testing on the harvest sample and a different approved laboratory must conduct testing on the processed sample. This revision creates checks and balances in the testing process.

The Department received a comment from IRRC regarding use of several non-regulatory phrases in subsection (c). To clarify, subsection (c) is revised on final-form by removing the phrases "at a minimum" and "as prescribed by the Department." Subsection (c)(3) is also added on final-form in response to comments from the regulated community requesting that additional non-mandatory testing be permitted.

One commentator expressed confusion as to the number of required tests under this subsection, incorrectly believing that four tests are required—two at harvest, and two at process. In actuality, the number of required tests is two—one at harvest, and one at process.

The Department received a plethora of public and legislative comments, including additional comments submitted after the original submission of this final rulemaking, reiterated by IRRC, regarding the new requirement that different labs perform the harvest lot and process lot tests. These comments raised myriad objections relating to the cost, optics, and need for this new requirement. IRRC asked the Department to: (1) explain why it believes the language of Section 704 of the Act allows for testing of harvest batches and final product by two different approved laboratories; (2) provide a more detailed explanation of the specific problems it has encountered with the existing testing protocols and how testing by two different approved laboratories solves those problems; and

(3) quantify the costs for growers/processors associated with entering into a contract with a second approved laboratory.

Regarding (1), Act 44 of 2021 specifically revised section 704 to require a grower/processor to contract with “one or more independent laboratories” to test medical marijuana. 35 P.S. 10231.704(a). Regarding (2), the Department frequently hears allegations from patients that lab results are inflated to reflect higher THC percentages than the product actually contains. While commentators correctly point out that Pennsylvania's medical marijuana program has not seen widespread corruption in the testing of medical marijuana, other states have experienced these issues. For example, FiveThirtyEight recently published an article highlighting the issues of lab testing across the country. Black, Lester. (June 29, 2021). America’s Pot Labs Have a THC Problem. Retrieved from <https://fivethirtyeight.com/features/americas-pot-labs-have-a-thc-problem/>. Similarly, a class action lawsuit was filed on July 12, 2022, alleging a laboratory has violated federal racketeering law by intentionally overstating the amount of THC in the medical marijuana products it sells to patients in Arkansas. See <https://www.classaction.org/news/class-action-alleges-steep-hill-overstated-amounts-of-thc-in-medical-marijuana-sold-to-arkansas-patients>. Instead of giving the same issues an opportunity to fester within the Commonwealth's medical marijuana program, the Department is proactively insulating the program from such issues.

Regarding (3), permittees are currently required to conduct two lab tests and the only change being made is that two different labs conduct those tests. As such, there should be no increase in operating costs. At least one permittee asserted that labs lower costs when quantity increases, making it financially prudent to use the same lab. However, since all permittees will have to comply with the new requirement to use different labs, it is expected that labs will adjust their pricing accordingly.

#### *Subsections (d), (e), and (f).*

These subsections provide the minimum elements for which a laboratory must test; that testing samples must be conducted with a statistically significant number and size of samples and methodologies approved by the Department; and that testing is prohibited on samples in the delineated circumstances. As proposed, these subsections mirrored the temporary regulatory provisions.

On final-form, per comments from IRRC regarding the use of non-regulatory language, the phrase “at a minimum” is removed from subsection (d) and “heavy metals” and “mycotoxins” are added in subsection (d)(7) and (d)(8), respectively, as samples are currently being tested for heavy metals and mycotoxins. Additionally, in response to a comment from IRRC regarding the use of non-regulatory phrases, “with methodologies acceptable to the Department” in subsection (e) is replaced with “with approved methodologies.” The phrase “[a]ll testing methods must be fully validated to address the accuracy, precision, specificity, linearity, range, and sensitivity of the testing method” is also added to subsection (e) to ensure sampling and testing meet the approved methodologies established within in this chapter. Subsection (e.1) is added to expressly exclude PCR testing as an approved methodology. Finally, IRRC opposed the unclear phrase “any other factor” in subsection (f). Accordingly, the phrase “any other factor sufficient to render the findings of questionable validity” is replaced with “any other obvious circumstance that compromises the sample.”

#### *Subsection (g).*

This subsection (g) specifies tracking and disposal requirements. Temporary subsection (g) requires that all tests be entered into the electronic tracking system. As proposed, subsection (g) provided that only testing performed on samples of harvest lots and process lots must be entered into the electronic tracking system, allowing for additional non-mandatory testing to be performed

without being entered into the electronic tracking system. Many permittees requested the ability to conduct additional testing prior to harvesting. This subsection was further amended on final-form to account for the addition of subsection (c)(3) and to make clear that these non-mandatory tests need not be entered into the electronic tracking system. Additionally, a citation was amended at proposed stage to refer to this new chapter and the new Chapter 1151a.

One commentator queried as to why grower/processors may want additional testing and not have to enter the test results into the electronic tracking system. The purpose behind the allowance of additional testing is requests from the grower/processors to allow for testing to occur for research and development purposes, which would fall outside of those tests currently required by the act to be entered into the electronic tracking system.

One commentator sought clarification as to which test result goes on the label. The correct test to be displayed on the label is the process lot test.

One commentator requested that harvest lot testing occur only once per year per strain. After consideration, the Department is unable to take action in response to this comment, as the act requires a test at each harvest. 35 P.S. § 10231.704(a).

#### *§ 1171a.30. Standards for testing*

This section requires that an approved laboratory follow the methodologies, ranges, and parameters that are contained in the scope of the certificate of accreditation issued to the laboratory and in accordance with this chapter. As proposed, this section mirrored the temporary § 1171.30 (relating to standards for testing). On final-form, the phrase "contained in" is changed to "consistent with." This change was made in response to a comment pointing out that the certificate of accreditation does not detail the laboratory's testing scope. The phrase and "in accordance with this chapter" is added in subsection (a) to address all laboratory testing methodologies and standards enumerated in the entire chapter. Additionally, in response to a comment from IRRC regarding the non-regulatory phrase "acceptable to the Department," the phrase is removed.

One commentator, though not referencing a specific provision, asserted that qPCR testing for yeast and mold is inadequate as it does not require the additional incubation time used by the plating method. The commentator states that qPCR is not fit for "quantitation of organisms" and is used for compliance in the interest of speed rather than efficacy. Another commentator directly opposed this qPCR conclusion, reasoning that (1) "qPCR can detect a wider array of fungal pathogens as most pathogens do not culture," (2) qPCR allows for internal controls that safeguard against misinterpreting negative results from failed results, (3) "qPCR assays used in cannabis industry have more public and open access data for evaluation than any test on the marketplace," and (4) it would be premature to make technology choices before the standards have been established in the marketplace. Based on the Department's research, qPCR was deemed an acceptable testing method. Accordingly, the Department will make no changes.

#### *§ 1171a.31. Test results and reporting*

This section details test reporting requirements. Several changes are made to the temporary § 1171.31 (relating to test results and reporting), as detailed below, in addition to changing citations to reflect this new chapter and the new Chapter 1151a (relating to growers/processors).

##### *Subsection (a).*

This subsection lists the tests to which the testing requirements of the chapter apply: testing on harvest lots and process lots. As proposed, subsection (a) mirrored the temporary provision. In



response to a public comment requesting that only a laboratory sampling agent handle the samples to ensure adherence to § 1151a.28(c), proper sanitary techniques and recording methods, subsection (a)(2) is revised in final-form to remove "either an employee of a grower/processor or" so that the language mirrors subsection (a)(1). This change emphasizes that only the laboratory employee should be selecting samples for testing.

#### *Subsection (b).*

Temporary subsection (b) requires all test results to be entered into the system. This subsection has been amended at proposed stage to clarify that only test samples collected under § 1171.28(c) were required to be entered into the electronic tracking system. This amendment allows a permittee to conduct additional testing outside of the two required to be entered into the system. Subsection (b) was revised on final-form to account for the addition of non-mandatory testing under § 1171.28(c), to clarify that only testing performed on harvest lots and process lots are required to be entered into the electronic tracking system.

The Department received a public comment, citing concerns that grower/processors will abuse the research and development testing. Specifically, this commentator stated that if a sample were to fail testing, the grower/processor would deem it as a research and development test, whereas if the sample passes testing, the grower/processor would deem it as a harvest test to be entered into the electronic tracking system. The commentators' concerns cannot occur as a grower/processor must designate the nature of the sample—research and development or harvest/process—*prior to* receiving the results from the approved laboratory. As this prevents grower/processors from adjusting the purpose of the test after receiving results, the Department takes no action in response to this comment.

One commentator informed the Department that if laboratory "a" tests the harvest lot and laboratory "b" tests the same harvest lot, both test results are visible to both laboratories in MJ Freeway. The Department investigated and confirmed that test results are only visible to the testing laboratory.

#### *Subsection (c).*

This subsection (c) provides the procedure for a sample that fails testing and allows a failed sample to be re-tested by the same laboratory. If the initially failed sample were then to pass re-testing, subsection (c)(2) requires a different laboratory to confirm that passing test. Subsection (3) requires disposal of the sample if the Department declines to accept the confirming results. As proposed, this subsection mirrored the temporary provision, except for adding the term "confirming" to subsection (c)(3) as a grammatical clarification and revising citations to refer to this new chapter and new Chapter 1151a.

On final-form, subsection (1.1) is added to provide that if a re-tested sample fails again, the lot is required to be disposed of in accordance with § 1151a.40 (relating to management and disposal of medical marijuana waste) unless the grower/processor opts to process the failed lot, failed for yeast or mold only, into a topical form under section 702(a)(3) of the act, 35 P.S. § 10231.702(a)(3). This language is added pursuant to Act 44 of 2021.

One commentator sought clarification on retesting procedures, citing that the regulations would create a "bottleneck" of products that fail an initial test, but pass subsequent tests. IRRC asked the Department to: (1) include language in the final-form regulation that clarifies and specifies what criteria will be used to implement this provision and determine if a result is unsatisfactory; and (2) explain the overall need for changes being made to this subsection, including the requirement that a

second approved laboratory confirm the test results of the first approved laboratory when retesting occurs. Regarding (1), to address how the Department will decide whether to accept a confirming passing result, subsection (c)(2.1) is added to detail the Department's considerations in determining whether to accept re-test results. The changes to this section are necessary to eliminate opportunities to manipulate test samples or test results and to keep patients safe. For these reasons, the Department is hesitant to simply release a previously failed batch or lot based solely on a confirming passing result and, therefore, requests this additional information with patient safety in mind. These requests for additional information sometimes result in a grower/processor abandoning its request to have a batch or lot released, apparently due to inability to provide one or more requested item. Some delays related to testing, reporting of information, and Department acceptance of those results, are a necessary element in ensuring that the product reaching the patient community is safe and of the highest quality. Additionally, Act 44 of 2021 allows for a different path for the processing of certain failed lots. 35 P.S. § 10231.702(a)(3).

Another commentator requested that if a sample fails an initial test, the grower/processor should be permitted to choose the laboratory to conduct a re-test. Additionally, this commentator (and others) sought to remove the Department's ability to reject test results under subsection (c)(3), citing a lack of criteria of when the Department would not accept test results. First, the grower/processor is permitted to choose the re-testing laboratory after an initial failed test. Further, subsection (c)(2.5) now lays out the Department's considerations in determining whether to accept re-test results.

One commentator objected to subsection (c)(3)'s requirement that lots that fail re-testing under this provision shall be disposed of, asserting that the requirement is more stringent than testing standards present in other states with a medical or recreational marijuana program. The commentator asserts that these burdensome standards subject the grower/processor to excessive costs and delays in the event of a failed test. Without directly stating as much, this commentator appears to suggest that grower/processors should have the option to remediate product to avoid disposal. Given that certain failed lots may be processed per Act 44 of 2021, 35 P.S. § 10231.702(a)(3), the Department takes no additional action on this comment.

Another commentator, though not referencing a specific provision, requested remediation following failed microbiological tests, allowing processing into medical marijuana infused products. Given that certain failed lots may be processed per Act 44 of 2021, 35 P.S. § 10231.702(a)(3), the Department takes no further action on this comment.

#### *Subsection (d).*

This subsection requires a grower/processor to notify the Department and the approved laboratory of its intent to re-test a sample that failed a test or test another sample from the same harvest batch, harvest lot, or process lot. No changes were made to this subsection from temporary to proposed to final-form.

One commentator requested the deletion of the requirement under subsection (d) of this provision for testing laboratories to notify the Department when the grower/processor makes the decision to retest a failed sample because the seed-to-sale tracking system already provides notice. Review of subsection (d) reveals no requirement for the laboratory to notify the Department. Rather, subsection (d) requires the grower/processor to notify the Department and the laboratory of the intent to re-test through the electronic tracking system. Accordingly, the Department takes no action on this comment.

#### *Subsection (e).*

This subsection (e) requires a laboratory to provide a grower/processor a certificate of analysis that reports the results of the testing, which must include the delineated information. As proposed, subsection (e) mirrored the temporary provision, except for using abbreviations and adding additional cannabinoids that must be included in the analysis.

On final-form, per comments from IRRC regarding the use of non-regulatory language, the phrases "as determined by the Department" in subsections (e)(1) and (e)(2) are removed. Subsection (e)(1) is revised to include "approved" and (e)(2) is revised to include "approved maximums" as the test results must meet or exceed the testing standards established under § 1171a.30. Further, in response to a public comment, "when applicable for process lot" is added to subsection (e)(2)(iv)(D) to account for the fact that moisture is not tested in certain processed products like oils and tinctures. Also, in response to a public comment, subsection (e)(2)(iii) is revised to add e. coli and salmonella, as the standards established in § 1171a.30(b) require testing for these bacteria.

One commentator requested that the Department add testing for Shiga-toxin producing *Escherichia coli* (STEC 1 and STEC 2) and *Salmonella Enterica* species, in addition to specifying that those contaminants and *Aspergillus Flavus*, *Aspergillus Fumigatus*, *Aspergillus Niger* and *Aspergillus Terreus* shall be absent in one-gram samples. In response, the Department uses the standards for testing established under § 1171a.30. The Department will continue to review and update the standards and methods of testing as appropriate. Therefore, the Department takes no action on this comment.

One commentator wished to remove the testing of those cannabinoids found in subsections (1)(vii), (1)(viii), and (1)(x) of this subsection, reasoning that only the remaining cannabinoids should require listing. After consideration, the Department declines to adopt this comment. As the cannabinoids do not have to be listed if the level is 0.0%, these cannabinoids may not need to be listed if they are not present within the tested sample.

One commentator requested the Department define total yeast mold count to ensure proper testing methodologies are employed. Contaminant limits can be found in the newly added resource for testing methods under § 1171a.30.

#### *Subsection (f)*

This newly added subsection addresses an approved laboratories duty to immediately report pesticides that exceed the normal or acceptable limits. Subsection (f)(1) provides the limit of quantification for pesticides. Subsection (f)(2) the sample size to analyze for residual pesticides.

#### *Subsection (g)*

This new subsection is added to allow the Department the oversight needed to ensure approved laboratories are reporting test results in the manner established under Chapter 1171a. *See* 35 P.S. § 10231.704(a).

#### *§ 1171a.32. Quality assurance program*

This section requires that an approved laboratory establish and implement a quality assurance program to ensure accuracy and delineates the components that the quality assurance program must include. As proposed, this section mirrored the temporary § 1171.32 (relating to quality assurance program). In final-form, per comments from IRRC regarding the use of non-regulatory language, subsection (a) is revised to clarify that devices must be calibrated annually or more frequently if recommended by the manufacturer.

### *§ 1171a.33. Transporting samples*

This section requires that the samples must be transported in accordance with §§ 1151a.35 and 1151a.36 (relating to transportation of medical marijuana; and transport manifest). Further, this section requires that samples be transported from a grower/processor to an approved laboratory in a manner that adequately protects the integrity and composition of the samples from outside interference. As proposed, this section mirrored the temporary § 1171.33 (relating to transporting samples), except for revising citations in subsection (a) to refer to the new Chapter 1151a.

On final-form, in response to a public comment requesting clarification, "process lot" is removed from subsection (b) to clarify that all samples, not just process lot samples, must be transported in a manner that protects the sample's integrity. Additionally, in response to comment from IRRC opposing the phrase "other environmental factors that may work to jeopardize the integrity of the sample," the phrase is replaced with "any other circumstance that appears to have compromised the sample."

The Department received a comment objecting to the requirement under this subsection of staffing two or more individuals performing transportation of medical marijuana. These comments largely focused on the financial burden to perform the additional staffing, and one comment suggested that only trips over five hours should have additional staffing. After consideration, the Department declines to adopt these comments. This requirement is done for the dual purposes of safety and diversion prevention. Reducing the current standards would pose a threat to those purposes.

The Department received another comment requesting to remove "grower/processor or third-party contractor" from this section, presumably to avoid someone other than the laboratory employee from selecting the sample. The Department declines to implement this comment because § 1171a.28 requires the laboratory employee to identify and collect the sample.

### *§ 1171a.34. Department request for testing*

This section provides that the Department, in its discretion, may identify and collect samples for testing by an approved laboratory, and the approved laboratory must provide a written report of the results within seven days or sooner if requested by the Department. No comments were received on this section and no changes were made from temporary to proposed to final-form.

### *§ 1171a.35. Laboratory reporting*

This section requires laboratories to enter test results into the electronic tracking system. As proposed, citations were amended to refer to this new chapter. Other changes are detailed below.

#### *Subsection (a).*

This subsection lists the specific information a laboratory must enter into the electronic tracking system when testing a sample. The temporary provision required reporting on all samples. As proposed, this subsection was revised to only pertain to samples collected pursuant to § 1171a.28(c) (relating to testing of samples from harvest lots and process lots). On final-form, this subsection is further revised to account for the addition of non-mandatory testing under § 1171.28(c), to clarify that only testing performed on harvest lots and process lots are required to be entered into the electronic tracking system.

One commentator asserted that the system does not provide a way or section to insert the information in (3), (4), and (5). The Department verified with MJ Freeway that the system does allow for entry of this information.

*Subsection (b).*

This subsection provides that an approved laboratory must maintain a certificate of analysis for four years. As proposed, subsections (b)(1) and (c) were added to address test results not required to be entered into the electronic tracking system. These provisions require an approved laboratory to immediately provide to the Department an electronic copy of a certificate of analysis for those test results that are not required to be entered into the electronic tracking system and allow the Department to conduct an investigation based on the results of a certificate of analysis. Further, the second sentence of subsection (b) was amended as subsection (b)(2).

The Department received public comments seeking clarification on subsection (b)(1)'s requirement that certificates of analysis for test results not entered into the electronic tracking system be immediately provided to the Department by the laboratory performing the test. These commentators thought this requirement to be excessive, given the burden it would impose upon laboratories and the quantity of data that the Department would receive. Another commentator expressed concerns that the mandatory reporting of test results may disclose the intellectual property of grower/processors utilizing this testing for research and development purposes, with another commentator asserting that the reporting violates their business' privacy rights. After consideration, the Department makes no change in response to these comments. The purpose underlying this requirement is to serve as a safeguard from potential abuse. Given the additional testing that grower/processors may now request outside of the two that are required to be entered into the electronic tracking system, the Department seeks to remain informed of the results of those tests to ensure that grower/processors are not conducting numerous tests on the same lot until it achieves passing results. Moreover, the act requires the Department establish an electronic database to, *inter alia*, "[m]onitor[] all growth, transfer, possession, processing, *testing* and dispensing of medical marijuana." 35 P.S. § 10231.301(a)(4)(iv) (emphasis added). Given the act's express authority to track testing, the asserted invasion of privacy and alleged compromise of intellectual property rights does not merit further revision of the language.

IRRC asked the Department to explain the need for subsection (b)(1)'s requirement that certificates of analysis for test results not entered into the electronic tracking system be immediately provided to the Department by the laboratory performing the test; how a laboratory is to comply; and to clarify how the provision will be implemented. To clarify how a laboratory is to comply with this requirement, "by email" is added to final-form subsection (b)(1). A dedicated email address will be provided to approved laboratories once established. This provision is necessary because these test results will not be entered into the electronic tracking system and requiring submission of these additional test results will allow the Department to monitor whether the same sample is being repeatedly tested until a passing result is achieved.

Another commentator cited confusion with this subsection and sought clarification. This commentator, however, did not indicate exactly what portion of this subsection caused the confusion. The Department believes this subsection, as previously written (and subsequently amended) is straightforward and, accordingly, takes no action in response to this comment.

*Subsection (c).*

This new subsection (c) provides that the Department may conduct an investigation based on the results of any certificate of analysis. This subsection is added to ensure product quality and patient safety.

#### *§ 1171a.36. Advertising*

This section prohibits a laboratory from advertising or promoting its services to the general public. This section clarifies that personal solicitation by a laboratory employee is considered advertising or promotional marketing. It also provides that a laboratory may only advertise to a grower/processor those services performed on site, subject to prior Department approval. Further, this section provides that a laboratory may erect signage at its facility, subject to compliance with local zoning requirements and this section. This section mirrors the temporary § 1171.36 (relating to advertising). No changes were made from temporary to proposed to final-form.

One commentator queried as to whether a laboratory contacting a grower/processor would be considered advertising. The substantive reason for the contact would dictate whether the contact constitutes advertising; solicitation constitutes advertising, per subsection (b). However, a laboratory is permitted to call a grower/processor as it relates to testing results.

#### *§ 1171a.37. Ownership prohibition*

This section delineates those individuals who may not have a management, financial (direct or indirect), or other ownership interest in an approved laboratory. No comments were received on this section. On final-form, “postharvest plant material” is added to subsection (4) consistent with Act 44 of 2021 and § 1151a.35.

#### *§ 1171a.38. Appeals*

This section provides that all actions of the Department under this chapter are governed by Chapter 5, Subchapter A of 2 Pa.C.S. and its accompanying regulations, as modified by Chapter 1230a. As proposed, this section mirrored the temporary § 1171.38 (relating to appeals), except for amending a citation to refer to the new final Chapter 1230a (relating to practice and procedure). No comments were received on this section and no changes were made from proposed to final-form.

### *Chapter 1181a. Physicians and Practitioners*

This chapter, which tracks chapter 4 of the act, pertains to practitioner registration, training requirements, and prohibitions, issuance and revocation of patient certifications. This chapter replaces the temporary Chapter 1181 (relating to physicians and practitioners -- temporary regulations). New sections and amendments to sections of the temporary regulations are discussed more fully below.

IRRC reiterated a commenter who stated that terms “practitioner” and “physician” appear to be used interchangeably in the regulations and asked the Department to review the use both terms throughout the rulemaking to ensure usage is clear and appropriate. The term “practitioner” is defined in Section 103 of the act as a physician who is registered with the department under section 401. 35 P.S. § 10231.103. Since “physician” is not defined in the act, it is defined in § 1141a.21 of these regulations as “the term as defined in section 2 of the Medical Practice Act of 1985 or section 2 of the Osteopathic Medical Practice Act.” Careful review of each term used throughout the regulations reveals that the terms are not used interchangeably. Rather, “physician” is used when referring to the individual who has not yet registered under section 401 of the act. “Practitioner” is used when referring to an individual who has already registered under section 401 of the act.

#### *§ 1181a.22. Practitioners generally*

This section requires that a practitioner must meet continuing qualifications to be registered with the Department and may not issue patient certifications prior to becoming registered. This section also requires a practitioner to notify the dispensing dispensary of a patient's adverse reaction to medical marijuana. Further, this section permits a practitioner to petition the Medical Marijuana Advisory Board to review any proposed change to the currently listed serious medical conditions for which medical marijuana could be beneficial. As proposed, this section mirrored the temporary § 1181a.22, except for revising the citation in subsection (b) to refer to this new chapter; deleting reference to the statute in subsection (d); and deleting the last sentence of subsection (d) as the Medical Marijuana Advisory Board has already created that process. No changes were made from proposed to final-form.

The Department received a comment regarding subsection (a) of this provision, averring that the provision is unclear and sought clarity as to if this provision intends to indicate that the qualifications needed for a physician to *remain* in the registry are continuing qualifications. To the extent the commentator is asserting that the requirements to be initially registered with the Department and approved as a practitioner are identical to those requirements to *remain* registered with the Department and approved as a practitioner, we agree. Those requirements can be found in § 1181a.24. *See* 28 Pa. Code § 1181a.24. Accordingly, as provided in this section, the requirements for registration with the Department and approval as a practitioner constitute both initial and ongoing qualifications to remain a practitioner in the program.

#### *§ 1181a.23. Medical professionals generally*

This section provides that, like the requirements for a registered practitioner, the requirements to be a registered medical professional are an ongoing responsibility to maintain. The section also provides that a medical professional may not assume any duties at a dispensary until all requirements are satisfied. This section further requires that a medical professional notify the practitioner listed on the patient certification of any adverse reaction suffered by the patient due to use of a medical marijuana product purchased at the dispensary. As proposed, this section mirrored the temporary § 1181.23 (relating to medical professionals generally), except for revising a citation in subsection (b) to refer to this new chapter. No changes were made from proposed to final-form.

The Department received a comment regarding subsection (a) of this provision, averring that the provision is unclear and sought clarity as to if this provision intends to indicate that the qualifications needed for a medical professional to *remain* employed at a dispensary are continuing qualifications. To the extent the commentator is asserting that the requirements to be employed as a medical professional within a dispensary are identical to those requirements to remain a medical professional within a dispensary, we agree. Those requirements can be found in § 1181a.25. *See* 28 Pa. Code § 1181a.25. Accordingly, as provided in this section, the requirements for a medical professional to be employed at a dispensary constitute both initial and ongoing qualifications.

One commentator sought clarification as to what "adverse reaction" means, as used in this section. The phrase "adverse reaction" is defined in § 1141a.21.

One commentator requested that the Department revise subsection (c) to allow for email communication as opposed to phone. After consideration, the Department declines to adopt this suggestion. Communications made under subsection (c) are for the purposes of communicating an adverse event—*i.e.*, a patient safety issue. The Department believes that phone calls to practitioners provide the most direct and immediate means of communication, as opposed to an email that may not be viewed for some time.

#### *§ 1181a.24. Practitioner registration*

This section details the requirements for practitioner registration. As proposed, this section mirrored the temporary § 1181.24 (relating to physician registration), except for clarifying reorganization and revision of a citation in subsection (c) to refer to this new chapter. This section as currently written in the temporary regulation implies that that a physician may not apply for registration as a practitioner unless the physician holds an active, unrestricted medical license and is determined by the Department to be qualified to treat patients with serious medical conditions. To clarify, the physician licensing requirement in temporary subsection (a)(1) was relocated at proposed stage to subsection (a). Additionally, temporary subsection (a)(2) was deleted, and subsection (c) was revised to clarify that the Department determines approval to issue patient certifications based on the information submitted in the application. Finally, temporary subsection (c) was revised to be subsection (d). With this reorganization, the section more clearly provides for licensing qualifications to apply in subsection (a), followed by application requirements in subsection (b), and ending with a determination of approval to issue patient certifications based on the submitted application in subsection (c). This section further provides that the Department may only list a physician on the practitioner registry after the physician has completed the training course required in § 1181a.32 (relating to training) and met all other requirements for registration.

On final-form, in response to a public comment, the Department revises the title of this section to mirror the title of the practitioner registration section in the act. 35 P.S. § 10231.401. Further, per comments from IRRC regarding the use of non-regulatory language, the phrase "at a minimum" is removed from subsection (b). No additional changes were made from proposed to final-form.

The Department received a comment regarding the requirement that a physician applying to be registered as a practitioner with the Department include in their application the physician's credentials, education, training, specialty, training, experience and supporting documentation, where available. This commentator questioned whether these pieces of information are directed towards a physician's qualifications to treat one of the serious medical conditions under section 402 of the act. *See* 35 P.S. § 10231.402. In short, yes. Specifically, subsection (c) of this provision provides that the information described in the comment will aid the Department in determining whether to approve the physician to issue patient certifications. *See* 28 Pa. Code § 1181a.24(b)(2).

Another commentator queried as to whether practitioners must be based in Pennsylvania to participate as a practitioner in the medical marijuana program. The answer is no; the practitioner must only be licensed to practice in the Commonwealth of Pennsylvania to participate as a practitioner within the medical marijuana program.

#### *§ 1181a.25. Practitioner registry*

This section provides that the Department will maintain a practitioner registry for use by patients or caregivers, and that inclusion in the registry is subject to annual review by the Department to ensure that the practitioner remains qualified. No comments were received on this section and no changes were made from temporary to proposed to final-form.

#### *§ 1181a.26. Denial, revocation or suspension of a practitioner registration*

This section provides the grounds upon which the Department may deny, revoke, or suspend a practitioner's registration. The section also prohibits a physician who has been denied registration or has had that registration revoked or suspended from accessing, issuing, modifying, or copying a patient's certification. Further, this section provides that a physician may reapply if the circumstances



leading to registration denial, revocation, or suspension have resolved. As proposed, this section mirrored the temporary § 1181.26 (relating to denial, revocation or suspension of a practitioner registration), except for revising a citation in subsection (c) to refer to this new chapter. No changes were made from proposed to final-form.

The Department received a comment seeking clarification on subsection (d)(3), which prohibits a physician who has been denied registration or whose practitioner registration has been revoked or suspended from providing a copy of a patient certification to any person, including a patient or caregiver, except in accordance with applicable law. The commentator sought clarification as to which applicable laws would qualify as a permitted disclosure under this law. IRRC reiterated this comment and asked the Department to clarify what the applicable law or laws are so that the regulated community can comply with those laws. In response, the language has been amended to clarify the intent and to provide an example of when the exception would apply, 42 Pa.C.S. § 6155(b)(1), which provides that "[a] patient or his designee . . . shall have the right of access to his medical charts and records and to obtain photocopies of the same."

#### *§ 1181a.27. Issuing patient certifications*

Consistent with section 403 of the act, 35 P.S. § 10231.403, this section specifies the conditions under which a practitioner may issue a patient certification, as well as specifying the information that is required on a patient certification. This section also requires a practitioner to provide a copy of a completed patient certification to the patient or the patient's caregiver and to the Department, as well as to retain a copy in the patient's file. As proposed, this section mirrored the temporary § 1181.27 (relating to issuing patient certifications).

In final-form, per comments from IRRC regarding the use of non-regulatory language, the phrase "and any other factor deemed relevant by the practitioner" is removed from subsection (a)(1). In its place, subsection (1.5) is added to include the statutory requirement for the patient to be under the practitioner's continuing care for the serious medical condition. 35 P.S. §§ 10231.403 and 10231.103. The Department additionally removes the phrase "at a minimum" from subsection (c) as it constitutes non-regulatory language.

The Department received a comment seeking to remove the requirements that practitioners provide a copy of the patient certification to the patient and file a copy of the patient certification in the patient's health care record under subsections (d)(1) and (d)(3), commenting that the requirements are excessive due to digital access to the patient certification. The Department is unable to adopt this comment as the act requires the practitioner to file a copy of the certification in the patient's health care record. 35 P.S. § 10231.403(d)(3).

One commentator objected to the list of required patient information on a patient certification under subsection (c)(1). Specifically, this subsection requires that a patient certification include the patient's name, home address, telephone number, date of birth, and email address. A similar provision found in the act, however, only requires that a patient certification include the patient's name, date of birth, and address. *See* 35 P.S. § 10231.403(b)(1). As subsection (c)(1) of this section requires more than provided under the act, the commentator expressed concerns related to the Department's authority to require more information than required by the act, in addition to raising concerns related to patient privacy. The Department disagrees with this commentator's assertions. The power of an administrative agency to prescribe rules and regulations under a statute is not the power to make law, but only the power to adopt regulations to carry into effect the will of the Legislature as expressed by the statute. *Commonwealth v. DiMeglio*, 122 A.2d 77, 80 (Pa. 1956). Although subsection (c)(1) requires more information to be listed on the patient certification than the act, the requirement is not *contrary* to the act. In promulgating the act, the Legislature vested authority in the Department

regulatory and enforcement authority over the use of medical marijuana. 35 P.S. § 10231.301(a)(3). Moreover, the act provides that the Department is responsible for creating the certification form. *Id.* at § 10231.404. Thus, subsection (c)(1)'s requirement of extra information is in line with this express grant of authority from the Legislature. Further, this commentator's fears related to patient privacy are unfounded. Patient certifications—and the information therein—are deemed confidential by the act. *See* 35 P.S. § 10231.302(a)(2). Thus, the Department does not share this commentator's concerns, and takes no action in response to this comment. This commentator shared a similar concern regarding the information in subsection (c)(2), citing a similar disparity between what is required here compared to under the act. The rationale applied to subsection (c)(1) also applies to this commentator's concerns under subsection (c)(2), and the Department similarly takes no action in response.

One commentator requested that the Department remove "if the records are available for review" from subsection (a)(2)(i). After consideration, the Department declines to adopt the requested revision, as the Department does not presuppose that patients have medical records for certain conditions, and the certifying practitioner may be making the initial diagnosis.

One commentator requested that the Department amend (c)(11) to include a statement that the patient is not pregnant or breastfeeding. After careful consideration, the Department will take no action in response to this comment. The practitioner's ability to make this statement would depend, in part, upon the patient's truthfulness. Further, the Department believes practitioners will adequately explain the existing risks to patients, which would include advising against using medical marijuana while pregnant or breastfeeding.

One commentator requested that the Department add "emergency medicine" to the list of medical professionals that can certify pediatric patients. After consideration, the Department declines to adopt this comment. Per the Board's recommendation, as adopted by the Secretary, a practitioner with specialized knowledge relating to minor patients is preferred because of the potential effects of medical marijuana use on a developing brain. 49 Pa.B. 2898 (May 12, 2018).  
<http://www.pacodeandbulletin.gov/Display/pabull?file=/secure/pabulletin/data/vol48/48-19/747.html>

One commentator questioned how this section will be implemented as it relates to the interaction between practitioners, medical professionals, caregivers, and patients that are homebound or physically unable to visit a dispensary. The commentator asked how the Department will implement the requirements of this section of the regulation and Section 801 of the Act (relating to dispensing to patients and caregivers). Specifically, this commentator asked how a homebound patient could consult with a medical professional to determine which form of medical marijuana is best. IRRC asked the Department to review these concerns, clarify how the final-form regulation will be implemented, ensure that the requirements of the regulation are consistent with the Act, and ensure that the health, safety, and welfare of the patients are protected. Homebound patients can receive patient certifications via telemedicine, which would allow for such a discussion. Act 44 of 2021 amended the definition of "continuing care" by eliminating the requirement of in-person patient assessments and permitting telemedicine. 35 P.S. § 10231.103. Homebound patients can also communicate with medical professionals at the dispensary via remote audio or video conferencing – another convenience measure implemented through Act 44 of 2021.

#### *§ 1181a.28. Modifying a patient certification*

This section provides for modifying a patient certification and requires a practitioner to provide a copy of a modified patient certification to the patient or the patient's caregiver and to the Department, as well as to retain a copy in the patient's file. As proposed, this section mirrored the temporary provision. Subsection (a) provided that a practitioner could not modify the form of medical marijuana

products specified on a patient certification for 30 days from the date the receipt is entered into the electronic tracking system unless the practitioner notifies the Department. Several commentators, including IRRRC, questioned the limitation in this subsection on a practitioner's modification of a patient certification within the first thirty days of issuance, which limits practitioners from correcting any mistakes. In response, subsection (a) is revised on final-form to remove the limitation and allows modification of a patient certification at any time after issuance and before expiration.

One commentator requested a two-year duration for patient certifications as opposed to the current one-year limit. After consideration, the Department takes no action in response to this request. In line with the medical focus of this program, practitioners providing continuing care to the patients they treat is critical to the treatment of the patient's serious medical condition. The act requires that a patient be under the "continuing care" of the practitioner issuing the patient certification. 35 P.S. § 10231.403(a)(3). This requirement contemplates that the continuing care occur more than bi-annually, as to allow the practitioner to monitor the patient's response to the current course of treatment and modify as necessary.

Like the previous section, one commentator queried as to why a practitioner must provide a patient with a copy of the patient certification, commenting that the requirements are excessive due to digital access to the patient certification. The Department is unable to revise this obligation as the act explicitly requires the practitioner to provide the certification to the patient. 35 P.S. § 10231.403(d)(1).

#### *§ 1181a.29. Revocation of a patient certification*

Consistent with section 401 of the act, 35 P.S. § 10231.401, this section provides that a practitioner must immediately notify the Department that a patient's circumstances have changed in a manner that would affect the patient's certification, for example, the patient no longer has the serious medical condition for which he or she was certified. The section also provides that the Department will revoke the patient's certification upon receiving such notification. Further, this section provides that a practitioner may withdraw the issuance of a patient certification at any time. The section also provides that the Department will immediately notify the medical marijuana cardholder of a certification revocation and enter the information into the electronic tracking system. As proposed, this section mirrored the temporary § 1181.29 (relating to revocation of a patient certification). No changes were made from proposed to final-form.

One commentator asked whether a practitioner is immune from suit or disciplinary sanctions if a practitioner were to revoke a patient certification, or if there were other implications regarding continuity of care under the requisite medical practice acts. Section 2103 of the act provides that a practitioner shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including civil penalty or disciplinary action by a Commonwealth licensing board or commission, solely for lawful use of medical marijuana or manufacture or sale or dispensing of medical marijuana, or for any other action taken in accordance with this act. 35 P.S. § 10231.2103(a)(3).

#### *§ 1181a.30. Prescription drug monitoring program*

Consistent with section 403 of the act, 35 P.S. § 10231.403, this section requires a practitioner to review the Prescription Drug Monitoring Program prior to issuing or modifying a patient certification to determine whether the controlled substance history of the patient would impact the patient's use of medical marijuana products. The section also specifies the reasons for which a practitioner may access the Prescription Drug Monitoring Program. No comments were received on this section and no changes were made from temporary to proposed to final-form.

### *§ 1181a.31. Practitioner prohibitions*

Consistent with section 402 of the act, 35 P.S. § 10231.402, this section lists the prohibitions for practitioners, including: (1) accepting any form of remuneration for issuing patient certifications other than a fee for the patient consultation; (2) holding a direct or economic interest in a medical marijuana organization; (3) advertising as a certifying physician; (4) issuing a patient certification for personal use or for a family or household member; (5) acting as a caregiver for a patient certified by the practitioner; and (6) receiving or providing medical marijuana samples. At proposed stage, subsection (g) was added, prohibiting a practitioner from charging patients excessive fees. The Department added this revision due to patient complaints of practitioners taking advantage of the certification process by charging excessive lab testing, follow-up, or other fees not initially disclosed. Section 301(a)(11) of the act provides that the Department "shall collaborate as necessary with other Commonwealth agencies or contract with third parties as necessary to carry out the provisions of this act." The Department will collaborate with the Department of State (DOS), which licenses physicians, and refer for investigation complaints that a practitioner is engaging in unscrupulous billing practices. DOS will investigate and, if DOS finds a violation of the Medical Practice Act of 1985, 63 P.S. §§ 422.1-422.51a, or the Osteopathic Medical Practice Act, 63 P.S. §§ 271.1-271.18, DOS will impose sanctions. If DOS suspends, revokes, limits, or otherwise restricts the practitioner's license, the practitioner will be removed from the medical marijuana physician registry pursuant to 28 Pa. Code § 1181a.26(a). As proposed, this section mirrored the temporary § 1181.31 (relating to practitioner prohibitions), except for adding subsection (g).

The Department received a comment seeking to remove the prohibition in subsection (c), which prohibits practitioners from advertising their services as a practitioner who can certify a patient for medical marijuana. This commentator believes that allowing practitioners to advertise their services would result in increased education and participation in the medical marijuana program. The Department, however, is unable to take any action in response to this comment, as this prohibition is found in the act. 35 P.S. § 10231.402(a)(3).

Other commentators sought clarification as to subsection (g)'s prohibition on excessively charging patients for expenses related to the certification and follow-up processes for medical marijuana patients. These commentators sought clarity as to what the Department would deem "excessive." IRRC agreed and asked the Department to either define "excessive" as it relates to this requirement or clarify in the final-form regulation how this provision will be implemented, indicating how the Department and the practitioner will make this determination. Since the Department approves applications for practitioners to issue patient certifications, it has an interest in ensuring that those practitioners are not taking advantage of patients in need of medical marijuana. Section 301(a)(11) of the act provides that the Department "shall collaborate as necessary with other Commonwealth agencies or contract with third parties as necessary to carry out the provisions of this act." The Department will collaborate with the Department of State (DOS), which licenses physicians, and refer for investigation complaints that a practitioner is engaging in unscrupulous billing practices. DOS will investigate and, if DOS finds a violation of the Medical Practice Act of 1985, 63 P.S. §§ 422.1-422.51a, or the Osteopathic Medical Practice Act, 63 P.S. §§ 271.1-271.18, DOS will impose sanctions. If DOS suspends, revokes, limits, or otherwise restricts the practitioner's license, the practitioner will be removed from the medical marijuana physician registry pursuant to 28 Pa. Code § 1181a.26(a). The facts of each case will dictate whether the physician's charges are appropriate in DOS' view.

One commentator, not referencing any specific provision, alleged that some medical practices that hire certifying practitioners would not pay those practitioners unless they issued patient certifications. The Department does not have jurisdiction over this issue. This commentator should raise this

concern with the proper authority. Accordingly, the Department is unable to adopt any action in response to this comment.

One commentator objected to the prohibition on certifying family members or oneself, citing familiarity and cost concerns. This prohibition is found in section 403(e) of the act. 35 P.S. § 10231.403(e). Accordingly, the Department is unable to remove the prohibition.

#### *§ 1181a.32. Training*

Consistent with section 301 of the act, 35 P.S. § 10231.301, this section specifies those individuals who must complete a four-hour training course prescribed by the Department and the requirements of that training course. Further, this section provides that completion of the training course qualifies as continuing education credits by certain medical boards, and that individuals who completed the training course must submit documentation to that effect to the Department. Finally, this section provides that the Department will provide on its website a list of approved training providers. As proposed, this section mirrored the temporary § 1181.32 (relating to training), except for revising a citation in subsection (a) to refer to this new chapter.

On final form, per comments from IRRC regarding the use of non-regulatory language, the phrase "at a minimum" is removed from subsection (b). Additionally, in response to a comment from IRRC questioning how and when an individual submits proof of training completion, subsection (d)(1) is revised to reflect actual practice that the training providers submit proof of training completion to the Department, and that proof must be submitted within the time specified in subsection (a).

Some commentators sought clarification on a multitude of facets relating to training under this section. These commentators' concerns largely center around the substance of the training under subsection (b) of this section and who may provide this training. IRRC additionally posed the same questions. In response, subsection (f) is added, which states that an application for approval to become an approved training provider is available on the Department's public website and any application meeting the requirements of subsections (b) and (c) will be approved. Information pertaining to training can be found on the Department's website at:

<https://www.health.pa.gov/topics/programs/Medical%20Marijuana/Pages/Physicians.aspx>. The application can be found here:

<https://www.health.pa.gov/topics/Documents/Programs/Medical%20Marijuana/DOH%20-%20Application%20for%20Approval%20to%20Provide%20a%204-hour%20Training%20Course%20in%20the%20Medical%20Marijuana%20Program.pdf>.

One commentator sought to require medical professionals to retake the 4-hour training every two years. The Department, however, believes that this is better handled through medical professionals' continuing education, as required by their respective licensures.

#### *§ 1181a.33. Appeals*

This section provides that all actions of the Department under this chapter are governed by Chapter 5, Subchapter A of 2 Pa.C.S. and its accompanying regulations, as modified by final chapter 1230a. As proposed, this section mirrored the temporary § 1181.33 (relating to appeals), except for revising a citation to reflect the new Chapter 1230a (relating to practice and procedure). No comments were received on this section and no changes were made from proposed to final-form.

#### *Chapter 1191a. Patients and caregivers*

This chapter, which tracks chapters 3, 5 and 8 in the act, details patient and caregiver registration, cardholder responsibilities, application and fees for cardholders, background checks, renewing, revoking or suspending identification cards, obtaining products, and patient authorization letters. This chapter replaces the temporary Chapter 1191 (relating to patients and caregivers -- temporary regulations). New sections and amendments to sections of the temporary regulations are discussed more fully below.

#### *§ 1191a.22. Patient and caregiver registry*

Consistent with section 302 of the act, 35 P.S. § 10231.302, this section provides that the Department will maintain a registry of patients and caregivers and lists the information that must be included in the registry. This section also provides that the information contained in that registry is confidential and not subject to disclosure. Further, this section provides that a caregiver may waive this confidentiality requirement and consent to providing the caregiver's name and contact information to the patient. As proposed, this section mirrored the temporary § 1191.22 (relating to patient and caregiver registry), except for revising a citation in subsection (b) to refer to this new chapter. No comments were received on this section and no changes were made from proposed to final-form.

#### *§ 1191a.23. Patients and caregivers generally*

This section provides that the qualifications to become a patient or caregiver are ongoing qualifications, and the Department may issue a certification card to those individuals who meet those qualifications. Further, this section provides that the Department may, with sufficient showing of suitability, allow a person under the age of 21 to serve as a caregiver. Finally, this section provides that a minor patient shall have a caregiver who meets the criteria specified in subsection (d). As proposed, this section mirrored the temporary § 1191.23 (relating to patients and caregivers generally), except for revising a citation in subsection (b) to refer to this new chapter. No changes were made from proposed to final-form.

The Department received a comment of general opposition to the regulatory packet, raising myriad questions regarding safety. One such question, though not aimed at this provision specifically, asked where in the regulations one can find protections for children. This provision, along with § 1191a.32, provides protections for minors, requiring additional components such as a mandatory caregiver, to ensure the safety of minor patients. *See* 28 Pa. Code §§ 1191a.23 and 1191a.32. These provisions can also be found in the act. *See* 35 P.S. § 10231.506; 35 P.S. § 10231.801(h)(4). As these protections currently exist in both the act and final regulations, the Department takes no action in response to this comment.

Another commentator, also not citing a specific regulatory provision, requested that the Department implement employment discrimination protections to combat patients who suffer adverse employment decisions due to their status as patients. These protections exist in the act. *See* 35 P.S. § 10231.2103(b). If a person suffers an adverse employment decision based solely on their status as a certified medical marijuana patient, Pennsylvania courts—state and federal—have determined that section 2103 of the act confers a private right of action for individuals alleging such discrimination. *See Hudnell v. Thomas Jefferson Univ. Hosp., Inc.*, 2020 WL 5749924 (E.D. Pa. 2020); *Palmiter v. Cmwlth. Health Sys., Inc.*, 260 A.3d 967 (Pa. Super. 2021); *Harrisburg Area Comm. Coll. v. Pa. Human Rels. Comm'n*, 245 A.3d 283 (Pa. Cmwlth. 2020). As these protections currently exist, the Department takes no action in response to this comment.

Another commentator, also not citing a specific regulatory provision, requested that the Department overhaul the zero-tolerance driving under the influence (DUI) laws as they relate to

medical marijuana cardholders. Such a change, however, would require legislative action beyond the Department's jurisdiction. Accordingly, the Department is unable to act in response to this comment.

In response to a comment from IRRC regarding the use of non-regulatory language “sufficient showing” and “as determined by the Department” in sections (c) and (d)(3), the Department opted to remove both provisions entirely.

#### *§ 1191a.24. Medical marijuana cardholder responsibilities*

This section details cardholder responsibilities. Changes to the temporary § 1191.24 (relating to medical marijuana cardholder responsibilities) are detailed below.

##### *Subsection (a).*

Subsection (a) lists the circumstances under which a medical marijuana cardholder must immediately contact the Department. Specifically, those instances include: (1) change of the cardholder's name or address; (2) practitioner withdrawal of a patient certification; (3) a patient's decision to discontinue the services of a caregiver; (4) a decision of a caregiver to no longer serve in such a capacity for the patient; and (5) a decision by patient to discontinue treatment from the practitioner who issued the patient certification. At proposed stage, subsection (a) was revised to correct a typographical error (changing "withdraw" to "withdrawal") and to change a citation in subsection (2) to refer to the new § 1181a.29 (relating to revocation of a patient certification). No changes were made from proposed to final-form.

##### *Subsection (b).*

As proposed, subsection (b) was replaced in its entirety and removed the temporary regulatory requirement that the cardholder must return the identification card upon receiving notification from the Department that the cardholder has been removed from the registry or the patient certification has been revoked. Returning the card is not necessary because the card will be deactivated and rendered unusable. Proposed subsection (b) provides that a medical marijuana cardholder must apply for a replacement identification card within ten business days of discovering the loss or defacement of the identification card. This provision was relocated from the temporary § 1191.28(f) (relating to identification cards) as it is more appropriately placed under this section detailing cardholder responsibilities. No changes were made from proposed to final-form.

#### *§ 1191a.25. Application for, and issuance or denial of, identification cards*

Consistent with section 501 of the act, 35 P.S. § 10231.501, this section requires patient or caregiver identification card applicants to submit the proper application, complete with the information required in subsections (b) and (d). Subsection (c) details the procedure where an application designates a caregiver who is not authorized to serve as a caregiver. Applicants for a caregiver identification card are subject to a criminal background check and subsection (e) provides the grounds upon which an application may be denied. Subsection (f) provides that the Department will notify the applicant of an incomplete application and of the additional information that is required. Subsection (g) provides the applicant with 60 days to submit the requested information. As proposed, this section read 60 days from receipt of a notification from the Department. In response to IRRC's question regarding how the Department will know when the notice was received, this section is amended on final-form to replace “receipt” with “mailing.” Finally, subsections (h) and (i) provide that the Department will notify an applicant in writing of the reasons for denial of an application, allow the applicant to submit a new application following that denial, and permit the Department to decline consideration of a re-application that does not correct previously identified deficiencies. As

proposed, this section mirrored the temporary § 1191.25 (relating to application for, and issuance or denial of, identification cards), except for revising citations throughout to refer to this new chapter and new Chapters 1181a (relating to practitioners).

On final-form, per comments from IRRC regarding the use of non-regulatory language, the following changes are made: the phrases "on a form prescribed by the Department" and "at a minimum" are removed from subsections (a), (b) and (d); subsection (d)(2) is revised to delete "or other documentation acceptable to the Department;" the word "promptly" is removed from subsection (f); and subsections (b)(9) and (d)(10) are removed as unnecessary. Further, subsections (d)(5) and (6) are revised to reflect removal of the background check requirement for caregiver renewal applications and of the 5-patient caregiver cap implemented by Act 44 of 2021. 35 P.S. §§ 10231.502(b) and 10231.303(b)(4), respectively. Additionally, "a caregiver" is added to subsections (f) through (i) to clarify that these subsections are only applicable to a caregiver applicant.

#### *§ 1191a.26. Application fees*

This section details application fees, consistent with section 501 of the act, 35 P.S. § 10231.501.

##### *Subsections (a) and (b).*

Subsections (a) and (b) provide that an applicant may pay no more than one \$50 fee in a twelve-month period for an identification card, unless the applicant is submitting a renewal application within the same twelve-month period or the applicant requires a replacement card, in which case the cardholder will pay \$25 for a replacement card. These subsections mirror the temporary subsections (a) and (b) and no changes were made from proposed to final-form.

##### *Subsection (c).*

Subsection (c) provides that the Department may establish higher fees for the issuance of a second and subsequent replacement cards by publishing notice thereof in the *Pennsylvania Bulletin*. As proposed, subsection (c) was revised to eliminate the requirement for the Department to publish these fees every January. No changes were made from proposed to final-form.

IRRC noted that Section 501 of the act permits the Department to establish higher fees for replacement cards and to waive or reduce fees and asked why the Department decided to administer these provisions by publishing notices in the *Pennsylvania Bulletin* instead of including them in this rulemaking. The Department wanted to ensure a fast method of communicating fee changes in the future.

##### *Subsection (d).*

Subsection (d) allows the Department to waive or reduce card fees for financial hardship and provides that the Department will publish on its website the qualification for financial hardship. As proposed, subsection (d) was revised to eliminate the requirement for the Department to publish these fees every January.

The Department received a comment from IRRC questioning the purpose of the opening phrase to this proposed subsection: "subject to § 1191a.32 (relating to medical marijuana patient authorization letters)." In response, the phrase is removed as unnecessary in final-form.

One commentator sought to add a requirement to this section that the date of the application fees be provided within the electronic system, to help dispensaries discern the reason that a patient card



might be rejected. After consideration, the Department will take no action in response to this comment as a dispensary may not dispense on a rejected identification card, regardless of the reason for the invalidity.

#### *§ 1191a.27. Criminal background checks*

This section requires an individual applying for an identification card as a caregiver submit to fingerprints to the Pennsylvania State Police for the purpose of obtaining a criminal background check. This section also provides that the Department reviews the individual's criminal history only to determine the caregiver's character, fitness, and suitability to serve in such a capacity. As proposed. This section mirrored the temporary provision. On final-form, this section is revised to eliminate background check requirements for caregivers renewing identification cards, per statutory changes made by Act 44 of 2021. 35 P.S. § 10231.502(b). No comments were received on this section and no changes were made from proposed to final-form.

#### *§ 1191a.28. Identification cards*

This section provides that the Department will issue identification cards as soon as practicable, and requires that the card must contain certain delineated information, including a photograph of the cardholder. Subsection (c) provides that the Department will not require a photograph if the applicant submits a statement that a photograph cannot be provided due to the applicant's religious beliefs. Further, this section outlines the circumstances under which an identification card issued to a patient or caregiver will expire. As proposed, this section omitted the requirement in temporary subsection (f) that cardholders apply for a replacement card within ten business days of discovering the loss or defacement of the card, as this requirement was relocated to § 1191a.24(b) (relating to cardholder responsibilities).

On final-form, per comments from IRRC regarding the use of non-regulatory language, subsection (b)(8) is removed as unnecessary.

One commentator sought clarification regarding not requiring a picture for religious reasons, asking whether this is similar to how the Commonwealth handles drivers' licenses or passports. Yes, this religious exemption to the photographic requirement is the same as that for drivers' licenses. The Department cannot speak to religious exemptions for passports, as passports are handled at the federal level.

#### *§ 1191a.29. Renewing an identification card*

This section provides that a cardholder shall submit an application for card renewal no later than 30 days prior to the expiration of the current card, and that a cardholder shall obtain a new or updated certification. Further, this section provides that the identification card will not be valid beyond the stated expiration date, and the Department may remove the individual from the patient and caregiver registry if the Department denies a renewal application or if the cardholder fails to submit a renewal application. As proposed, subsection (a) was revised to require a medical marijuana cardholder to obtain a new patient certification at the time the cardholder applies for a new identification card only if the certification is expired. This change is made because the time in which a patient must submit a new certification may not coincide with the time in which the patient must obtain a new identification card. Additionally, the citation in subsection (a) was revised to refer to the new Chapter 1181a (relating to practitioners).

Subsection (c) is added on final-form to effectuate the statutory change in Act 44 of 2021, eliminating the background check requirement for an applicant who was previously approved by the

Department to serve as a caregiver. 35 P.S. § 10231.502(b). No comments were received on this section and no changes were made from proposed to final-form.

#### *§ 1191a.30. Revocation or suspension of identification card*

This section provides the instances in which the Department may suspend or revoke a cardholder's identification card and that, in such an instance, the Department will notify the cardholder of the Department's action. Further, this section provides that if a patient's practitioner's registration has been revoked or suspended under final § 1181a.26 (relating to denial, revocation or suspension of a practitioner registration), or if a patient's practitioner withdraws the patient's patient certification under § 1181a.29(c) (relating to revocation of a patient certification), the cardholder is required to obtain a new patient certification within 90 days of receiving notice from the Department or prior to the expiration of the identification card, whichever is sooner. As proposed, subsection (c) was revised to reflect that a patient does not need to apply for a new medical marijuana identification card when a practitioner's registration has been revoked or suspended or a practitioner withdraws the patient's certification under § 1181a.29(c). Instead, subsection (c) provides that a patient is required to obtain a new patient certification as explained above. Additionally, citations were amended, at proposed stage, throughout this section to refer to the new Chapter 1181a (relating to practitioners).

On final-form, per comments from IRRC regarding the use of non-regulatory language, the phrase "as determined by the Department" is removed from subsection (a)(3); subsection (a)(5) is revised to eliminate the word "promptly" by inserting a period after "invalid" and deleting the remainder of the sentence as unnecessary (an invalid caregiver card need not be returned, as it cannot be used); and the word "promptly" is deleted from subsection (b). Language is also added to subsection (a)(5) to address deactivation of a card when a patient desires to withdraw from participation in the program.

#### *§ 1191a.31. Obtaining medical marijuana products from a dispensary*

This section provides that a medical marijuana cardholder may only obtain medical marijuana products from a dispensary in accordance with section 1161a.24 (relating to limitations on dispensing), and that the cardholder may only obtain medical marijuana products from a dispensary based on the recommendation provided in a valid patient certification that the dispensary may access through the electronic tracking system. As proposed, this section mirrored the temporary § 1191.31 (relating to obtaining medical marijuana products from a dispensary), except for revising citations to refer to the new Chapters 1161a (relating to dispensaries) and 1181a (relating to practitioners).

One commentator requested that the Department allow dispensaries to determine limitations on dispensing medical marijuana, as patient certifications rarely include them. A limitation on dispensing is already provided for in section 801 of the act. 35 P.S. § 10231.801(e). No changes were made from proposed to final-form.

#### *§ 1191a.32. Medical marijuana patient authorization letters*

This section provides that the Department will issue a medical marijuana patient authorization letter to a minor patient and may issue a patient authorization letter to an adult patient, instead of issuing an identification card. Further, this section provides that when the minor patient who has been issued a patient authorization letter turns 18, the patient is entitled to apply for an identification card. This section also provides that a medical marijuana patient authorization letter confers the same rights and obligations, and is subject to the same terms and conditions, as apply to a medical marijuana cardholder, except that an identification card will be required for entry into a dispensary. Finally, this section provides that a patient who has been issued a medical marijuana patient

authorization letter will not be required to pay an identification card application fee or an identification card renewal application fee. As proposed, this section mirrored the temporary provision, except that language was added to subsection (b) to clarify that a patient authorization letter may be issued to an adult patient only when the patient's illness or infirmity permanently prevents the patient from visiting a dispensary.

The medical marijuana patient authorization letter is not intended to, and may not be, a substitute for a medical marijuana identification card, which is required to access a dispensary. The patient authorization letter may be used only to signify authorization to be in possession of, or to consume, medical marijuana. It was developed because schools and child-care programs have requested documentary evidence that minor patients, who cannot get a photo identification card from the Pennsylvania Department of Transportation (PennDOT), the agency that verifies Pennsylvania addresses for the issuance of a medical marijuana identification card, are permitted to consume medical marijuana. The letter does not afford access to a dispensary or authorize a caregiver to be dispensed medical marijuana. All patients holding a patient authorization letter must have a caregiver, who has an identification card, who visits the dispensary and obtains medical marijuana on the patient's behalf and delivers the medication to the patient. This letter is also used to accommodate homebound patients who also cannot obtain a PennDOT photo identification card. The Department also developed the patient authorization letter because it does not want to require payment for an identification card (\$50.00 fee) from a patient who will never independently access a dispensary due to the patient's minor age or due to illness or infirmity that permanently prevents the patient from visiting a dispensary. No comments were received on this section and no changes were made from proposed to final-form.

#### *§ 1191a.33. Appeals*

This section provides that all actions of the Department under this chapter are governed by Chapter 5, Subchapter A of 2 Pa.C.S., as modified by Chapter 1230a. As proposed, this section mirrored the temporary § 1191.33 (relating to appeals), except for revising a citation to reflect the new Chapter 1230a (relating to practice and procedure). No comments were received on this section and no changes were made from proposed to final-form.

#### *Chapter 1211a. Clinical Registrants and Academic Clinical Research Centers*

This chapter tracks chapter 20 in the act and details application for, and approval or certification of, clinical registrants and ACRCs, research contracts, practices and procedures for research programs, renewal and revocation of clinical registrant approval, dispensing and tracking of products, prohibitions, reporting requirements and sale or exchange of plant material and products. This chapter replaces the temporary Chapter 1211 (relating to clinical registrants and academic research centers -- temporary regulations). Consistent with removing the definition of "certified ACRC" from Chapter 1141a, references to "certified" ACRC are removed from subsections 1211a.25(b) and (d), 1211a.27(b)-(d), 1211a.27a, 1211a.30(c), 1211a.31(b), 1211a.32, 1211a.34, and 1211a.35. Other amendments to sections of the temporary regulations are discussed more fully below.

#### *§ 1211a.22. Clinical registrants generally*

This section provides that the qualifications to be a clinical registrant are ongoing qualifications. Further, this section outlines the process of becoming a clinical registrant, including holding or applying for dispensary and grower/processor permits. This section further provides that the clinical registrant may not engage in dispensing activities until it receives Department approval, both grower/processor and dispensary facilities are operational, and the clinical registrant demonstrates ability to begin research within six months of becoming operational. Finally, this section provides

that clinical registrants may dispense to a cardholder regardless of whether the patient is participating in a research study. As proposed, this section mirrored the temporary provision.

Subsection (c) is revised in final-form to increase the permissible number of clinical registrants to ten in accordance with Act 44 of 2021. 35 P.S. § 10231.2002(a). In response to IRRC's request for clarification of the "ready, willing and able" language, subsection (d)(1) is revised to clarify that a clinical registrant may not dispense products until both its grower/processor and dispensary facilities have been inspected and deemed operational by the Department.

#### *§ 1211a.23. Limitation on permits*

This section provides that a clinical registrant may not hold more than one dispensary and one grower/processor permit. Further, this section provides that a clinical registrant may dispense medical marijuana at up to six separate locations, each of which must dispense medical marijuana to conduct research, and that no more than three of those locations may be in the same medical marijuana region or county. As proposed, this section mirrored the temporary § 1211.23 (relating to limitation on permits).

In response to IRRC's request to remove non-regulatory language, the phrase "approved by the Department" in subsection (b) is replaced on final-form with "as approved in its application or under § 1161a.40." No other changes were made from proposed to final-form.

#### *§ 1211a.24. Capital requirements*

This section outlines the capital requirements for a clinical registrant applicant, which must be affirmed via affidavit submitted with the application to become a clinical registrant, along with a release to allow the Department to verify this information. As proposed, this section mirrored the temporary § 1211.24 (relating to capital requirements), except for revising citations to refer to new chapters. No comments were received on this section and no changes were made from proposed to final-form.

#### *§ 1211a.25. Certifying ACRCs*

This section provides that the qualifications to become an ACRC are ongoing qualifications. This section also provides that an accredited medical school may become approved to be an ACRC by application and that the Department will publish a notice in the *Pennsylvania Bulletin* announcing the availability of the application and the time for applying. This section specifies the information that must be included in an application and provides that the Department will publish a list of the ACRCs on its publicly available website and in the *Pennsylvania Bulletin*. As proposed, this section mirrored the temporary § 1211.25 (relating to certifying ACRCs). Per comments from IRRC regarding the use of non-regulatory language, subsection (c)(8) is removed in final-form as unnecessary. No other changes were made from proposed to final-form.

IRRC questioned whether the Department is still accepting applications and if this subsection needed. Act 44 of 2021 increased the number of permissible clinical registrants, who partner with ACRCs, to 10. 35 P.S. § 10231.2002. The Department subsequently completed an application cycle wherein only one additional clinical registrant was approved to partner with an ACRC, bringing the current total to 9. Act 44 also provides that if the statutory maximum number of approved academic clinical research centers or approved clinical registrants are not approved, the department shall reopen the application process for the approval of academic clinical research centers and clinical registrants. 35 P.S. § 10231.2002(a)(2).

#### *§ 1211a.26. Revocation of a certification of an ACRC*

This section outlines the circumstances under which the Department will revoke the certification of an ACRC. Further, should such an event occur, the Department will provide written notice of the action, and the ACRC will receive an opportunity to retain its certification by submitting proof of corrective action within 90 days of receiving the notice from the Department. No comments were received on this section and no changes were made from temporary to proposed to final-form.

#### *§ 1211a.27. Application for approval of a clinical registrant*

This section provides that an entity wishing to become a clinical registrant must apply to do so via application. This section specifies the information that must be included in an application, some of which is confidential under the Right-to-Know Law, 65 P.S. §§ 67.101-67.3104, and not subject to disclosure. This subsection also provides that the Department will publish a notice in the *Pennsylvania Bulletin* announcing the availability of the application and the time for applying. This section further provides that an applicant may only include one ACRC in its application for approval as a clinical registrant. As proposed, this section mirrored the temporary § 1211a.27 (relating to application for approval of a clinical registrant), except for revising citations to refer to this, and other, new chapters.

IRRC questioned whether the Department is still accepting applications and if subsection (a) is still needed. Act 44 of 2021 increased the number of permissible clinical registrants to 10. 35 P.S. § 10231.2002. The Department subsequently completed an application cycle wherein only one additional clinical registrant was approved, bringing the current total to 9. Act 44 also provides that if the statutory maximum number of approved academic clinical research centers or approved clinical registrants are not approved, the department shall reopen the application process for the approval of academic clinical research centers and clinical registrants. 35 P.S. § 10231.2002(a)(2).

In response to IRRC's request for clarification of the "ready, willing and able" language, subsection (b)(7)(iii) is revised to clarify that a clinical registrant may not dispense products until both its grower/processor and dispensary facilities have been inspected and deemed operational by the Department. Additionally, subsection (b)(11), mistakenly noted by IRRC as subsection (c)(11), is removed as non-regulatory and unnecessary as all application requirements are detailed in the preceding subsections.

#### *§ 1211a.27a. Research contracts*

This section provides that an applicant for approval as a clinical registrant shall provide with its application either (1) an executed agreement or (2) a letter of intent to enter into an agreement with an ACRC. This section further provides that an applicant may submit more than one application, with separate applications identifying distinct ACRCs, and that although an ACRC may execute a letter of intent with more than one clinical registrant applicant, it may only execute a research contract with one approved clinical registrant. Further, this section provides that if more than one applicant for approval as a clinical registrant submits an application that includes a letter of intent with the same ACRC, the Department will follow the outlined prioritization in approving applications. Finally, this section provides the minimum acceptable scores for a clinical registrant grower/processor and dispensary permit application. No comments were received on this section and no changes were made from temporary to proposed to final-form.

#### *§ 1211a.28. Request for conversion of an existing permit*

This section provides that a dispensary or grower/processor permittee must submit a request for conversion of an existing grower/processor or dispensary permit with its application for approval as a clinical registrant. This section further provides that upon approval as a clinical registrant, the clinical registrant will surrender its current dispensary or grower/processor permit, which will increase the number of available grower/processor or dispensary permits available under chapter 6 of the act. Finally, this section provides that an applicant may include additional dispensary locations in its request for conversion of an existing permit or may request additional dispensary locations later. As proposed, this section mirrored the temporary § 1211.28 (relating to request for conversion of an existing permit), except for revising citations to refer to this, and other, new chapters. No comments were received on this section and no changes were made from proposed to final-form.

#### *§ 1211a.29. Practices and procedures of research programs, projects or studies*

This section requires medical marijuana to be dispensed to a patient or caregiver as part of a research program in a form that conforms to the act or this part. Subsection (b) provides that marijuana may be dispensed from a clinical registrant directly to an ACRC in any form deemed safe by an institutional review board (IRB). This section further provides requirements for research approval committees and IRBs, including (1) establishing policies and procedures, (2) reviewing research studies, and (3) ensuring each research study addresses the issues specified in subsection (e). As proposed, this section mirrored the temporary § 1211.29 (relating to practices and procedures of research programs, projects or studies). Per comments from IRRC regarding the use of non-regulatory language, the phrase "at a minimum" is removed from final-form subsection (e).

IRRC asked whether the word "medical" should be added to the beginning of the first sentence of subsection (b). The answer is no. Subsection (b) pertains to research projects or studies, which will not begin until marijuana is rescheduled at the federal level. *See* 35 P.S. § 10231.2003(a) (pertaining to research studies).

One commentator asked whether patients in research programs must pay for the medical marijuana they are instructed to take and questioned whether unapproved forms of medical marijuana are being used in these research programs. As to the first question, research patients may be charged a reduced cost for medical marijuana products, but the products may not be free of charge. *See* 28 Pa. Code § 1161.27(e)(2). Additionally, research conducted pursuant to the act must be limited to forms of medical marijuana already approved for use. *See* definitions of "research program" and "medical marijuana" in 28 Pa. Code § 1141a.21.

#### *§ 1211a.29a. Research initiative*

This new section is added pursuant to Act 44 of 2021, which allows an academic clinical research center, in coordination with its contracted clinical registrant, to conduct a research initiative on the antimicrobial effects of applying solvent-based extraction methods and processes to microbial contamination of immature medical marijuana plants, medical marijuana plants, medical marijuana, or medical marijuana products. 35 P.S. § 10231.2003.1. This section outlines the submission and approval process for a research initiative and details the process for implementation of approved findings.

#### *§ 1211a.30. Approval or denial of an application for approval of a clinical registrant*

This section provides that an applicant shall be a clinical registrant upon the Department's approval of an application under § 1211a.27 (relating to application for approval of a clinical registrant). This section further provides that the Department may deny the application if the applicant has disclosed prior payments to an ACRC. This section also specifies that prior to denying

an application, the Department will issue written notice to the applicant and the applicant will have the opportunity to cure the prohibited payments by submitting to the Department a supplemental affidavit indicating that the ACRC or its affiliate has refunded to the applicant the prohibited payment. This section also provides that a clinical registrant will have the same rights and obligations as a grower/processor or dispensary permittee, and a clinical registrant's dispensary and grower/processor permits will expire upon expiration, revocation, or nonrenewal of the clinical registrant's approval. As proposed, this section mirrored the temporary § 1211.30 (relating to approval or denial of an application for approval of a clinical registrant), except for revising citations to refer to this and other new chapters and adding a subsection.

In final-form, subsection (c.1) is added pursuant to Act 44 of 2021, which provides that the department shall not approve an applicant for a grower/processor permit if the applicant has previously had a specified contractual relationship with an academic clinical research center. 35 P.S. § 10231.2002(b)(4)(i). No other changes were made from proposed to final-form.

One commentator expressed confusion as to the Department denying applications due to payments to an ACRC occurring previously. The purpose for this prohibition is to prevent any favoritism in contracting as the ACRC must execute a contract with a clinical registrant.

#### *§ 1211a.31. Renewal of approval of a clinical registrant*

This section provides that the term of a clinical registrant's approval will coincide with the term of the clinical registrant's grower/processor permit and dispensary permit, and that an approved clinical registrant will be required to renew its approval as part of its dispensary and grower/processor permit renewals. This section further provides that the renewal application must be submitted on a form prescribed by the Department, must include the information specified in subsection (b), and is subject to Department approval. Finally, this section provides that the Department will not renew approval for a clinical registrant if the Department determines that the clinical registrant's dispensary locations are not engaging in research and do not intend to engage in research within six months of renewal. As proposed, this section mirrored the temporary § 1211.31 (relating to renewal of approval of a clinical registrant), except for revising a citation to reflect the new Chapter 1141a (relating to general provisions).

Per comments from IRRC regarding the use of non-regulatory language, subsection (b)(6) is removed as unnecessary. No other changes were made from proposed to final-form.

#### *§ 1211a.32. Revocation of approval of a clinical registrant.*

This section outlines the circumstances under which a clinical registrant's approval will be revoked, including revocation or suspension of the clinical registrant's grower/processor or dispensary permit, revocation of the partnered ACRC certification, and lack of a research contract. This section provides that the Department will issue written notice of its intention to revoke approval. Thereafter, the clinical registrant will have 90 days to contract with another ACRC that is not already contractually committed, or have its approval revoked. As proposed, this section mirrored the temporary § 1211.32 (relating to revocation of approval of a clinical registrant), except for revising a citation to refer to this new chapter. No comments were received on this section and no changes were made from proposed to final-form.

#### *§ 1211a.33. Dispensing and tracking medical marijuana products*

This section provides that the dispensary of an approved clinical registrant shall enter information into the electronic tracking system, as required by the Department, identifying patients who are

enrolled in an approved research program or research study, in addition to entering information about medical marijuana products dispensed to all patients and caregivers. As proposed, this section mirrored the temporary § 1211.33 (relating to dispensing and tracking medical marijuana products), except for revising a citation to refer to the new Chapter 1161a (relation to dispensaries). No changes were made from proposed to final-form.

Some commentators questioned where the patient information will be recorded for patients participating in research programs. This information will be located in the electronic tracking system as will be other patient data. Clinical registrants have access to the electronic tracking system and can access patient information through that system.

#### *§ 1211a.34. Prohibition*

This section provides that, except for reasonable remuneration specified in a research contract for the services to be performed or costs to be incurred by the ACRC, an ACRC may not solicit or accept anything of value from an approved clinical registrant or a principal or financial backer of an approved clinical registrant. Further, this section clarifies that the prohibition does not apply to charitable contributions that are part of a history of giving to a ACRC established one year or more prior to the effective date of the act. No comments were received on this section and no changes were made from temporary to proposed to final-form.

#### *§ 1211a.35. Reporting requirements*

This section outlines when an approved clinical registrant must provide the Department a report of the findings of a research activity. This section further provides that the Department will publish these findings on its publicly available website and share them with other approved clinical registrants, ACRCs, or other persons the Department determines would benefit from the findings. No comments were received on this section and no changes were made from temporary to proposed to final-form.

#### *§ 1211a.36. Sale or exchange*

This section outlines the items a grower/processor of a clinical registrant may sell or exchange with another grower/processor. This section is revised in final-form to reflect statutory change made by Act 44 of 2021, which permits a grower/processor of a clinical registrant to sell its medical marijuana products to any dispensary, rather than just to its own or to another clinical registrant dispensary. 35 P.S. § 10231.2002(b)(8). Subsections (c) and (d) are removed due to the statutory change.

One commentator requested that the Department remove subsections (c) and (d) from this provision. As indicated above, this change was made due to the statutory change.

The Department received several comments concerned about grower/processors of clinical registrants being able to meet patient demands, including having access to specific medical marijuana for the research programs, and objecting to the limitation on clinical registrants selling medical marijuana products only to clinical registrant dispensaries. As indicated above, these concerns were addressed by Act 44 of 2021.

#### *§ 1211a.37. Appeals*

This section provides that all actions of the Department under this chapter are governed by Chapter 5, Subchapter A of 2 Pa.C.S. and its accompanying regulations, as modified by the new final



Chapter 1230a (relating to practice and procedure). As proposed, this section revised the temporary § 1211.37 by adding the language that the accompanying regulations to 2 Pa. C.S. Chapter 5, as modified by Chapter 1230a, apply to the appeal process. The citation was also revised to refer to the new Chapter 1230a. No comments were received on this section and no changes were made from proposed to final-form.

#### *Chapter 1230a. Practice and Procedure*

This chapter pertains to practice and procedure on appeals and other administrative proceedings. Section 301 of the act grants the Department the authority to promulgate all regulations necessary to carry out the provisions of this act. This chapter is necessary to define appeal rights and procedures surrounding actions taken by the Department pursuant to its regulatory and enforcement authority. This chapter replaces the temporary Chapter 1230 (relating to practice and procedure -- temporary regulations). Amendments to sections of the temporary regulations are discussed more fully below.

##### *§ 1230a.21. Scope*

This section provides that this final chapter and the General Rules of Administrative Practice and Procedure govern practice and procedure before the Department in medical marijuana appeals. No comments were received on this section and no changes were made from temporary to proposed to final-form.

##### *§ 1230a.22. Definitions*

This section provides definitions not referenced in § 1141a.21 (relating to definitions) and supplements the definitions in 1 Pa. Code § 31.3 (relating to definitions). No comments were received on this section and no changes were made from temporary to proposed to final-form.

##### *§ 1230a.23. Docket*

This section provides the general duties and address of the docket clerk for mailing of filings. Further, this section provides that pleadings must be filed within prescribed time periods and are considered filed when received by the docket clerk. This section also provides that the clerk will maintain the docket, that the docket is available for public inspection, and that subsections (a) through (e) supersede 1 Pa. Code §§ 33.11 and 33.51 (relating to execution; and docket). No comments were received on this section and no changes were made from temporary to proposed to final-form.

##### *§ 1230a.24. Filing generally*

This section provides the general requirements for a filing to be accepted by the Department and provides for rejection or correction of deficient pleadings. This section further provides that redundant, immaterial, or inappropriate pleadings may be stricken before being accepted for filing. No comments were received on this section and no changes were made from temporary to proposed to final-form.

##### *§ 1230a.25. Effective date of adjudication, actions or order*

This section provides that an adjudication, action, or order is effective as of the date of mailing unless specifically provided otherwise, and that subsection (a) supersedes 1 Pa. Code § 31.14 (relating to effective dates of agency orders). No comments were received on this section and no changes were made from temporary to proposed to final-form.

*§ 1230a.26. Representation*

This section provides that, except for an individual appearing on their own behalf, a party, corporation, or group of individuals acting in concert must be represented by an attorney in good standing and outlines how that representation must be effectuated. This section also provides that final subsections (a) through (d) supersede 1 Pa. Code §§ 31.21 through 31.23 (relating to appearance in person; appearance by attorney; and other representation prohibited at hearings). No comments were received on this section. However, the Department amended “his own behalf” to “their own behalf” to make the section gender-neutral on final-form.

*§ 1230a.38. Commencement, form and content of Notice of Appeal*

This section details the proper form of, and procedure for filing, a Notice of Appeal. This section also provides that final subsections (a) through (g) supersede 1 Pa. Code §§ 35.5 through 35.7. and 35.20 (relating to informal complaints; and appeals from actions of the staff). No comments were received on this section and no changes were made from temporary to proposed to final-form.

*§ 1230a.39. Timeliness of Notice of Appeal*

This section provides that the timeliness of a Notice of Appeal is measured from the mailing date of the written notice of the action, and an untimely filed Notice of Appeal may be deemed an admission or be dismissed with prejudice. This section further provides that the Department may file an answer and new matter to a Notice of Appeal within 30 days of service of the Notice but is not required to do so. This section also provides that subsection (a) supersedes 1 Pa. Code §§ 35.5 through 35.7, 35.20, and 35.35 (relating to informal complaints; appeals from actions of the staff; and answers to complaints and petitions). As proposed, subsection (a) was revised to provide that the timeliness of an appeal will be measured from the mailing date of the written notice of the action instead of the date the appellant receives the written notice. This revision removes ambiguity relating to timeliness of appeals and removes the possibility for differing time periods for appeal. Further, subsection (b) was revised to provide that an untimely filed Notice of Appeal may be deemed an admission or may be dismissed by the Department, instead of the language in the temporary § 1230.39 that one's "failure to file" a timely Notice of Appeal results in the same. This amendment is a technical clarification. No changes were made from proposed to final-form.

One commentator sought clarification on the timeframe for an appeal and whether it has been extended due to mail delays. The timeframe for an appeal will remain unchanged, and untimely appeals may be permitted if acceptable extenuating circumstances are established.

*§ 1230a.43. Orders to Show Cause, orders or petitions filed by the Office*

This section provides that the Office may start an action by filing an Order to Show Cause. As proposed, subsection (b) was revised to provide that the date of service is the date indicated on the certificate of service, regardless of the method of service, as opposed service being deemed complete three days after the date on the certificate of service if service is completed by mail. This amendment eliminates ambiguity as to the date of service. This section also specifies the required content for an Order to Show Cause and provides the required format for a notice to respond. Finally, this section provides that final subsections (a) through (d) supersede 1 Pa. Code § 35.14 (relating to orders to show cause). No changes were made from proposed to final-form.

One commentator raised concerns with the mail system relating to the filing and service of Orders to Show Cause under this section. Specifically, the commentator requested that the date of service be

the date the mail is received by the entity. Such a change, however, is unnecessary. The Department—and, by extension, the courts—are aware of such issues and take such issues into account when determining the timeliness of these materials. Therefore, the Department will take no action in response to this comment.

*§ 1230a.44. Answers to Orders to Show Cause, orders or other petitions filed by the Office*

This section outlines the content, form, and substance of responses to Orders to Show Cause, orders, or other petitions filed by the Office, in addition to providing penalties for failure to file a timely response. This section also prohibits the filing of new matter or preliminary objections and specifies that subsections (a) through (e) supersede 1 Pa. Code § 35.37 (relating to answers to orders to show cause). As proposed, this section mirrored the temporary § 1230.44 (relating to answers to orders to show cause, orders or other petitions filed by the Office), except for revising a citation to refer to this new chapter. No changes were made from proposed to final-form.

*§ 1230a.45. Verifications and affidavits*

This section provides that a pleading or other document containing an averment of fact not appearing of record in the action or containing a denial of fact shall be personally verified in a manner prescribed by this section by a party thereto or by an authorized officer of the party if a corporation or other business entity. No comments were received on this section and no changes were made from proposed to final-form.

*§ 1230a.46. Entry of default judgment*

This section provides that the Department, on motion of the Office, may enter default judgment against the respondent for failure to file within the required time an answer to an Order to Show Cause, order, or other petition, to which the respondent may answer and have an opportunity to be heard; default judgment may not be granted prior to the hearing and the filing of an answer. No comments were received on this section and no changes were made from proposed to final-form.

*Uncategorized Comments/Responses*

One commentator requested the removal of the word “marijuana” from “all regulatory items” because of the negative connotations and history related to the word. As this would require a legislative change, the Department takes no action in response to this comment.

One commentator requested that the Department ensure that dispensaries only sell forms of medical marijuana that are permitted under the Act and regulations. Specifically, this commentator took umbrage with dispensaries selling what are commonly referred to as “moon rocks” or “caviar”—marijuana buds dipped in oil and rolled in marijuana trichomes—as the commentator alleges that this product cannot be legally consumed under the Act and regulations. The act authorizes forms “medically appropriate: for administration by vaporization or nebulization.” 35 P.S. § 10231.303(b)(2)(iv). The Department has received evidence that “moon rocks,” “caviar,” or “flower concentrate” can be legally consumed by vaporization or nebulization and will take no action in response to this comment.

One commentator requested that the Department require a law enforcement presence at dispensary parking lots, citing concerns that patients are selling their products to non-patients in the parking lot. While the Department has supported its permittees in policing and seeking justice against patients engaging in diversion, the Department does not find continual law enforcement presence in dispensary parking lots to be necessary. Dispensaries are required to maintain video surveillance over

parking lots. *See* 28 Pa. Code § 1161a.31. As these areas are already monitored, the Department will take no action in response to this comment.

One commentator disagreed with prohibiting 18-year-old patients from enter dispensaries. This comment, however, is misguided, as those individuals can permissibly enter a dispensary facility. *See* 35 P.S. § 10231.506. As this practice is currently permitted, the Department takes no action in response to this comment.

One commentator took umbrage with the current state of gun laws—presumably concealed carry permits and their interplay with medical marijuana use. The Department, however, is unable to take any action in response to this comment, as those gun laws are federal.

One commentator remarked that some dispensaries are holding themselves out as recreational facilities, as opposed to medical. To the extent this is occurring, the Department shares the commentator's concerns and urges the commentator to submit a complaint to the Department, identifying the offending entities.

One commentator requested that dispensary menus display the top three cannabinoids and terpenes for each product. This comment, however, would be best addressed to dispensary permittees. The Department does not dictate what a dispensary lists on its menu. Accordingly, the Department takes no action in response to this comment.

One commentator objected generally to the cost of medical marijuana products and suggested that the Department lower the cost. The Department, however, does not exercise authority over pricing of product (only enforcing pricing limitations—*i.e.*, no zero-cost products). Beyond that isolated area, pricing is solely controlled by the permittees. While the Department has the authority under the act to implement a pricing cap, 35 P.S. § 10231.705, the Department hesitates to do so as the establishment of a pricing cap often becomes the pricing floor, *i.e.*, already lower prices on products will be raised to meet the pricing cap. Pricing will decline with increased supply, as has already been demonstrated over several years.

One commentator requested generally that the Department allow for more medical marijuana organizations within the Commonwealth. The Department, however, is unable to adopt such a revision, as the number of available permits is set by the act itself. 35 P.S. § 10231.616.

One commentator requested that the Department allow an expedited approval process for terminal/cancer patients. While the Department is cognizant of the differing needs of these patients, the Department has streamlined its approval process so that all patients are approved and receive their cards in the most expedient way possible, often in as little as a few days.

One commentator raised concerns as to whether not allowing unapproved visitors—*e.g.*, an individual supporting a disabled person—violated discrimination laws against handicapped persons. All permittee facilities must be handicapped accessible. Additionally, to the extent the person needs help with mobility, dispensary staff or an approved caregiver can provide the necessary aid. Accordingly, the Department takes no action in response to this comment.

One commentator requested that the Department amend section 2103 of the act to add protections for housing for medical marijuana patients. The Department, however, is unable to enact legislative change, and the commentator would be best served by reaching out to their legislators.

Multiple commentators sought a continuation of the statutory waivers that the Department received during the COVID-19 pandemic. These waivers were made permanent by Act 44 of 2021. All necessary regulatory changes have been made in response to Act 44 of 2021.

One commentator sought to include a dispensary medical professional as part of the physician workgroup. While the composition of the physician workgroup is not part of these regulations, the Department will take this request under advisement.

One commentator questioned why dispensary patient consultants are not currently allowed to touch display items stored in glass display cases to aid in patient education. To the extent that this comment is suggesting that patient consultants should be permitted to open products or devices that are for sale in the dispensary, the act requires dispensing of sealed packages. 35 P.S. § 10231.801(i). If the commentator is proposing to permit the display of approved devices appropriate for administering medical marijuana but not for sale, nothing in the act or regulations currently prohibit the visual display of devices that do not contain medical marijuana.

One commentator raised concerns as to the Department's current process and timing of approvals and submissions as well as suggested the Department adopt an online platform such as those used by other states, like Ohio, that allow requests to be tracked and uploaded in real-time. The Department appreciates this comment and will continue to examine whether funding will be available to implement an online platform.

Several commentators, though not referencing a specific regulatory provision, requested that the Department establish regulations related to the Medical Marijuana Program Fund (Fund) created by section 902 of the act and referenced in this regulatory section. *See* 35 P.S. § 10231.902. Particularly, these commentators sought regulation related to establishing a program to assist patients demonstrating financial hardship. 35 P.S. § 10231.902(c)(1)(i). Funding of the assistance program for patients demonstrating financial hardship begins after the Department repays the money appropriated for the initial funding of the medical marijuana program. 35 P.S. § 10231.902(c). This repayment recently occurred, and creation of the assistance program is underway. Regulations are not necessary to administer the Fund.

The Department received a lengthy comment from the Pennsylvania Cannabis Coalition (PCC), who represents some, but not all, of the medical marijuana program's permittees. PCC asserted that the Department did not conduct stakeholder outreach for input before proposing final form regulations and lacks a collaborative relationship with stakeholders. To the contrary, the Department held multiple meetings throughout 2019, 2020, 2021, and 2022 with the PCC and received feedback from the industry regarding proposed regulatory changes, many of which were incorporated into the final regulations. The Department continues to have meetings with the PCC regularly. Additionally, all permittees have ongoing access to regional field supervisors and email resource accounts to convey questions and concerns. The Department communicates regularly with permittees. PCC further asserted that the Department fails to provide data transparency in reporting aggregate or de-identified data metrics. The Department does limit dissemination of certain data as the act deems "[a]ll information obtained by the department relating to patients, caregivers and other applicants" confidential. 35 P.S. § 10231.302(a). Additionally, section 701(c) of the act deems information maintained in electronic tracking system to be confidential, preventing the release of most seed-to-sale tracking data. 35 P.S. § 10231.701(c). PCC finally asserted that the Department failed to adequately address the regulatory impact on small businesses in the medical marijuana marketplace and the fiscal impact on operators. The Department addresses small business and fiscal impacts in the corresponding questions provided within the regulatory analysis form. The Department takes no further action in response to these comments.

### *C. Affected Persons*

Medical marijuana applicants, patients, and their caregivers, as well as grower/processor and dispensary permittees, approved practitioners and approved labs, will be required to comply with the provisions in this rulemaking. Additionally, those individuals or entities that have not yet been issued a permit to grow, process, or dispense medical marijuana as well as successful future applicants will be required to comply with the provisions contained in this rulemaking.

### *D. Cost and Paperwork Estimate*

#### *Cost*

#### *Commonwealth*

The Department will experience increased demands to maintain compliance control over the Medical Marijuana Program. This increased demand will be handled by the existing Medical Marijuana Program complement. While the Department did not expect to incur any cost increases as a result of this rulemaking, the passage of Act 44 of 2021, and the resultant changes to this regulatory packet will result in an estimated \$2 million increase to the Department, particularly as it relates to the implementation of API integration with the MJ Freeway tracking system.

#### *Local Government*

The rulemaking will impose no additional costs and have no negative fiscal impact upon political subdivisions. Further, the rulemaking does not impose any additional burden of enforcement or review on political subdivisions.

#### *Regulated Community*

The rulemaking will impose no additional costs upon medical marijuana patients and caregivers.

Grower/processor and dispensary permittees may experience minimal cost increases in complying with the revised policies regarding facility security and testing and reporting requirements imposed by this rulemaking.

Practitioners will not experience any additional costs because of this rulemaking.

#### *General public*

This rulemaking will have no fiscal impact on the general public.

#### *Paperwork Estimates*

#### *Commonwealth and the regulated community*

This rulemaking imposes no additional paperwork requirements on the Commonwealth or the regulated community.

#### *Local Government*

This rulemaking imposes no additional paperwork requirements on local government.

## *General Public*

This rulemaking imposes no additional paperwork requirements on the general public.

### *E. Statutory Authority*

The Department obtains its authority to promulgate regulations relating to the Medical Marijuana Program from the provisions of the Medical Marijuana Act (35 P.S. §§ 10231.101-10231.2110). The act provides the Department with the authority to promulgate all regulations necessary to carry out the provisions set forth in the act. (35 P.S. § 10231.301(b)). Further, under § 301 of the act, the Department has (1) regulatory and enforcement authority over the growing, processing, dispensing, testing, practitioner certification, transportation, and use, of medical marijuana in the Commonwealth, and (2) authority to promulgate all regulations necessary to carry out the provisions of the act. (35 P.S. § 10231.301(a)(3), (b)).

### *F. Effectiveness and Sunset Dates*

The rulemaking becomes effective upon publication in the *Pennsylvania Bulletin* as final-form rulemaking. No sunset date will be established. The Department will continually review and monitor the effectiveness of these regulations after they are published as final.

### *G. Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on February 16, 2021, the Department submitted notice of this proposed rulemaking, published at 51 Pa.B. 1141 (March 6, 2021), to IRRC and the Chairpersons of the Senate Health and Human Services Committee and the House Health Committee for review and comment.

Under section 5(c) of the Regulatory Review Act, 71 P.S. § 745.5(c), IRRC, the Senate Health and Human Services Committee and the House Health Committee were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Department has considered all comments from IRRC, the Senate Health and Human Services Committee, the House Health Committee and the public.

Under section 5.1(e) of the Regulatory Review Act, 71 P.S. § 745.5a(e), on \_\_\_\_\_, 2022, the final-form rulemaking was deemed approved by the Senate Health and Human Services Committee and the House Health Committee. Under section 5.1(e) of the Regulatory Review Act, IRRC met on \_\_\_\_\_, 2022 and approved the final-form rulemaking.

### *H. Contact Person*

Additional information regarding this final-form rulemaking may be obtained by contacting Laura Mentch, Director, Office of Medical Marijuana, Department of Health, Room 628, Health and Welfare Building, 625 Forster Street, Harrisburg, PA 17120, (717) 547-3454, or by emailing [RA-DHMMregulations@pa.gov](mailto:RA-DHMMregulations@pa.gov). Persons with a disability who wish to submit comments, suggestions, or objections regarding the final regulations may do so by using the above number or address. Speech and/or hearing-impaired persons may use the Pennsylvania AT&T Relay Service at (800) 654-5984 (TDD users) or (800) 654-5988 (voice users).

### *I. Findings*

The Department finds that:

(1) Public notice of intention to adopt the regulations adopted by this order has been given under sections 201 and 202 of the Act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202), and the regulations promulgated under those sections at 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered in drafting this final-form rulemaking.

(3) The amendments made to the final-form rulemaking do not enlarge the original purpose of the proposed rulemaking as published under section 201 of the Act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. § 1201).

(4) The adoption of the regulations is necessary and appropriate for the administration of the Medical Marijuana Act (35 P.S. §§ 10231.101—10231.2110).

#### **J. Order**

(1) The regulations of the Department at Title 28 of the Pennsylvania Code are amended to delete Part IX and add Part IXa, as set forth in Annex A.

(2) The Department shall submit this final-form regulation to the Office of Attorney General and the Office of General Counsel for approval as required by law.

(3) The Department shall submit this final-form regulation to IRRC, the Senate Health and Human Services Committee and the House Health Committee as required by law.

(4) The Department shall certify this final-form regulation, as approved for legality and form, and shall deposit it with the Legislative Reference Bureau as required by law.

(5) This final-form regulation shall take effect upon publication in the *Pennsylvania Bulletin*.



**LIST OF COMMENTATORS WHO REQUESTED ADDITIONAL INFORMATION ON  
FINAL-FORM REGULATION #10-219  
DEPARTMENT OF HEALTH**

<b>Requestor</b>	<b>Email</b>
Lynsi Sheckler	<a href="mailto:l.sheckler@acreageholdings.com">l.sheckler@acreageholdings.com</a>
Marcia McCarroll	<a href="mailto:marciaxmccarroll@gmail.com">marciaxmccarroll@gmail.com</a>
Deborah Shoemaker	<a href="mailto:dshoemaker@pamedsoc.org">dshoemaker@pamedsoc.org</a>
Pamela Epstein	<a href="mailto:pamela@edenenterprises.com">pamela@edenenterprises.com</a>
Bob Miller	<a href="mailto:bobm@actlabllc.com">bobm@actlabllc.com</a>
Luke Shultz	<a href="mailto:kimlukes@gmail.com">kimlukes@gmail.com</a>
Michael Bronstein	<a href="mailto:michael@atach.org">michael@atach.org</a>
Tim Schnupp	<a href="mailto:tschnupp@uscannalytics.com">tschnupp@uscannalytics.com</a>
Michael Hutter	<a href="mailto:mhutter@fgbmp.com">mhutter@fgbmp.com</a>
Samantha Kramer	<a href="mailto:Samantha.Kramer@gtigrows.com">Samantha.Kramer@gtigrows.com</a>
Nico Pento	<a href="mailto:npento@terrapincarestation.com">npento@terrapincarestation.com</a>
Tina Brunetti	<a href="mailto:tinambrunetti@gmail.com">tinambrunetti@gmail.com</a>
Theodore C. Flowers	<a href="mailto:ted@moriconiflowers.com">ted@moriconiflowers.com</a>
Dr. Charles Harris	<a href="mailto:aimmed420@gmail.com">aimmed420@gmail.com</a>
Julia Naccarato	<a href="mailto:jnaccarato@mcrlabs.com">jnaccarato@mcrlabs.com</a>
Debra Flinn	<a href="mailto:dflinn13@gmail.com">dflinn13@gmail.com</a>
Zachary Paschke	<a href="mailto:paschke02@gmail.com">paschke02@gmail.com</a>
Matthew Franchak	<a href="mailto:Matthew.Franchak@pasenate.com">Matthew.Franchak@pasenate.com</a>
Michele Kessler	<a href="mailto:MKessler@UFCW1776.ORG">MKessler@UFCW1776.ORG</a>
Bellew Asfa	<a href="mailto:8Asfa@UFCW1776.ORG">8Asfa@UFCW1776.ORG</a>
Jennifer Minkovich	<a href="mailto:jenniferho@pcom.edu">jenniferho@pcom.edu</a>
Brian Schwab, DO	<a href="mailto:Brian.SCHWAB@ahn.org">Brian.SCHWAB@ahn.org</a>
Meredith Buettner	<a href="mailto:meredith@pcanna.org">meredith@pcanna.org</a>
Maryfrances Koester	<a href="mailto:mfcrow@aol.com">mfcrow@aol.com</a>
Alison Corradini	<a href="mailto:doyennecannabis@gmail.com">doyennecannabis@gmail.com</a>
Ellen Parkin	<a href="mailto:ellen.parkin@pa.steepphill.com">ellen.parkin@pa.steepphill.com</a>
Karissa Miller	<a href="mailto:kmiller@uscannalytics.com">kmiller@uscannalytics.com</a>
NO NAME GIVEN	<a href="mailto:ggottheimer@uscannalytics.com">ggottheimer@uscannalytics.com</a>
NO NAME GIVEN	<a href="mailto:tpendergraft@uscannalytics.com">tpendergraft@uscannalytics.com</a>
NO NAME GIVEN	<a href="mailto:jhaun@uscannalytics.com">jhaun@uscannalytics.com</a>
Judith Cassel	<a href="mailto:JDCassel@hmslegal.com">JDCassel@hmslegal.com</a>
James Leventis	<a href="mailto:james.leventis@verano.com">james.leventis@verano.com</a>
Sarah Hassinger	<a href="mailto:sarah.hassinger.pharmd@gmail.com">sarah.hassinger.pharmd@gmail.com</a>
Holly Lang	<a href="mailto:hslang@comcast.net">hslang@comcast.net</a>
Tina Brunetti	<a href="mailto:tinambrunetti@gmail.com">tinambrunetti@gmail.com</a>
Lauren Vrabel	<a href="mailto:lauren.vrabel@gmail.com">lauren.vrabel@gmail.com</a>
Bruce Stern	<a href="mailto:brucestern@aol.com">brucestern@aol.com</a>

**Annex A**

**TITLE 28. HEALTH AND SAFETY**

**PART IX. (Reserved)**

**CHAPTER 1131. (Reserved)**

**§§ 1131.1—1131.7. (Reserved).**

**CHAPTER 1141. (Reserved)**

**§§ 1141.21—1141.52. (Reserved).**

**CHAPTER 1151. (Reserved)**

**§§ 1151.21—1151.45. (Reserved).**

**CHAPTER 1161. (Reserved)**

**§§ 1161.21—1161.41. (Reserved).**

**CHAPTER 1171. (Reserved)**

**§§ 1171.21—1171.39. (Reserved).**

**CHAPTER 1181. (Reserved)**

**§§ 1181.21—1181.34. (Reserved).**

**CHAPTER 1191. (Reserved)**

**§§ 1191.21—1191.34. (Reserved).**

**CHAPTER 1211. (Reserved)**

**§§ 1211.21—1211.37. (Reserved).**

**CHAPTER 1230. (Reserved)**

**§§ 1230.21—1230.46. (Reserved).**

*(Editor's Note: The following Part is proposed to be added and printed in regular type to enhance readability.)*

**PART IXa. MEDICAL MARIJUANA**

**CHAPTER 1141a. GENERAL PROVISIONS**

**Sec.**

1141a.21. Definitions.

1141a.22. Records subject to disclosure; confidentiality.

1141a.23. Limitation on number of permits.

1141a.24. Medical marijuana regions.

1141a.25. General requirements for permits.

1141a.26. Privilege and nontransferability.

1141a.27. General requirements for application.

1141a.28. Fees.

1141a.29. Initial permit application.

1141a.30. Capital requirements.

1141a.31. Background checks.

1141a.32. Diversity goals.

1141a.33. Review of initial permit applications.

1141a.34. Denial of a permit.

1141a.35. Notice of denial.

1141a.36. Permit renewal applications.

1141a.37. Denial of renewal of a permit.

1141a.38. Duty to report.

1141a.39. [Application for change]Change in ownership of a medical marijuana organization.

1141a.40. Application for approval of a change in location of an operational facility.

1141a.40.1 Request to change location of a non-operational facility.

1141a.41. Application for approval of alteration of a facility.

1141a.42. Failure to be operational.

1141a.43. Closure of a facility.

1141a.44. Insurance requirements.

1141a.45. Inspection and investigation.

1141a.46. Reports.

1141a.47. General penalties and sanctions.

1141a.48. Training.

1141a.49. Zoning.

1141a.50. Advertising by a medical marijuana organization.

1141a.51. Technical advisories.

## **§ 1141a.21. Definitions.**

The following words and terms, when used in this part, have the following meanings, unless the context clearly indicates otherwise:

*ACRC—Academic Clinical Research Center*—An accredited medical school in this Commonwealth that operates or partners with an acute care hospital licensed and operating in this Commonwealth that has been approved and certified by the Department to enter into a contract with a clinical registrant.

*Accreditation body*—An organization which:

(i) Certifies the competency, expertise and integrity of a laboratory and operates in conformance with the current version of International Organization Standard ISO/IEC 17011.

(ii) Determines a laboratory's compliance with and conformance to the relevant standards established by the International Organization for Standardization, including ISO/IEC 17025.

(iii) Is a signatory to the International Accreditation Cooperation Mutual Recognition Arrangement for Testing.

(iv) Is not affiliated with a laboratory applicant for which it has or will issue a certificate of accreditation.

*Accredited medical school*—An institution that is:

(i) Located in this Commonwealth.

(ii) Accredited by the Liaison Committee of Medical Education or the Commission on Osteopathic College Accreditation.

*Act*—The Medical Marijuana Act (35 P.S. §§ 10231.101—10231.2110).

*Acute care hospital*—A facility having an organized medical staff that provides equipment and services primarily for inpatient medical care and other related services to persons who require definitive diagnosis or treatment, or both, for injury, illness, pregnancy or other disability and is licensed by the Department to operate as a hospital in this Commonwealth under the Health Care Facilities Act (35 P.S. §§ 448.101—448.904b) and the regulations promulgated thereunder.

*Added substance*—Any additional ingredient added to medical marijuana during or after processing that is present in the final product or any substance used to change the viscosity or consistency of a cannabinoid product.

*Adult patient*—A patient who is 18 years of age or older.

*Adverse event*—An injury resulting from the use of medical marijuana dispensed at a dispensary. An injury includes physical harm, mental harm or loss of function.

*Adverse loss*—A loss, discrepancy in inventory, diversion or theft of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products, funds or other property of a medical marijuana organization.

*Advertising*—The publication, dissemination, solicitation or circulation, for a fee, that is visual, oral, written or electronic to induce directly or indirectly an individual to patronize a particular dispensary, laboratory or practitioner, or to purchase particular medical marijuana products.

*Applicant*—Depending on the context the term may mean any of the following:

(i) A person who wishes to submit or submits an application to the Department for a permit to operate as a grower/processor or dispensary, or both, under the act and this part.

(ii) A patient or a caregiver who submits an identification card application to the Department.

(A) The term includes a legal guardian or a parent who submits an application on behalf of a patient.

(B) The term does not include an individual under 21 years of age unless the Department has determined under section 507(a) of the act (35 P.S. § 10231.507(a)) that the individual should be permitted to serve as a caregiver.

(C) A person who submits an application to the Department to become an approved laboratory, an ACRC or a clinical registrant.

*Approved laboratory*—A laboratory that has applied for, and received, the approval of the Department to identify, collect, handle and conduct tests on samples from a grower/processor and test samples from the Department used in the growing and processing of medical marijuana or dispensing of medical marijuana products as required by the act and this part.

*CAS number*—The unique numerical identifier assigned to every chemical substance by Chemical Abstracts Service, a division of the American Chemical Society.

*CBC*—Cannabichromene, CAS number 20675-51-8.

*CBD*—Cannabidiol, CAS number 13956-29-1.

*CBDA*—Cannabidiolic acid, CAS number 1244-58-2.

*CBDV*—Cannabidivarin, CAS number 24274-48-4

*CBG*—Cannabigerol, CAS number 25654-31-3.

*CBN*—Cannabinol, CAS number 521-35-7.

*Cannabinoids*—The chemical compounds that are the active constituents of marijuana.

*Caregiver*—One of the following:

(i) An individual designated by a patient to obtain on behalf of a patient, and provide to a patient, a medical marijuana product.

(ii) For a minor patient, an individual who meets the requirements in section 506(2) of the act (35 P.S. § 10231.506(2)).

(iii) Individuals designated in writing by an organization that provides hospice, palliative or home care services and who:

(a) Are employed by an organization licensed under the Health Care Facilities Act, 35 P.S. 448.101 et seq.

(b) Have significant responsibility for managing the health care and well-being of a patient.

(c) Were designated by the organization to provide care to a patient who authorized the designation.

(iv) Individuals designated in writing by a residential facility, a long-term care nursing facility, a skilled nursing facility, an assisted living facility, a personal care home, an independent long-term care facility or an intermediate care facility for individuals with intellectual disabilities who:

- (a) Are licensed by the Department or Department of Human Services.
- (b) Have significant responsibility for managing the health care and well-being of the patient.
- (c) Were designated by the residential facility to provide care to a patient who authorized the designation.

*Certificate of accreditation*—A document issued by an accreditation body evidencing that a laboratory is in compliance with International Organization for Standardization Standard ISO/IEC 17025 or other standards relevant to the operation of laboratories conducting tests on medical marijuana, medical marijuana products and other items used in the growing and processing of medical marijuana or dispensing of medical marijuana products.

*Certificate of analysis*—A document that confirms that the test performed by an approved laboratory on a harvest batch, harvest lot, [or] process lot, or sample for stability meets the testing requirements set forth by the Department.

*Certified medical use*—The acquisition, possession, use or transportation of medical marijuana products by a patient; or the acquisition, possession, delivery, transportation or administration of medical marijuana products by a caregiver, for use as part of the treatment of the patient's serious medical condition, as authorized in a patient certification, including enabling the patient to tolerate treatment for the serious medical condition.

*Certified registered nurse practitioner*—The term as defined in section 2 of The Professional Nursing Law (63 P.S. § 212).

*Chain of custody*—The written procedures used by employees of an approved laboratory to record the possession and transfer of samples and test samples and the real-time documentation of actions taken from the time the samples and test samples are collected until the test of the sample or test sample is completed.

*Change in control*—The acquisition by a person or group of persons acting in concert of a controlling interest in an applicant or permittee either all at one time or over the span of a 12-consecutive-month period.

*Change in ownership*—The addition or removal of a principal, operator or financial backer or a change in control of a medical marijuana organization after the Department approves an initial permit application or a permit renewal application.

*Clinical registrant*—An entity that:

- (i) Holds a permit as both a grower/processor and a dispensary;
- (ii) Has a contractual relationship with an academic clinical research center under which the academic clinical research center or its affiliate provides advice to the entity, regarding, among other areas, patient health and safety, medical applications and dispensing and management of controlled substances; and

(iii) Is approved by the Department [as a clinical registrant].

*Continuing care*—Treating a patient, in the course of which the practitioner has completed a full assessment of the patient's medical history and current medical condition, including [an in-person] a consultation with the patient.

*Controlled substance*—A drug, substance or immediate precursor included in Schedules I—V as listed in section 4 of The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. § 780-104).

*Controlling interest*—

(i) For a publicly traded entity, voting rights that entitle a person to elect or appoint one or more of the members of the board of directors or other governing board or the ownership or beneficial holding of 5% or more of the securities of the publicly traded entity.

(ii) For a privately held entity, the ownership of any security in the entity.

*D8*—Delta 8 Tetrahydrocannabinol, CAS number 5957-75-5.

*De-identified data* – a record retrieved from the electronic tracking system transmitted to an ACRC for medical marijuana research purposes after removal of all personal information that could identify a patient.

*Department*—The Department of Health of the Commonwealth.

*Device*—An object used, intended for use or designed for use in preparing, storing, ingesting, inhaling or otherwise introducing medical marijuana into the human body.

*Disadvantaged business*—The term as defined in 74 Pa.C.S. § 303(b) (relating to diverse business participation).

*Dispensary*—

(i) A person who holds a permit issued by the Department to dispense medical marijuana products.

(ii) The term does not include a health care medical marijuana organization as defined under sections 1901—1908 of the act (35 P.S. §§ 10231.1901—10231.1908).

*Dispense*—The activity of lawfully providing to a patient or caregiver medical marijuana products in a suitable container that is appropriately labeled for subsequent administration or use under a patient certification issued by a practitioner.

*Diverse group*—A disadvantaged business, minority-owned business, women-owned business, service-disabled veteran-owned small business or veteran-owned small business that has been certified by a third-party certifying organization.

*Diverse participants*—The term includes the following:

(i) Individuals from diverse racial, ethnic and cultural backgrounds and communities.

(ii) Women.

(iii) Veterans.

(iv) Individuals with disabilities.

**Diversity plan**—A strategy that promotes or ensures participation by diverse groups in the management and operation of a medical marijuana organization through contracting and employment opportunities.

**Electronic tracking system**—An electronic seed-to-sale system approved by the Department that is utilized by:

(i) A grower/processor to log, verify and monitor the receipt, use and sale of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products, the funds received by a grower/processor for the sale of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products to another medical marijuana organization, the disposal of medical marijuana waste and the recall of defective seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

(ii) A dispensary to log, verify and monitor the receipt of medical marijuana product from a grower/processor, the verification of the validity of an identification card presented by a patient or caregiver, the dispensing of medical marijuana product to a patient or caregiver, the disposal of medical marijuana waste and the recall of defective medical marijuana products.

(iii) An approved laboratory to log, verify and monitor the receipt of samples and test samples for testing, the results of tests performed by the approved laboratory, and the disposal of tested and untested samples and test samples.

**Employee**—An individual who is hired for a wage, salary, fee or payment to perform work for an applicant or permittee.

**Excipients**—Solvents, chemicals or materials reported by a medical marijuana organization and approved by the Department for use in the processing of medical marijuana.

**Facility**—A structure and other appurtenances or improvements where a medical marijuana organization grows and processes or dispenses medical marijuana.

**Family or household member**—The term as defined in 23 Pa.C.S. § 6102 (relating to definitions).

**Financial backer**—An investor, mortgagee, bondholder, note holder, or other source of equity, capital or other assets other than a financial institution.

**Financial institution**—A bank, a National banking association, a bank and trust company, a trust company, a savings and loan association, a building and loan association, a mutual savings bank, a credit union or a savings bank.

**Form of medical marijuana**—The characteristics of the medical marijuana recommended or limited for a particular patient, including the method of consumption and any particular dosage, strain, variety and quantity or percentage of medical marijuana or particular active ingredient.

**Fund**—The Medical Marijuana Program Fund established in section 902 of the act (35 P.S. § 10231.902).

**Grower/processor**—

(i) A person who holds a permit from the Department under the act to grow and process medical



marijuana.

(ii) The term does not include a health care medical marijuana organization as defined under sections 1901—1908 of the act.

*Harvest batch*—A specifically identified quantity of medical marijuana plant that is uniform in strain, cultivated utilizing the same growing practices, harvested at the same time and at the same location, and cured under uniform conditions.

*Harvest lot*—A specifically identified quantity of medical marijuana plant taken from a harvest batch.

*"Harvested hemp"*— Plant material, certified as hemp by a Department of Agriculture approved laboratory, obtained directly from a person holding a permit issued by the Department of Agriculture to grow or cultivate hemp under the 3 Pa.C.S. Ch. 15 (relating to controlled plants and noxious weeds) by a grower/processor holding a permit under the act.

*Health care medical marijuana organization*—A vertically integrated health system approved by the Department to dispense medical marijuana or grow and process medical marijuana, or both, in accordance with a research study under sections 1901—1908 of the act.

*Hydroponic nutrient solution*—A mixture of water, minerals and essential nutrients without soil used to grow medical marijuana plants.

*IRB—Institutional review board*—A board, committee, RAC or group designated by an ACRC that reviews and approves the anticipated scope of an approved clinical registrant's research study involving human subjects under the criteria in 45 CFR 46.111 (relating to criteria for IRB approval of research) and 21 CFR 56.111 (relating to criteria for IRB approval of research).

*Identification card*—A document issued under section 501 of the act (35 P.S. § 10231.501) that authorizes a patient or caregiver to have access to medical marijuana products under the act.

*Immature medical marijuana plant*—A rootless, nonflowering part of a medical marijuana plant that is no longer than 12 inches and no wider than 12 inches produced from a cutting, clipping or seedling and that is in a growing container that is no larger than 2 inches wide and 2 inches tall that is sealed on the sides and bottom.

[*Immediate family*—The term as defined in 4 Pa.C.S. § 1512(b) (relating to financial and employment interests).]

[*Industrial hemp*—The plant *Cannabis sativa* L., and any part of the plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3% on a dry-weight basis.]

*Initial permit application*—The document submitted to the Department by an applicant that, if approved, grants a permit to an applicant.

*Institution of higher education*—A community college, State-owned institution, State-related institution, or private college or university approved by the Department of Education.

*Laboratory*—A place, establishment or institution within this Commonwealth that has been issued a certificate of accreditation.

*Legal guardian*—

(i) An individual appointed as a guardian of a patient under the laws of the Commonwealth.

(ii) The term does not include an individual who has been appointed a guardian only of a patient's property.

*Limited access area*—Any area on a site or within a facility where:

(i) Immature medical marijuana plants or medical marijuana plants are growing or being processed into medical marijuana.

(ii) Immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products are being loaded into or out of transport vehicles.

(iii) Seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products are packaged for sale or stored.

(iv) Medical marijuana waste is processed, stored or destroyed.

(v) Surveillance system devices are stored or maintained.

*Marijuana*—

(i) All parts of the plant *Cannabis sativa* L., whether growing or not, the seeds of that plant and resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin. [

(ii) The term does not include industrial hemp.]

[(iii)] (ii) The term does not include the mature stalks of *Cannabis sativa* L., fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt or derivative, mixture or preparation of the mature stalks.

[(iv)] (iii) The term does not include synthetic cannabinoids as defined in section 4(1)(vii) of The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. § 780-104(1)(vii)).

*Medical Board*—Either of the following:

(i) The State Board of Medicine as defined in section 2 of the Medical Practice Act of 1985 (63 P.S. § 422.2).

(ii) The State Board of Osteopathic Medicine as defined in section 2 of the Osteopathic Medical Practice Act (63 P.S. § 271.2).

*Medical marijuana*—Marijuana for certified medical use, limited to the following forms:

(i) Pill.

(ii) Oil.

(iii) Topical forms, including gels, creams or ointments.

(iv) A form medically appropriate for administration by vaporization or nebulization, including dry leaf or plant form for administration by vaporization.

(v) Tincture.

(vi) Liquid.

*Medical marijuana cardholder*—An adult patient or caregiver who possesses a valid identification card.

*Medical marijuana container*—A sealed, traceable, food compliant, tamper resistant, tamper evident container used for the purpose of containment of packaged medical marijuana products being transported from a grower/processor to a medical marijuana organization or an approved laboratory.

*Medical marijuana extract*—A substance obtained by separating cannabinoids from a medical marijuana plant by a mechanical, chemical or other process.

*Medical marijuana organization*—

- (i) A dispensary or a grower/processor.
- (ii) The term does not include a health care medical marijuana organization under sections 1901—1908 of the act.

*Medical marijuana patient authorization letter*—A document issued by the Department under § 1191a.32 (relating to medical marijuana patient authorization letters).

*Medical marijuana plant*—A plant which is greater than 12 vertical inches in height from where the base of the stalk emerges from the growth medium to the tallest point of the plant, or greater than 12 horizontal inches in width from the end of one branch to the end of another branch.

*Medical marijuana product*—The final form and dosage of medical marijuana that is grown, processed, produced, sealed, labeled and tested by a grower/processor and sold to a dispensary.

*Medical Marijuana Program*—The program authorized under the act and implemented by the Department.

*Medical marijuana unit* – an amount of medical marijuana equivalent to 3.5 grams of dry leaf, 1 gram of concentrate, or 100 milligrams of THC infused into a pill, capsule, oil, liquid, tincture, or topical form.

*Medical marijuana waste*—

- (i) Solid, liquid, semi-solid or contained gaseous materials that are generated by a grower/processor or an approved laboratory.
- (ii) The term includes:
  - (A) Unused, surplus, returned, recalled, contaminated or expired medical marijuana, except as described in subsection (iii).
  - (B) Any medical marijuana plant material that is not used in the growing, harvesting or processing of medical marijuana, including flowers, stems, trim, leaves, seeds, dead medical marijuana plants, dead immature medical marijuana plants, unused medical marijuana plant parts, unused immature medical marijuana plant parts or roots.
  - (C) Spent hydroponic nutrient solution.
  - (D) Unused containers for growing immature medical marijuana plants or medical marijuana plants or for use in the growing and processing of medical marijuana.

(E) Unused fertilizers and pesticides.

(F) Unused excipients.

(G) Wastewater.

(iii) The term does not include medical marijuana products erroneously delivered to a dispensary other than the dispensary intended for sale, provided that the packaging remains unopened, with tamper-evident seals intact, and the medical marijuana products are immediately delivered to the correct dispensary.

*Medical professional*—A physician, pharmacist, physician assistant or certified registered nurse practitioner employed by a dispensary.

*Minor patient*—A patient who is under 18 years of age.

*Minority-owned business*—The term as defined in 74 Pa.C.S. § 303(b).

*Municipal waste*—The term as defined in section 103 of the Solid Waste Management Act (35 P.S. § 6018.103).

*Municipality*—A county, city, borough, incorporated town or township, or any similar general-purpose unit of government which shall hereafter be created by the General Assembly.

*Nebulization*—The generation of medical marijuana products in the form of fine spray for medicinal inhalation.

*Nutrient*—The essential elements and compounds necessary for the growth, metabolism and development of medical marijuana plants.

*Nutrient practice*—The use by a grower/processor of essential elements and compounds necessary for the growth, metabolism and development of seeds, immature medical marijuana plants or medical marijuana plants.

*Office*—The Department's Office of Medical Marijuana.

*Operational*—The time at which the Department determines that a medical marijuana organization is ready, willing and able to properly carry on the activity for which a permit has been issued under this part, including the implementation of an electronic tracking system.

*Operator*—An individual who directly oversees or manages the day-to-day business functions for an applicant or permittee and has the ability to direct employee activities onsite and offsite or within a facility for which a permit is sought or has been issued under this part.

*Parent*—The biological, natural or adoptive mother or father of a patient.

*Patient*—An individual who:

- (i) Has a serious medical condition.
- (ii) Has met the requirements for certification under the act.
- (iii) Is a resident of this Commonwealth.

*Patient and caregiver registry*—A list of patients and caregivers established and maintained by

the Department.

*Patient certification*—The document issued by a practitioner under § 1181a.27 (relating to issuing patient certifications) certifying that a patient has one or more serious medical conditions.

*Patient consultation*—A complete [in-person] examination of a patient, if physically present, and the patient's health care records at the time a patient certification is issued by a practitioner.

*Permit*—An authorization issued by the Department to a medical marijuana organization to conduct activities authorized under the act.

*Permittee*—A person who has been issued an authorization to operate as a medical marijuana organization under the act and this part.

*Person*—A natural person, corporation, foundation, organization, business trust, estate, limited liability company, licensed corporation, trust, partnership, limited liability partnership, association or other form of legal business entity.

*Pharmacist*—The term as defined in section 2 of the Pharmacy Act (63 P.S. § 390-2).

*Physician*—The term as defined in section 2 of the Medical Practice Act of 1985 [and] or section 2 of the Osteopathic Medical Practice Act.

*Physician assistant*—The term as defined in section 2 of the Medical Practice Act of 1985 (63 P.S. § 422.2) [and] or section 2 of the Osteopathic Medical Practice Act (63 P.S. § 271.2).

*Postharvest plant material* - all unfinished plant and plant-derived material, whether fresh, dried, partially dried, frozen or partially frozen, oil, concentrate or similar byproducts derived or processed from medical marijuana or medical marijuana plants.

*Practitioner*—A physician who is registered with the Department under section 401 of the act (35 P.S. § 10231.401).

*Practitioner registry*—A list of practitioners established and maintained by the Department.

*Prescription Drug Monitoring Program*—The Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) Act (35 P.S. §§ 872.1—872.40).

*Principal*—An officer, director or person who directly or beneficially owns securities of an applicant or permittee, or a person who has a controlling interest in an applicant or permittee or who has the ability to elect the majority of the board of directors of an applicant or permittee or otherwise control an applicant or permittee, other than a financial institution.

*Process lot*—Any amount of a medical marijuana product of the same type and processed using the same medical marijuana extract, standard operating procedures and the same or combination of different harvest lots.

*Processing*—The compounding or conversion of medical marijuana extract by a grower/processor into a medical marijuana product.

*Professional disciplinary action*—A disciplinary proceeding taken by the applicable Medical Board against a practitioner that results in a corrective action or measure.

*Publicly traded company*—A person other than an individual who:

- (i) Has a class or series of securities registered under the Securities Exchange Act of 1934 (15

U.S.C.A. §§ 78a—78qq) or on a foreign stock exchange determined by the Department to have similar listing and reporting requirements to exchanges that are regulated under the Securities Exchange Act of 1934.

(ii) Is a registered management company under the Investment Company Act of 1940 (15 U.S.C.A. §§ 80a-1—80a-64).

(iii) Is subject to the reporting obligations imposed by section 15(d) of the Securities Exchange Act of 1934 (15 U.S.C.A. § 780(d)) by reason of having filed a registration statement which has become effective under the Securities Act of 1933 (15 U.S.C.A. §§ 77a—77aa).

*RAC—Research approval committee*—A board, committee or group created or designated by an ACRC to review and approve the scope and research protocols of a research program proposed by an approved clinical registrant.

*Research*—Any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

*Research contract*—A written agreement between an approved clinical registrant and an ACRC that contains the responsibilities and duties of each party with respect to the research program or research study that the approved clinical registrant and the ACRC intend to conduct under this chapter and under which the ACRC will provide medical advice to the approved clinical registrant regarding, among other areas, patient health and safety, medical applications, and dispensing and management of controlled substances. This term shall include a letter of intent to enter into an agreement for purposes of a clinical registrant application.

*Research initiative*—A nonpatient investigation not subject to Institutional Review Board or Research Approval Committee approval requirements of a patient-based research program, project or study, conducted by an academic clinical research center and its contracted clinical registrant.

*Research program*—Research on the therapeutic or palliative efficacy of medical marijuana limited to the serious medical conditions defined by the act and this part.

*Research project or study*—Any other research on medical marijuana or its effectiveness in treating a medical or psychological condition.

*Research protocol*—A written procedure for conducting a research program, project or [research] study that includes all of the following information:

(i) With respect to the investigator:

(A) Name and address.

(B) Institutional affiliation.

(C) Qualifications, including a curriculum vitae and list of publications, if any.

(ii) With respect to the research program, project or [research] study:

(A) Title of the research program, project or [research] study.

(B) Statement of the purpose.

(C) Type of medical marijuana product involved and the amount needed.

(D) Description of the research to be conducted, including the number and type of medical marijuana product, the dosage, the route and method of administration, and the duration of the

research program, project or [research] study.

(E) The locations of the dispensaries that will be participating in the research program, project or [research] study.

*Sample*—Medical marijuana or medical marijuana products collected by an employee of an approved laboratory from a grower/processor facility for testing by the laboratory.

*Security*—The term as defined in section 102(t) of the Pennsylvania Securities Act of 1972 (70 P.S. § 1-102(t)).

*Serious medical condition*—Any of the conditions listed in Appendix A. [following conditions:

- (i) Cancer, including remission therapy.
- (ii) Positive status for Human Immunodeficiency Virus or Acquired Immune Deficiency Syndrome.
- (iii) Amyotrophic lateral sclerosis.
- (iv) Parkinson's disease.
- (v) Multiple sclerosis.
- (vi) Damage to the nervous tissue of the central nervous system (brain-spinal cord) with objective neurological indication of intractable spasticity, and other associated neuropathies.
- (vii) Epilepsy.
- (viii) Inflammatory bowel disease.
- (ix) Neuropathies.
- (x) Huntington's disease.
- (xi) Crohn's disease.
- (xii) Post-traumatic stress disorder.
- (xiii) Intractable seizures.
- (xiv) Glaucoma.
- (xv) Sickle cell anemia.
- (xvi) Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain.
- (xvii) Autism.
- (xviii) Neurodegenerative diseases.
- (ixx) Terminal illness.
- (xx) Dyskinetic and spastic movement disorders.
- (xxi) Opioid use disorder for which conventional therapeutic interventions are contraindicated or

ineffective, or for which adjunctive therapy is indicated in combination with primary therapeutic interventions.

(xxii) Anxiety disorders

(xxiii) Tourette's Syndrome

(xxiv) Any other condition recommended by the Medical Marijuana Advisory Board and approved by the Secretary.]

*Service-disabled*—The term as defined in 51 Pa.C.S. § 9601 (relating to definitions).

*Service-disabled veteran-owned small business*—The term as defined in 51 Pa.C.S. § 9601.

*Site*—The total area contained within the property line boundaries in which a facility is operated by a medical marijuana organization.

*Species* – cannabis sativa, cannabis indica or a hybrid of the two.

*Spent hydroponic nutrient solution*—Hydroponic nutrient solution that has been used and can no longer serve the purpose for which it was produced.

*Synchronous interaction*—A two-way or multiple-way exchange of information between a patient and a health care provider that occurs in real time via audio or video conferencing.

*THC*—Delta-9 Tetrahydrocannabinol, CAS number 1972-08-3.

*THCA*—Tetrahydrocannabinolic acid, CAS number 23978-85-0.

*THCV*—Tetrahydrocannabivarin, CAS number 31262-37-0.

*Terminal illness*—A condition or disease for which the medical prognosis of life expectancy is approximately 1 year or less if the condition or disease runs its normal course.

*Terpenes*—Naturally occurring hydrocarbons found in essential oil secreted from the marijuana plant.

*Test sample*—An amount of medical marijuana, medical marijuana products or an amount of soil, growing medium, water or solvents used to grow or process medical marijuana, dust or other particles obtained from the swab of a counter or equipment used in the growing or processing of medical marijuana, or other item used in the growing or processing of medical marijuana in a grower/processor facility taken by an employee of an approved laboratory or an agent of the Department at the request of the Department from a grower/processor facility and provided to an approved laboratory for testing.

*Third-party certifying organization*—The term as defined in 74 Pa.C.S. § 303(b).

*Transport vehicle*—A vehicle that meets the requirements of the act and is used to transport seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products between medical marijuana organizations or between medical marijuana organizations and an approved laboratory.

*Unit*—The weight or volume of total usable medical marijuana products, calculated in metric units.

*Vaporization*—The generation of medical marijuana products in the form of vapor for medicinal inhalation.



*Veteran*—The term as defined in 51 Pa.C.S. § 9601.

*Veteran-owned small business*—The term as defined in 51 Pa.C.S. § 9601.

*Women-owned business*—The term as defined in 74 Pa.C.S. § 303(b).

## **§ 1141a.22. Records subject to disclosure; confidentiality.**

(a) The following records are public records and are subject to disclosure under the Right-to-Know Law (65 P.S. §§ 67.101—67.3104):

(1) An application submitted under the act, except to the extent that the application contains any of the information listed in subsection (b).

(2) The name, business address and medical credentials of a practitioner.

(3) Information regarding penalties or other disciplinary actions taken against a permittee by the Department for a violation of the act.

(b) The following information is considered confidential, is not subject to the Right-to-Know Law and will not otherwise be released to a person unless under court order:

(1) Information in the possession of the Department or any of its contractors regarding a practitioner's registration information that is not listed as a public record under subsection (a).

(2) The name or other personal identifying information of a patient or caregiver who applies for or is issued an identification card.

(3) Individual identifying information concerning a patient or caregiver, or both.

(4) A patient certification issued by a practitioner.

(5) Any information on an identification card.

(6) Information provided by the Pennsylvania State Police regarding a caregiver, including criminal history record information, as set forth in § 1141a.31 (relating to background checks).

(7) Information regarding a patient's serious medical condition.

(8) Other information regarding a patient, caregiver, practitioner or medical marijuana organization not listed in subsection (a) that falls within an exception to the Right-to-Know Law, or is otherwise considered to be confidential proprietary information by other law.

(9) Information regarding the physical features of, and security measures installed in, a facility.

(10) Information maintained in the electronic tracking system of a grower/processor, an approved laboratory and a dispensary.

(11) Any information that would identify persons reviewing permit applications, including a reviewer's name, individual permit application reviews and notes.

(12) Information relating to an applicant's diversity plan that is marked confidential proprietary or trade secret.

(c) An applicant shall mark confidential proprietary information as confidential proprietary or trade secret information, as defined in section 102 of the Right-to-Know Law (65 P.S. § 67.102), prior to submission of a permit application to the Department.

(d) An applicant's failure to redact confidential proprietary or trade secret information [in its submitted permit application] in accordance with § 1141a.29(a)(2) will result in disclosure to the public of the confidential proprietary or trade secret information in response to a Right-to-Know Law request.

(e) [An applicant is responsible for defending its own redactions to protect confidential proprietary or trade secrets in any administrative or court proceeding, including any appeals. Any information not adequately defended by the applicant may result in full disclosure of the information in un-redacted form.] In accordance with section 707(b) of the Right-to-Know Law (65 P.S. 67.707(b)), the Department will make an independent determination as to whether to release the information marked as confidential proprietary or trade secret.

(f) Nothing in this section shall preclude the Department from releasing de-identified data for research purposes, subject to approval and oversight by the Department and an IRB to ensure that the use of the data is limited to the specified research purposes.

(g) Notwithstanding subsection (b), in accordance with section 301(a)(11) of the act (35 P.S. § 10231.301(a)(11)), the Department may collaborate with other Commonwealth agencies as necessary to carry out the provisions of the act and this part. Collaboration shall include the sharing of information, including information deemed confidential under the act and this part, with any other agency, when needed to investigate a potential violation of the act or this part. Any information shared under this section shall remain confidential and may not be disclosed except for investigatory or enforcement purposes.

### **§ 1141a.23. Limitation on number of permits.**

Except as provided in section 2002 of the act (35 P.S. § 10231.2002), the following limitations apply regarding the number of permits to be issued under this part:

(1) The Department will not initially issue permits to more than 25 applicants for grower/processor permits. The following apply:

(i) The Department will not issue more than one individual grower/processor permit to one person.

(ii) The Department will not issue an individual dispensary permit to more than five individual grower/processors.

(2) The Department will not initially issue permits to more than 50 applicants for dispensary permits. The following apply:

(i) The Department will not issue more than five individual dispensary permits to one person.

(ii) A dispensary permit may be used to provide medical marijuana at no more than three separate locations as approved [by the Department] in the initial permit application or under § 1161a.40. [

(3) [In accordance with section 1201(j)(5)(iv) of the act (35 P.S. § 10231.1201(j)(5)(iv)), the Department may issue permits in addition to those in paragraphs (1) and (2) if necessary as the Medical Marijuana Program expands, including to comply with an order of court. No more than 20% of the total number of growers/processors may also be issued permits as dispensaries.]

## **§ 1141a.24. Medical marijuana regions.**

(a) The Department will issue permits to applicants in each of six medical marijuana regions. The six medical marijuana regions are as follows:

(1) *Region 1*—The geographical region comprised of the counties of the Department's Southeast District, which includes Berks, Bucks, Chester, Delaware, Lancaster, Montgomery, Philadelphia and Schuylkill.

(2) *Region 2*—The geographical region comprised of the counties of the Department's Northeast District, which includes Carbon, Lackawanna, Lehigh, Luzerne, Monroe, Northampton, Pike, Susquehanna, Wayne and Wyoming.

(3) *Region 3*—The geographical region comprised of the counties of the Department's Southcentral District, which includes Adams, Bedford, Blair, Cumberland, Dauphin, Franklin, Fulton, Huntingdon, Juniata, Lebanon, Mifflin, Perry and York.

(4) *Region 4*—The geographical region comprised of the counties of the Department's Northcentral District, which includes Bradford, Centre, Clinton, Columbia, Lycoming, Montour, Northumberland, Potter, Snyder, Sullivan, Tioga and Union.

(5) *Region 5*—The geographical region comprised of the counties of the Department's Southwest District, which includes Allegheny, Armstrong, Beaver, Butler, Cambria, Fayette, Greene, Indiana, Somerset, Washington and Westmoreland.

(6) *Region 6*—The geographical region comprised of the counties of the Department's Northwest District, which includes Cameron, Clarion, Clearfield, Crawford, Elk, Erie, Forest, Jefferson, Lawrence, McKean, Mercer, Venango and Warren.

(b) The Department will consider the following factors about each region in its determination to grant or deny an initial permit to an applicant:

(1) Regional population.

(2) The number of patients suffering from a serious medical condition.

(3) The types of serious medical conditions in the region.

(4) Access to public transportation.

(5) The health care needs of rural and urban areas.

(6) Areas with recognized need for economic development.

(c) The publication of this section in the *Pennsylvania Bulletin* is deemed to be the notice of the establishment of the regions required under section 604 of the act (35 P.S. § 10231.604). The Department may change the number or boundaries of the regions every 2 years upon publication of notice of the adjustment in the *Pennsylvania Bulletin*.

## **§ 1141a.25. General requirements for permits.**

(a) The Department may issue a permit to an applicant only for the specific location identified in the applicant's application, by name and address. A permit will specify that the applicant is authorized to begin the process necessary to become operational. A permit is only valid for the person named in the permit and only for the location specified in the permit.

(b) The medical marijuana organization shall conspicuously post its permit in a location within its facility that is visible to the Department or its authorized agents and law enforcement.

(c) A permit will not be issued to a medical marijuana organization for use in a personal residence or any other location where the Department or its authorized agents or law enforcement would have limited access.

(d) A permit will not be issued to a medical marijuana organization for a site or facility located on lands owned by the United States or the Commonwealth.

(e) A permit is valid for 1 year from the date of issuance.

#### **§ 1141a.26. Privilege and nontransferability.**

(a) The issuance or renewal of a permit to a medical marijuana organization is a revocable privilege.

(b) A permit issued under this part is not transferable to any person or any location.

#### **§ 1141a.27. General requirements for application.**

(a) The types of applications to be submitted to the Department under this part include:

(1) An initial permit application.

(2) A permit renewal application.

(3) An application for change in ownership of a medical marijuana organization.

(4) An application for approval of a change of location of an operational facility.

(5) An application for approval of alteration of a facility.

(6) An application for additional dispensary locations.

(7) An application for approval or renewal of a laboratory.

(b) By submitting an application to the Department, an applicant consents to any investigation [, to the extent deemed appropriate by the Department,] of the applicant's ability to meet the requirements under the act applicable to the application.

(c) An application for an initial permit or for a renewal permit is not complete and will be rejected by the Department unless:

(1) The payment of the applicable application fee in § 1141a.28 (relating to fees) is submitted with the application.

(2) The applicant and its principals and other persons affiliated with the applicant identified by the Department are current in all tax obligations due and owing to the Commonwealth. An applicant, as part of the application, shall provide tax clearance certificates issued by the Department of Revenue and the Department of Labor and Industry for the applicant and its principals and other persons affiliated with the applicant identified by the Department verifying that the applicant does not have outstanding tax obligations to the Commonwealth. The Department may consider the application to be complete if the applicant states on a form prescribed by the Department of Revenue or the Department of Labor and Industry that tax clearance certificates have

been requested at the time the application was submitted to the Department.

(3) All required information for each section of the application, including attachments and any supplemental information required by the Department, is submitted to the Department.

(4) Nothing in this subsection requires the Department to request additional or supplemental information from an applicant.

(d) An application for an initial permit that is incomplete will be rejected by the Department.

(e) An application submitted under this part must contain the following statement signed by the applicant:

A false statement made in this application is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).

### **§ 1141a.28. Fees.**

(a) An applicant for an initial grower/processor permit or renewal permit shall pay the following fees by certified or cashier's check or money order to the Department:

(1) Initial permit application fee—\$10,000. The initial permit application fee shall be submitted with the initial permit application and is nonrefundable, except as provided in § 1141a.29(a)(3) (relating to initial permit application).

(2) Initial permit fee—\$200,000. The initial permit fee shall be submitted with the initial permit application and will be refunded if the initial permit is not granted or the application is rejected.

(3) Permit renewal fee—\$10,000. The permit renewal fee shall be submitted with a renewal application and will be refunded if the renewal permit is not granted.

(4) An initial permit fee refund will be issued to the business named by the applicant in the permit application, in care of the primary contact provided by the applicant and mailed to the primary contact's mailing address provided by the applicant.

(b) An applicant for an initial dispensary permit or renewal permit shall pay the following fees by certified or cashier's check or money order to the Department:

(1) Initial permit application fee—\$5,000. The initial permit application fee shall be submitted with the initial permit application and is nonrefundable, except as provided in § 1141a.29(a)(3).

(2) Initial permit fee—\$30,000 for each dispensary location. The initial permit fee shall be submitted with the initial permit application and will be refunded if the initial permit is not granted or the application is rejected.

(3) Permit renewal fee—\$5,000. The permit renewal fee shall be submitted with a renewal application and will be refunded if the renewal permit is not granted.

(4) An initial permit fee refund will be issued to the business named by the applicant in the permit application, in care of the primary contact provided by the applicant and mailed to the primary contact's mailing address provided by the applicant.

(c) A medical marijuana organization shall pay a fee of \$250 by certified or cashier's check or money order to the Department with the submission of the following:

(1) An application for change in ownership of a medical marijuana organization.

(2) An application for approval of a change of location of an operational facility.

(3) An application for approval of alteration of a facility.

### **§ 1141a.29. Initial permit application.**

(a) The Department will publish in the *Pennsylvania Bulletin* notice of initial permit application availability and the time frame during which initial permit applications will be accepted.

(1) An applicant shall only use the initial permit application form prescribed by the Department on its web site.

(2) An applicant shall submit an initial permit application using the form posted on the Department's web site together with a version that is redacted in accordance with the Right-to-Know Law (65 P.S. §§ 67.101—67.3104), as set out in § 1141a.22 (relating to records subject to disclosure; confidentiality), by mail in an electronic format that is prescribed by the Department in the initial permit application instructions.

(3) An initial permit application received from an applicant after the time frame during which the Department is accepting applications will be rejected by the Department and returned to the applicant without further consideration along with the initial permit application fee and initial permit fee submitted by the applicant with the permit application.

(b) In addition to the requirements in § 1141a.27 (relating to general requirements for application), the applicant shall provide the Department with the following information in the initial permit application:

(1) The legal name of the applicant.

(2) Certified copies of the applicant's organizational documents, if applicable, and, if the applicant was not organized in this Commonwealth, evidence that it is authorized to conduct business in this Commonwealth.

(3) The physical address of the applicant's proposed site and facility, including the following, as applicable:

(i) Evidence of the applicant's clear legal title to or option to purchase the proposed site and the facility.

(ii) A fully-executed copy of the applicant's unexpired lease for the proposed site and facility that includes the consent by the property owner to the use by the applicant of that site and facility on the proposed site for [, at a minimum,] the term of the initial permit.

(iii) Other evidence satisfactory to the Department that shows the applicant has the authority to use the proposed site and facility as a site and facility for [, at a minimum,] the term of the permit.

(4) Evidence that the applicant is or will be in compliance with the municipality's zoning requirements.

(5) The following apply to the proposed facility:

(i) If the facility is in existence at the time the initial permit application is submitted to the Department, the applicant shall submit plans and specifications drawn to scale for the interior of the facility.

(ii) If the facility is in existence at the time the initial permit application is submitted to the Department, and the applicant intends to make alterations to the facility, the applicant shall submit

renovation plans and specifications for the interior and exterior of the facility to be altered.

(iii) If the facility is not in existence at the time the initial permit application is submitted to the Department, the applicant shall submit a plot plan that shows the proposed location of the facility and an architect's drawing of the facility, including a detailed drawing, to scale, of the interior of the facility.

(6) The name, residential address, date of birth, title and short version of a curriculum vitae of each principal, operator, financial backer and employee of the applicant, or of any person holding an interest in the applicant's proposed site or facility, including:

(i) A verification of identity that is satisfactory to the Department.

[(ii) Evidence of good moral character and reputation of each principal, operator, financial backer or employee.]

[(iii)] (ii) A copy of a criminal history records check for each individual performed in accordance with § 1141a.31 (relating to background checks). This subparagraph does not apply to an applicant who is an owner of securities in a publicly traded [company if the Department determines that the owner of the securities is not substantially involved in the activities of the applicant] corporation or an owner of 5% or less in a privately held business entity and who does not have voting rights to elect or appoint one or more members of the board of directors or other governing board.

[(iv)] (iii) An affidavit from each principal, operator or financial backer of the applicant setting forth the following:

(A) Any position of management or ownership held during the 10 years preceding the filing date of the initial permit application of a controlling interest in any other business in this Commonwealth or any other jurisdiction involving the manufacturing or distribution of medical marijuana, medical marijuana products or a controlled substance.

(B) Whether the principal, operator or financial backer has been convicted of a felony criminal offense [graded higher than a summary offense in this Commonwealth or the lowest-graded criminal offense in another State or country] related to the manufacture, delivery or possession with intent to manufacture or deliver a controlled substance in violation of the Act of April 14, 1972 (P.L. 233, No. 64), known as the Controlled Substance, Drug, Device and Cosmetic Act, or similar law in any other jurisdiction and, if yes, whether ten or more years have passed since entry of a final disposition on the conviction or one or more years have passed since the individual's release from incarceration for the conviction, whichever is later.

(C) Whether the principal, operator or financial backer has been a party in any civil or administrative action under the laws of the Commonwealth or any other state, the United States or a military, territorial or tribal authority relating to the principal, operator or financial backer's profession, occupation or fraudulent practices, including fraudulent billing practices.

(D) Whether the principal, operator or financial backer has attempted to obtain a registration, license, permit or other authorization to operate a medical marijuana organization in any jurisdiction by fraud, misrepresentation or the submission of false information.

(7) If a principal, operator or financial backer is a corporation or limited liability company:

(i) The names, residential addresses, titles and short version of a curricula vitae of each principal of the corporation or limited liability company.

(ii) A certified copy of the filed articles of incorporation of the corporation or filed certificate of organization of the limited liability company.

(iii) Unless the corporation or limited liability company is a publicly traded company, the names and mailing addresses of all persons owning securities in the corporation or membership interests in the limited liability company.

(8) If a principal, operator or financial backer is a general partnership, limited partnership, limited liability partnership or limited liability limited partnership:

(i) The names, residential addresses, titles and short version of a curricula vitae of each partner and general partner of a general partnership, limited partnership, limited liability partnership or limited liability limited partnership, and if any of the partners is a corporation or a limited liability company, the names, residential addresses, titles and short version of a curricula vitae of each principal of that corporation or limited liability company.

(ii) A certified copy of its filed certificate of limited partnership or other formation document, if applicable.

(iii) A certified copy of its partnership agreement.

(iv) Unless the entity is a publicly traded company, the names and mailing addresses of each of its partners.

(9) Evidence that the applicant is responsible and capable of successfully establishing and operating a facility, including the following:

(i) Demonstrated experience, if any, running a for-profit or nonprofit organization or other business within this Commonwealth or any other jurisdiction and the nature of the business conducted by the organization.

(ii) History relating to a similar license, permit or other authorization in other jurisdictions, including provisional licenses, suspensions, revocations or disciplinary actions, including civil monetary penalties or warnings.

(iii) History of response to sanctions, disciplinary actions or civil monetary penalties imposed relating to any similar license, permit or other authorization in another jurisdiction, and the plans of correction or other responses made to those actions.

(iv) Evidence that the applicant and its principals and other persons affiliated with the applicant identified by the Department is in compliance with all the laws of the Commonwealth regarding the payment of State taxes as shown on the tax clearance certificates issued by the Department of Revenue and the Department of Labor and Industry under § 1141a.27.

(v) A statement that the applicant shall provide evidence of workers' compensation insurance if the applicant is issued a permit and the facility is determined to be operational by the Department.

(10) A description of the duties, responsibilities and roles of each principal, operator, financial backer and employee.

(11) A timetable outlining the steps the applicant will take to become operational.

(12) A summary of the intended plan of operation that describes [, at a minimum,] how the applicant's proposed business operations will comply with the act and this part relating to:

(i) Security.

(ii) Employee qualifications and training.



(iii) Transportation of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

(iv) Storage of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

(v) With respect to an application for a grower/processor permit, packaging and labeling of medical marijuana products.

(vi) Inventory management.

(vii) With respect to a grower/processor's facility, nutrient and additive practice.

(viii) With respect to a grower/processor's facility, quality control and testing of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products for potential contamination.

(ix) With respect to a grower/processor's facility, processing and extraction.

(x) Sanitation and safety.

(xi) Recordkeeping.

(xii) Preventing unlawful diversion of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

(xiii) With respect to a grower/processor's facility, growing of medical marijuana, including a detailed summary of policies and procedures for its growth.

(xiv) Establishment, implementation and monitoring of diversity goals under § 1141a.32 (relating to diversity goals).

(13) The relevant financial information in § 1141a.30 (relating to capital requirements).

(14) Statements that:[

(i) The applicant and each principal, operator, financial backer and employee are of good moral character.]

[(ii)] (i) The applicant possesses the ability to obtain in an expeditious manner the right to use the proposed site and facility, including equipment, to properly perform the activity described in the initial permit application.

[(iii)] (ii) The grower/processor permit applicant is able to continuously maintain effective security, surveillance and accounting control measures to prevent diversion, abuse and other illegal conduct regarding seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products. The dispensary permit applicant is able to continuously maintain effective security, surveillance and accounting control measures to prevent diversion, abuse and other illegal conduct regarding medical marijuana products.

[(iv)] (iii) The applicant is able to continuously comply with all applicable laws of the Commonwealth, the act, this part, and the terms and conditions of the initial permit.

(15) The applicant shall provide the Department with releases sufficient to obtain information from a governmental agency, financial institutions, an employer or any other person. Failure to provide these releases will result in the rejection of the initial permit application.

(16) [Other information required by the Department] A diversity plan demonstrating ability to

meet the diversity goals outlined in section 615 of the act.

- (17) A statement summarizing how the applicant intends to positively impact the community where operations are proposed to be located.

(c) If the Department determines that an initial permit application is complete but lacking sufficient information upon which to make a determination, the Department may notify the applicant in writing of the factors that require additional information and documentation. An applicant has 30 days from the mailing date of the notice to provide the requested information and documentation to the Department. An applicant's failure to provide the requested information to the Department by the deadline may be grounds for denial of the issuance of a permit. Nothing in this subsection requires the Department to request additional or supplemental information from an applicant.

(d) At the discretion of the Department, the Department may extend the deadline in subsection (c) for up to an additional 15 days.

(e) The Department may conduct an inspection to determine the appropriateness of a proposed site and facility, the applicant's operational status, the applicant's compliance with the laws and regulations of the Commonwealth, the municipality's zoning requirements relating to the applicant's proposed site and facility, if applicable, and its use as outlined in the permit application. The Department may do the following:

(1) Interview principals, operators, financial backers and employees, including physicians, pharmacists, physician assistants and certified registered nurse practitioners, engaged and to be engaged in the applicant's operations for the purpose of verifying the information contained in the initial permit application.

(2) Inspect transport vehicles that are or will be utilized in the transportation of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products to a facility or an approved laboratory.

### **§ 1141a.30. Capital requirements.**

(a) An applicant for a grower/processor permit shall provide an affidavit that the applicant has at least \$2 million in capital, \$500,000 of which is on deposit with one or more financial institutions.

(b) An applicant for a dispensary permit shall provide an affidavit that the applicant has at least \$150,000 on deposit with one or more financial institutions.

(c) The affidavit will be in a form prescribed by the Department.

(d) An applicant shall submit with the initial permit application a signed release allowing the Department to contact each financial institution listed in the application to verify the requirements of subsection (a) or (b).

### **§ 1141a.31. Background checks.**

(a) To provide the criminal history record check required under § 1141a.29 (relating to initial permit application), an applicant shall submit fingerprints of its principals, financial backers, operators and employees to the Pennsylvania State Police. The Pennsylvania State Police or its authorized agent will submit the fingerprints to the Federal Bureau of Investigation for the purpose of verifying the identity of the individuals whose fingerprints have been submitted and obtaining a current record of criminal arrests and convictions.

(b) The Department may only use criminal history background check information obtained under this section to determine the character, fitness and suitability to serve in the designated capacity of the principal, financial backer, operator and employee.

(b.1) After submitting proof to the Department that fingerprints have been obtained, an individual may begin employment at a medical marijuana organization in a supervised capacity until the Department approves the individual to affiliate with the medical marijuana organization. If the Department does not approve the individual to affiliate with the medical marijuana organization, the individual shall be immediately terminated from the medical marijuana organization.

(c) This section does not apply to an owner of securities in a publicly traded [company except where the owner holds 5% or more of the company's securities or the owner has voting rights to elect or appoint one or more members of the board of directors or other governing board] corporation or an owner of 5% or less in a privately held business entity and who does not have voting rights to elect or appoint one or more members of the board of directors or other governing board.

(d) A financial backer, principal or employee may not hold a volunteer position, position for remuneration or otherwise be affiliated with a medical marijuana organization or a clinical registrant if the individual has been convicted of a felony criminal offense relating to the [sale or possession of illegal drugs, narcotics or controlled substances] manufacture, delivery or possession with intent to manufacture or deliver a controlled substance in violation of the Act of April 14, 1972 (P.L. 233, No. 64), known as the Controlled Substance, Drug, Device and Cosmetic Act, or similar law in any other jurisdiction unless: ten or more years have passed since the entry of a final disposition of the felony conviction, or one year has passed since the individual's release from imprisonment for the felony conviction, whichever is later.

## **§ 1141a.32. Diversity goals.**

(a) In accordance with section 615 of the act (35 P.S. § 10231.615), this section establishes the procedures for promoting and ensuring the involvement of diverse participants and diverse groups in the activities permitted by the act and this part.

(b) In furtherance of the policy in section 615 of the act, the Department will:

(1) Allocate appropriate staff of the Department to assist medical marijuana organizations in fostering the involvement of diverse participants and diverse groups in their operations.

(2) Provide enhanced publicity of permitting opportunities and information to assist diverse participants and diverse groups in learning how to apply for permits to be issued under the act and this part.

(3) Compile, maintain and make available to medical marijuana organizations lists of diverse participants and diverse groups for the purpose of encouraging medical marijuana organizations to provide employment and contracting opportunities consistent with the act.

(c) Each medical marijuana organization shall include in its permit application a diversity plan that establishes a goal of equal opportunity and access in employment and contracting by the medical marijuana organization. The Department will determine whether the stated goals in the diversity plan [are reasonable and represent a good faith effort to] meet the diversity goals of section 615(a) of the act.

(d) A medical marijuana organization may demonstrate achievement of its diversity goals by employing diverse participants and transacting business with diverse groups.

(e) The list of diverse groups that are verified by the Department of General Services, Bureau of

Diversity, Inclusion and Small Business Opportunities may be used by a medical marijuana organization to establish the eligibility of a diverse group for purposes of this section.

(f) As part of each application to renew a permit submitted to the Department, a medical marijuana organization shall include information of its efforts to meet the diversity goals of the act and the effectiveness of its diversity plan. The report must include information regarding the following, as applicable:

- (1) Representation of diverse participants in the medical marijuana organization's workforce.
- (2) Efforts to reach out to and recruit diverse participants for employment, including for executive and managerial positions.
- (3) Employee retention efforts.
- (4) A list of all contracts entered into or transactions conducted by the medical marijuana organization for goods or services with diverse groups.

(g) A medical marijuana organization may request that any proprietary information submitted to the Department under this section be treated as confidential proprietary information and shall clearly mark this information as confidential proprietary information or trade secret under the Right-to-Know Law (65 P.S. §§ 67.101—67.3104) as set forth in § 1141a.22 (relating to records subject to disclosure; confidentiality).

(h) The Department will review the diversity plan and provide the medical marijuana organization with [advice] information regarding activities that [should] may be undertaken by the medical marijuana organization to improve its efforts to encourage and promote participation by diverse participants and diverse groups to comply with the diversity goals of the act. The Department may consult with the Department of General Services, Bureau of Diversity, Inclusion and Small Business Opportunities in the review of diversity plans and the reports submitted by medical marijuana organizations under this section.

### **§ 1141a.33. Review of initial permit applications.**

(a) The Department will review initial permit applications submitted by applicants according to the criteria in section 603(a.1) of the act (35 P.S. § 10231.603(a.1)) and the factors in § 1141a.24(b) (relating to medical marijuana regions).

(b) The Department will publish the number of permits to be issued and the location of each permit in the *Pennsylvania Bulletin* before the initial permit applications are made available for submission.

### **§ 1141a.34. Denial of a permit.**

The Department may deny the issuance of a permit for any of the following reasons:

(1) Failure or refusal to submit information or documentation requested by the Department during the review process. Nothing in this paragraph requires the Department to request additional or supplemental information from an applicant.

(2) Misrepresentation by an applicant of fact, or failure to disclose a material fact to the Department during the review process.

(3) The results of the criminal history record check received by the Department under § 1141a.31 (relating to background checks) for a principal, financial backer, operator or employee of

the applicant indicates that the individual has been convicted of a prohibitive criminal offense [relating to the sale or possession of illegal drugs, narcotics or controlled substances] as detailed under § 1141a.31(d) and, following notification by the Department, the applicant fails or refuses to provide the Department with evidence satisfactory to the Department that the individual is no longer associated with the applicant in this capacity.

(4) Failure to meet the capital funding requirements identified in an affidavit by the applicant or a determination by the Department that the capital funding identified by the applicant is unverifiable.

(5) The applicant denies the Department or its authorized agents access to any place where a permitted activity is proposed to take place or fails to produce any book, paper, record, document, data or other information when requested by the Department.

(6) The applicant's medical marijuana license, permit or other authorization in another state or jurisdiction was, is or has been suspended or revoked or the applicant was otherwise disciplined.

(7) The applicant's plan of operation does not demonstrate, to the satisfaction of the Department, that the applicant is qualified for a permit.

(8) The Department determines, in its sole discretion, that the applicant has not met the criteria under § 1141a.33 (relating to review of initial permit applications).

(9) The Department determines, in its sole discretion, that the issuance of the permit will not be in the best interest of the welfare, health or safety of the citizens of this Commonwealth.

### **§ 1141a.35. Notice of denial.**

(a) The Department will provide written notice of denial to an applicant.

(b) The applicant may appeal a notice of denial under 2 Pa.C.S. Chapter 5, Subchapter A (relating to practice and procedure of Commonwealth agencies) and its accompanying regulations, as modified by Chapter 1230a (relating to practice and procedure).

### **§ 1141a.36. Permit renewal applications.**

(a) A medical marijuana organization wishing to renew its permit shall submit to the Department a permit renewal application not more than 6 months, nor less than 4 months, prior to the current permit's expiration.

(b) A medical marijuana organization shall submit the applicable fee in § 1141a.28 (relating to fees) with the permit renewal application.

(c) A medical marijuana organization shall include the following in the permit renewal application:

(1) Information regarding any charge, or any initiated, pending or concluded investigation, during the period of the initial permit or prior renewal period, by any governmental or administrative agency with respect to:

(i) Any incident involving the theft, loss or possible diversion of medical marijuana by the medical marijuana organization or from the medical marijuana organization's facility.

(ii) Compliance by the medical marijuana organization with the laws of the Commonwealth with respect to any substance in section 4 of The Controlled Substance, Drug, Device and Cosmetic Act

(35 P.S. § 780-104).

(2) Information concerning the medical marijuana organization's ability to carry on the activity for which the permit was issued, including medical marijuana product shortages or wait lists occurring during the 12 months prior to the date the renewal permit application was submitted.

(3) The medical marijuana organization's history of compliance with the act and this part, including a summary of any noncompliance and corrective action taken or a statement indicating that the medical marijuana organization has not violated the act or regulations as of the date the renewal application is submitted.

(d) If the Department determines that a permit renewal application is complete but lacking sufficient information upon which to make a determination, the Department will notify the medical marijuana organization in writing of the factors that require additional information and documentation. The medical marijuana organization shall have 30 days from the mailing date of the notice to provide the requested information and documentation to the Department. A medical marijuana organization's failure to provide the requested information to the Department by the deadline may be grounds for denial of the permit renewal application. Nothing in this subsection requires the Department to request additional or supplemental information from an applicant.

(e) The Department may conduct an onsite inspection of the medical marijuana organization's site and facility to determine an applicant's continuing compliance with the act and this part.

### **§ 1141a.37. Denial of renewal of a permit.**

(a) The Department will deny the renewal of a permit if the Department determines:

(1) The medical marijuana organization has not or is unlikely to be able to continuously maintain effective control against diversion of medical marijuana at its facility.

(2) The medical marijuana organization falsified any part of the permit renewal application or any other application submitted to the Department under this part.

(3) The medical marijuana organization is unlikely to comply with all Commonwealth and local laws applicable to the activities in which it may engage under the permit, if renewed.

(b) An existing permit is immediately invalid upon expiration if the medical marijuana organization has not filed a permit renewal application in accordance with § 1141a.36 (relating to permit renewal applications) and remitted the required fees in accordance with § 1141a.28 (relating to fees).

(c) Except as provided in subsection (e), a medical marijuana organization may not operate if its permit is not renewed prior to expiration.

(d) If the Department denies renewal of the permit or if the medical marijuana organization fails to submit a permit renewal application and permit renewal fee as required under § 1141a.28, the medical marijuana organization shall do the following upon the expiration of the permit:

(1) Cease all operations authorized by the permit.

(2) In the case of a grower/processor, dispose of any remaining seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products, plant matter or any growing equipment as set forth in § 1151a.40 (relating to management and disposal of medical marijuana waste).

(3) In the case of a dispensary, return the medical marijuana products to the grower/processor

where the medical marijuana products originated.

(c) If a medical marijuana organization submits a permit renewal application and permit renewal fee to the Department as required under § 1141a.28, the Department may administratively extend the existing permit from the date the existing permit expires until the Department can complete its permit renewal application review.

### **§ 1141a.38. Duty to report.**

(a) During the application process, or at any time during the permit period if a permit is issued, an applicant or medical marijuana organization shall notify the Department:

(1) In writing of any change in facts or circumstances reflected in the initial permit application or any permit renewal application submitted to the Department, or any newly discovered or occurring fact or circumstance which would have been included in the application if known at the time the application was submitted.

(2) In writing of any proposed modification of its plan of operation [at least] no less than 30 days prior to the proposed modification.

(3) Immediately [upon becoming aware, and State and local law enforcement immediately upon becoming aware,] when they become aware or state and local law enforcement make them aware of any adverse loss from a facility operated by the medical marijuana organization or any vehicle transporting seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products to or from a facility operated by the medical marijuana organization.

(b) If the change in information involves a change in control of the medical marijuana organization, the medical marijuana organization shall surrender its existing permit to the Department, unless the medical marijuana organization [submits an application for] notifies the Department of the change in ownership of a medical marijuana organization in accordance with § 1141a.39 (relating to [application for] change in ownership of a medical marijuana organization).

(c) If the change in information involves a change in any of the activities on the medical marijuana organization site, including any of the following, the medical marijuana organization shall surrender its existing permit to the Department and take action as required under § 1141a.43 (relating to closure of a facility):

(1) Discontinuance of operations.

(2) Removal of all seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products from the sites and locations by State or Federal authority.

### **§ 1141a.39. [Application for change] Change in ownership of a medical marijuana organization.**

(a) In the event of an impending change in ownership involving a change in control of a medical marijuana organization from the ownership listed in the initial permit application or a permit renewal application, the medical marijuana organization shall submit [an application for change in ownership, on a form prescribed by the Department,] to the Department the name of each individual affiliating, and each individual no longer affiliating, with the medical marijuana organization, together with the fee required under § 1141a.28 (relating to fees).

(b) A medical marijuana organization's [application for] change in ownership will not be

considered complete by the Department until [all portions of the application are completed] the names of all incoming and outgoing affiliates have been submitted to the Department and the appropriate application fee under § 1141a.28 is submitted.

(c) For each individual that is part of the proposed change in ownership, the medical marijuana organization shall include all of the information required under § 1141a.29 (relating to initial permit application) for the individuals listed in those capacities in the medical marijuana organization's initial permit application or any previously submitted permit renewal application.

(d) A change in ownership of a medical marijuana organization that occurs without the Department's knowledge [and written approval] of all individuals affiliating with the medicalmarijuana organization is a violation of the act and this part.

#### **§ 1141a.40. Application for approval of a change in location of an operational facility.**

(a) A medical marijuana organization wishing to change the location of an operational facility shall submit an application for approval of a change in location to the Department together with the fee required under § 1141a.28 (relating to fees).

(b) A change in location of an operational facility may not occur until the Department approves the change, in writing, under this section.

(c) The medical marijuana organization shall submit an application for approval of a change in location on a form prescribed by the Department.

(d) An application for approval of a change in location must include the reason for requesting the change and other information about the new location as the Department may require.

(e) The Department will issue a new permit to the medical marijuana organization for the new location if the request is approved.

(f) Within 180 days of the issuance by the Department of a new permit under subsection (e), the medical marijuana organization shall change the location of its operation to the new location designated in the new permit. Simultaneously with the completion of the move, the medical marijuana organization shall cease to operate at the former location and surrender its existing permit to the Department. The following apply:

(1) At no time may a medical marijuana organization operate or exercise any of the privileges granted under the permit in both locations.

(2) At the discretion of the Department, the Department may extend the 180-day deadline for relocation for up to an additional 90 days.

(3) Once the new facility is determined to be operational by the Department, the medical marijuana organization may resume operations under the new permit at the new location.

(g) The Department will not approve a change of location that is outside the boundaries of the region for which the initial permit was issued.

(h) The Department will approve a change in location if the permittee submits an application containing complete information that the Department deems compliant with 28 Pa. Code §§ 1141a.29, 1151a.23, 1151a.26, 1151a.33, 1161a.26, 1161a.31, 1161a.34 regarding the following:

(1) Application Name, Address and Contact Information.



- (2) Facility Information
- (3) Principals, Financial Backers, Operators and Employees.
- (4) Operational Timetable.
- (5) Security and Surveillance.
- (6) Sanitation and Safety.
- (7) Community Impact.
- (8) Property Title, Lease or Option to Acquire Property Location.
- (9) Site and Facility Plan

**§ 1141a.40.1. Request to change location of a non-operational facility.**

(a) The Department will review a request to change the location of a non-operational facility based upon individual circumstances and in consideration of the following factors:

(1) Inability to operationalize the location due to circumstances beyond the permittee's control and the permittee knew, or should have known, of the circumstances prior to selecting the site location.

(2) Viability of the permittee, the ability to sustain the permitted location, or both, is at risk.

(3) Impact on patient access to medical marijuana, resulting acquisition costs of medical marijuana in this market, or both, may be excessive.

(b) The Department will not approve a change of location that is outside the boundaries of the region for which the initial permit was issued and may require relocation within the same municipality or county as the originally designated location.

**§ 1141a.41. Application for approval of alteration of a facility.**

(a) Except as provided in subsection (b), after the issuance of a permit, a medical marijuana organization may not make a physical change, alteration or modification to the facility that materially or substantially alters the facility or its usage as listed in the plot plans originally approved by the Department.

(b) A medical marijuana organization wishing to make any of the following alterations to the facility for which its permit was issued shall submit an application for approval of alteration of a facility, on a form prescribed by the Department, to the Department together with the fee required under § 1141a.28 (relating to fees):

- (1) An increase or decrease in the total square footage of the facility.
- (2) The sealing off, creation of or relocation of a common entryway, doorway, passage or other means of public ingress or egress when the common entryway, doorway or passage alters or changes limited access areas.
- (3) Any of the following made to enhance activities authorized under the permit:

- (i) Additional electric fixtures or lighting equipment.
- (ii) The lowering of a ceiling.
- (iii) Electrical modifications that require inspection by the local municipality.

#### **§ 1141a.42. Failure to be operational.**

(a) Within 6 months from the date of issuance of a permit, a medical marijuana organization shall notify the Department, on a form prescribed by the Department, that it is operational.

(b) After the Department receives the notification in subsection (a), the Department will inspect the facility to determine if the medical marijuana organization is operational to the satisfaction of the Department.

(c) If the medical marijuana organization has not met the operational timetable in the initial permit application to the satisfaction of the Department at the time of the inspection conducted under subsection (b), the Department will notify the medical marijuana organization of the deficiencies. Within 30 days of [receiving] the mailing date on the Department's notice, the medical marijuana organization shall submit to the Department for approval a plan of correction that sets forth the medical marijuana organization's timeline and a date certain, which may not extend beyond 90 days following the date the Department approves the plan of correction, for correcting the deficiencies.

(d) If the medical marijuana organization does not comply with its plan of correction as approved by the Department within 90 days following the Department's approval, the Department may revoke or suspend the medical marijuana organization's permit under § 1141a.47 (relating to general penalties and sanctions).

#### **§ 1141a.43. Closure of a facility.**

(a) A medical marijuana organization shall notify the Department in writing immediately, but in no event less than 60 days prior to the projected date of closure, upon making a determination that it intends to close a facility.

(b) A medical marijuana organization may not accept or purchase seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, other plant matter, medical marijuana products, equipment, or medical devices or instruments as of the date of notice.

(c) The notice must be accompanied by the medical marijuana organization's written plan for the facility being closed that must include the following information:

- (1) The projected date of closure.
- (2) How it intends to notify in writing, prior to the projected date for closure, any person to which the medical marijuana organization provides seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products or medical marijuana services prior to closure.
- (3) How it intends to dispose of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products or other plant matter projected to still be in the facility at the time of the projected closure in accordance with § 1151a.40 (relating to management and disposal of medical marijuana waste).
- (4) How it intends to dispose of equipment or medical devices or instruments used by the medical marijuana organization in its operations at the facility.

(d) A medical marijuana organization may not remove or destroy any seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, other plant matter, medical marijuana products, equipment, or medical devices or instruments until the Department has approved its plan for closure submitted under subsection (c) and shall comply with all requirements regarding disposal of medical marijuana in § 1151a.40.

(e) The Department may enter and inspect the site and facility and the medical marijuana organization's vehicles following receipt of a medical marijuana organization's plan of closure to determine whether to approve the medical marijuana organization's closure plan.

(f) If the Department approves the medical marijuana organization's plan to close a facility submitted under this section, the medical marijuana organization shall surrender its permit to the Department on or before the date for closure provided in the plan.

#### **§ 1141a.44. Insurance requirements.**

(a) A medical marijuana organization shall obtain and maintain an appropriate amount of insurance coverage that insures the site and facility and equipment used in the operation of the facility. An adequate amount of comprehensive liability insurance covering the medical marijuana organization's activities authorized by the permit shall begin on the date the initial permit is issued by the Department and continuing for as long as the medical marijuana organization is operating under the permit.

(b) A medical marijuana organization shall obtain and maintain workers' compensation insurance coverage for employees at the time the medical marijuana organization is determined to be operational by the Department.

#### **§ 1141a.45. Inspection and investigation.**

(a) The Department may conduct announced or unannounced inspections or investigations to determine the medical marijuana organization's compliance with its permit, the act or this part.

(b) An investigation or inspection may include:

(1) Inspection of a medical marijuana organization's site, facility, vehicles, books, records, papers, documents, data, and other physical or electronic information.

(2) Questioning of employees, principals, operators, financial backers, authorized agents of, and any other person or entity providing services to the medical marijuana organization.

(3) Inspection of a grower/processor facility's equipment, instruments, tools and machinery that are used to grow, process and package medical marijuana, including containers and labels.

(c) The Department and its authorized agents will have free access to review and, if necessary, make copies of books, records, papers, documents, data, or other physical or electronic information that relates to the business of the medical marijuana organization, including financial data, sales data, shipping data, pricing data and employee data.

(d) Failure of a medical marijuana organization to provide the Department and its authorized agents immediate access to any part of a medical marijuana organization's site or facility, requested material, physical or electronic information, or individual as part of an inspection or investigation may result in the imposition of a civil monetary penalty, suspension or revocation of its permit, or an immediate cessation of operations under a cease and desist order issued by the Department.

(e) The Department and its authorized agents will have free access to any area within a site or facility that is being used to store seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products for testing purposes and are permitted to collect test samples for testing at an approved laboratory.

#### **§ 1141a.46. Reports.**

(a) A medical marijuana organization shall submit the following reports to the Department, on forms prescribed by the Department, at the end of the first 12-month period following the issuance of a permit, and as of the end of each 3-month period thereafter:

(1) In the case of a grower/processor:

(i) The number of medical marijuana products sold by the grower/processor to dispensaries during the period for which the report is being submitted.

(ii) The average price per unit of medical marijuana products sold by the grower/processor to a medical marijuana organization.

(iii) The number or amount of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products sold by the grower/processor to other growers/processors during the period for which the report is being submitted.

(2) In the case of a dispensary:

(i) The number of medical marijuana products purchased by the dispensary during the period for which the report is being submitted.

(ii) The average price per unit of medical marijuana products purchased by the dispensary.

(iii) The average price per unit of an amount of medical marijuana products dispensed to a patient or caregiver by the dispensary [and in a unit of measurement as determined by the Department].

(b) The Department will aggregate the information in the reports submitted by medical marijuana organizations under subsection (a) and post the information on the Department's web site.

(c) The Department may require ongoing reporting of operational and financial information [in a form and manner prescribed by the Department].

(d) The Department may require any reports necessary to carry out its responsibilities under the act and this part.

#### **§ 1141a.47. General penalties and sanctions.**

(a) In addition to any other penalty imposed by law for violations of the act or this part, the Department may take one or more of the following actions:

(1) Suspend or revoke a permit if any of the following occur:

(i) The medical marijuana organization fails to maintain effective control against diversion of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products from a facility operated by it or under its control.

(ii) The medical marijuana organization violates a provision of the act or this part, or an order

issued under the act or this part.

(iii) The medical marijuana organization violates a provision of other State or local laws regarding the operation of its facility.

(iv) The medical marijuana organization engages in conduct, or an event occurs, that would have disqualified the medical marijuana organization from being issued a permit or having its permit renewed.

(v) The medical marijuana organization submitted falsified information on any application submitted to the Department including, but not limited to:

(A) failure to comply with an executed labor peace agreement submitted with the permit application.

(B) failure to follow through on commitments made in the Community Impact section of the permit application.

(2) Impose a civil penalty of not more than \$10,000 for each violation and an additional penalty of not more than \$1,000 for each day of a continuing violation. In determining the amount of each penalty, the Department will take the following into consideration:

(i) The gravity of the violation.

(ii) The potential harm resulting from the violation to patients, caregivers or the general public.

(iii) The willfulness of the violation.

(iv) Previous violations, if any, by the medical marijuana organization being assessed.

(v) The economic benefit to the medical marijuana organization being assessed resulting from the violation.

(3) Suspend or revoke a permit pending the outcome of a hearing if the Department determines that the health, safety or welfare of the public, a patient or a caregiver is at risk.

(4) Order the restitution of funds or property unlawfully obtained or retained by a medical marijuana organization.

(5) Issue a cease and desist order to immediately restrict the operations of a medical marijuana organization conducted under the permit to protect the public's health, safety and welfare. The following requirements apply:

(i) An order may include a requirement that a medical marijuana organization cease or restrict some or all of its operations. In addition, the order may prohibit the use of some or all of the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products grown, processed or to be sold by the medical marijuana organization.

(ii) An order may be issued by an authorized agent of the Department immediately upon completion of an inspection or investigation if the agent observes [or suspects] an operational failure or evidence of [determines that the conditions will likely create a] diversion or contamination of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products[, or a risk to patients or the public].

(iii) An order may include:

(A) An immediate evacuation of the site and facility and the sealing of the entrances to the

facility.

(B) A quarantine of some or all of the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products found at the facility.

(C) The suspension of the sale or shipment of some or all of the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products found at the facility.

(6) Issue a written warning if the Department determines that either:

(i) The public interest will be adequately served under the circumstances by the issuance of the warning.

(ii) The violation does not threaten the safety or health of a patient, caregiver or the general public, and the medical marijuana organization took immediate action to remedy the violation.

(b) A person who aids, abets, counsels, induces, procures or causes another person to violate the act or this part, or an order issued under the act or this part, shall also be subject to the civil penalties provided under this section.

(c) For violations of the act or this part, the Department may require a medical marijuana organization to develop and adhere to a plan of correction approved by the Department. The Department will monitor compliance with the plan of correction. Failure to comply with the plan of correction may result in the Department's taking action under applicable provisions of this section as it deems appropriate.

(d) The Department's actions under subsections (a) and (b) are subject to 2 Pa.C.S. Chapter 5, Subchapter A (relating to practice and procedure of Commonwealth agencies) and its accompanying regulations, as modified by Chapter 1230a (relating to practice and procedure).

#### **§ 1141a.48. Training.**

(a) As required under the act, the principals and employees of a medical marijuana organization who either have direct contact with patients or caregivers or physically handle seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products shall complete a 2-hour training course developed by the Department.

(1) Principals must successfully complete the course prior to starting initial operation of a facility.

(2) Employees must successfully complete the course no later than 90 days after starting employment at the facility.

(b) The training course required under subsection (a) must provide the following information:

(1) The provisions of the act and this part relevant to the responsibilities of principals and employees of medical marijuana organizations.

(2) Proper handling of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

(3) Proper recordkeeping.

(4) How to prevent and detect the diversion of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

(5) Best practice security procedures.

(6) Best practice safety procedures, including responding to the following:

(i) A medical emergency.

(ii) A fire.

(iii) A chemical spill.

(iv) A threatening event including:

(A) An armed robbery.

(B) A burglary.

(C) A criminal incident.

(c) A medical marijuana organization shall retain the attendance records of its principals and employees and make them available for inspection by the Department and its authorized agents upon request.

(d) The Department will make the 2-hour training course available at no cost to the medical marijuana organization, its principals or employees.

#### **§ 1141a.49. Zoning.**

(a) A grower/processor shall meet the identical municipal zoning and land use requirements as other manufacturing, processing and production facilities that are located in the same zoning district.

(b) A dispensary shall meet the identical municipal zoning and land use requirements as other commercial facilities that are located in the same zoning district.

#### **§ 1141a.50. Advertising by a medical marijuana organization.**

(a) In the advertising and marketing of medical marijuana and medical marijuana products, a medical marijuana organization shall be consistent with the Federal regulations governing prescription drug advertising and marketing in 21 CFR 202.1 (relating to prescription-drug advertisements).

(b) Promotional, advertising and marketing materials shall be approved by the Department prior to their use.

(c) This part does not apply to information provided by a grower/processor to a dispensary listing various medical marijuana products, instruments and devices that the grower/processor is offering for sale to the dispensary.

#### **§ 1141a.51. Technical advisories.**

The Department may issue technical advisories to assist permittees in complying with the act and this part. Technical advisories do not have the force of law or regulation. Technical advisories provide guidance on the Department's interpretation of, and how a permittee may maintain compliance with, the act and this part. Notice of the availability of a technical advisory will be published in the *Pennsylvania Bulletin*.

## **CHAPTER 1151a. GROWERS/PROCESSORS**

Sec.

- 1151a.21. Growers/processors generally.
- 1151a.22. Plans of operation.
- 1151a.23. Grower/processor facilities.
- 1151a.24. [Start-up] Growing and processing inventory.
- 1151a.25. Access to grower/processor facilities.
- 1151a.26. Security and surveillance.
- 1151a.27. Requirements for growing and processing medical marijuana.
- 1151a.28. Forms of medical marijuana.
- 1151a.29. Limit on medical marijuana processing.
- 1151a.30. Inventory data.
- 1151a.31. Storage requirements.
- 1151a.32. Equipment, operation and maintenance.
- 1151a.33. Sanitation and safety in a facility.
- 1151a.34. Packaging and labeling of medical marijuana products.
- 1151a.35. Transportation of medical marijuana.
- 1151a.36. Transport manifest.
- 1151a.37. Transportation of seeds, immature medical marijuana plants, [and] medical marijuana plants, and postharvest plant material.
- 1151a.38. Evidence of adverse loss during transport.
- 1151a.39. Electronic tracking system.
- 1151a.40. Management and disposal of medical marijuana waste.
- 1151a.42. Complaints about or recall of medical marijuana products.
- 1151a.43. Pesticides.
- 1151a.44. Treatment and quarantine orders.

### **§ 1151a.21. Growers/processors generally.**

(a) The qualifications that a grower/processor shall meet to receive a permit are continuing qualifications to maintain the permit.

(b) In addition to any other requirements in the act or this part, a grower/processor shall comply with the following:

(1) A grower/processor may not engage in the business of growing, processing, possessing, selling or offering to sell seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products to another medical marijuana organization without first being issued a permit by the Department and without first being determined operational by the Department as required under § 1141a.42 (relating to failure to be operational).

(2) A grower/processor may not employ an individual at its facility who is under 18 years of age.

### **§ 1151a.22. Plans of operation.**

(a) At the time the Department determines a grower/processor to be operational, the grower/processor shall provide the Department with a full and complete plan of operation for review that includes the following:



- (1) Employment policies and procedures.
- (2) Security policies and protocols including:
  - (i) Staff identification measures.
  - (ii) Monitoring of attendance of staff and individuals requiring access to the facility.
  - (iii) Alarm systems.
  - (iv) Video surveillance.
  - (v) Monitoring and tracking inventory.
  - (vi) Personal security.
- (3) A process for growing, receiving, processing, packaging, labeling, handling, tracking, transporting, storing, disposing and recalling of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, and a process for handling, tracking, transporting, storing and disposing of medical marijuana waste in accordance with applicable laws, rules and regulations.
- (4) Workplace safety, including conducting necessary safety checks prior to starting the growing and processing of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products.
- (5) Contamination protocols.
- (6) Maintenance, cleaning and sanitation of equipment in the facility or on the site, or both.
- (7) Maintenance and sanitation of the site or the facility, or both.
- (8) Proper handling and storage of any solvent, gas or other chemical used in growing or processing seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products in accordance with this part and other applicable laws, rules and regulations.
- (9) Quality control, including regulation of the amount of THC in each process lot, proper labeling and minimization of contamination of medical marijuana or medical marijuana products.
- (10) Inventory maintenance and reporting procedures.
- (11) The investigation of complaints and potential adverse events from other medical marijuana organizations, patients, caregivers or practitioners regarding the operation of the grower/processor.
- (12) A recall plan meeting the requirements of § 1151a.42(d) (relating to complaints about or recall of medical marijuana products).
  - (b) A grower/processor shall make the full and complete plan of operation available to the Department upon request and during any inspection of a site or a facility, or both.
  - (c) A grower/processor shall comply with its plan of operation.

### **§ 1151a.23. Grower/processor facilities.**

- (a) A grower/processor may only grow, store, harvest or process seeds, immature medical

marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products in an indoor, enclosed, secure facility [as approved by the Department] that has been inspected and deemed operational.

(b) The following areas of a facility must be clearly marked with proper signage:

(1) Growing and processing areas. These areas shall be easily observed by the Department and its authorized agents and by law enforcement.

(2) Nongrowing and nonprocessing areas.

(3) Limited access areas. All areas of ingress and egress to a limited access area must be clearly identified by the posting of a sign which must be not less than 12 inches wide and 12 inches long, composed of letters not less than 1/2 inch in height, which must state: Do Not Enter—Limited Access Area—Access Limited to Authorized Personnel and Escorted Individuals.

(4) Areas that include business offices and reception rooms.

(c) A facility must have an enclosed secure area out of public sight for the loading and unloading of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products into and from a transport vehicle.

#### **§ 1151a.24. [ Start-up] Growing and processing inventory.**

(a) A grower/processor may obtain and transport seeds or immature medical marijuana plants from outside of this Commonwealth for the purpose of securing its start-up inventory. Seeds or immature medical marijuana plants obtained from outside of this Commonwealth shall be obtained within 30 days from the date that the Department determines that the grower/processor is operational; between December 1 and December 30 annually; or within any 30-day window established by the Department [if the Department determines that the importation of additional seeds is necessary.] under the following process:

(1) A grower/processor may make a written request to the Department to open an additional 30-day window for the importation of seeds and immature medical marijuana plants.

(2) The written request must provide a justification for the importation of additional seeds or immature medical marijuana plants including, but not limited to, the need to refresh or improve genetics, patient demand, and the need to ensure ample supply of product.

(3) The written request must state the starting and ending date being requested.

(4) The request must be submitted at least 60 days in advance of the proposed start date.

(5) The Department will provide written notice to the grower/processor, no later than 30 days prior to the proposed start date, approving or denying the request based on sufficiency of the justification presented.

(b) A grower/processor may not obtain medical marijuana plants from outside of this Commonwealth at any time.

(c) Within 24 hours of receipt, a grower/processor shall, record in the electronic tracking system each seed or immature medical marijuana plant that enters the site during [the] any 30-day period under subsection (a).

(d) Outside any 30-day period permitted under subsection (a), a grower/processor shall only

grow medical marijuana plants from seeds or immature medical marijuana plants located physically in its facility, or purchase seeds, immature medical marijuana plants or medical marijuana plants from another grower/processor.

(e) A grower/processor may obtain and transport bulk postharvest medical marijuana plant material from another grower/processor within this Commonwealth to process medical marijuana.

(f) A grower/processor may obtain harvested hemp from a person holding a permit issued by the Department of Agriculture to grow or cultivate hemp under the 3 Pa.C.S. Ch. 15 (relating to controlled plants and noxious weeds) if the hemp received by a grower/processor is subject to the laboratory testing requirements of section 704 of the act.

(g) A grower/processor may add hemp or hemp-derived additives obtained or cultivated in accordance with subsection (f).

### **§ 1151a.25. Access to grower/processor facilities.**

(a) A grower/processor facility may not be open to the general public. When an individual who is not approved to enter the facility requires access to the facility for purposes regarding the growing, processing or testing of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, or for potential investment or employment, a grower/processor shall require the individual to sign a log, detailing the need for entry, and to wear a temporary identification badge that is visible to others at all times while on the site and in the facility.

(b) A grower/processor shall require an individual to present government-issued identification that contains a photo to gain access to the site and facility.

(c) No one under 18 years of age is permitted to enter a grower/processor site or facility.

(d) A grower/processor shall post a sign in a conspicuous location at each entrance of a site and a facility that states:

THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE. NO ONE UNDER THE AGE OF 18 IS PERMITTED TO ENTER.

(e) A grower/processor shall do the following when admitting an individual to a site or facility:

(1) Require the individual to sign a log and detail the need for entry upon entering and to sign the log when leaving the facility.

(2) Check the individual's government-issued identification to verify that the name on the identification provided matches the name in the log. A photocopy of the identification must be retained with the log.

(3) Issue a temporary identification badge with the individual's name and company, if applicable, and a badge number.

(4) Escort the individual while the individual remains in the facility or on the site.

(5) Ensure that the individual does not touch any seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products located in a limited access area.

(f) The following apply to the log required under subsections (a) and (e):

(1) The grower/processor shall maintain the log for [4 years] 180 days, unless otherwise required for investigative or litigation purposes, either in paper or electronic form, and make the log available to the Department, State or local law enforcement, and other State or local government officials upon request if necessary to perform the government officials' functions and duties.

(2) The log must include the full name of each individual granted access to the facility, the temporary identification badge number, the date and time of arrival, the date and time of departure and the purpose of the visit, including the areas of the site and the facility visited and the name of each employee visited.

(g) This section does not limit the right of the Department or its authorized agents, State or local law enforcement or other Federal, State or local government officials, from entering any area of a grower/processor site or facility if necessary to perform the governmental officials' functions and duties that pertain to the act or this part.

(h) A principal, financial backer, operator or employee of a grower/processor may not receive any type of consideration or compensation for allowing an individual to enter a limited access area.

## **§ 1151a.26. Security and surveillance.**

(a) A grower/processor shall have security and surveillance systems, utilizing commercial-grade equipment, to prevent unauthorized entry and to prevent and detect an adverse loss. The security and surveillance systems must include all of the following:

(1) A professionally-monitored security alarm system that includes the following:

(i) Coverage of all facility entrances and exits; rooms with exterior windows, exterior walls, roof hatches or skylights; storage rooms, including those that contain seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products and safes; and the perimeter of the facility.

(ii) A silent security alarm system signal, known as a duress alarm, generated by the entry of a designated code into an arming station to signal that the alarm user is being forced to turn off the system.

(iii) An audible security alarm system signal, known as a panic alarm, generated by the manual activation of a device intended to signal a life-threatening or emergency situation requiring law enforcement response.

(iv) A silent alarm signal, known as a holdup alarm, generated by the manual activation of a device intended to signal a robbery in progress.

(v) An electrical, electronic, mechanical or other device capable of being programmed to send a prerecorded voice message requesting dispatch, when activated, over a telephone line, radio or other communication system to a law enforcement, public safety or emergency services agency.

(vi) A failure notification system that provides an audible, text or visual notification of any failure in the systems. The failure notification system must provide by telephone, e-mail or text message an alert to a designated security person within the facility within five minutes after the failure.

(vii) Smoke and fire alarms.

(viii) Auxiliary power sufficient to maintain operation of specified growing and processing areas

identified in the grower/processor's plan of operation for [at least] no less than 48 hours following a power outage.

(ix) The ability to ensure all access doors are not solely controlled by an electronic access panel to prevent locks from becoming released during a power outage.

(x) Motion detectors.

(2) A professionally-monitored security and surveillance system that is operational 24 hours per day, 7 days per week and records [all activity] continuously in images capable of clearly revealing facial detail. The security and surveillance system must include all of the following:

(i) Fixed camera placement that allows for a clear image of all individuals and activities in and around the following:

(A) All limited access areas.

(B) A room or area containing a security and surveillance system storage device or equipment.

(C) Entrances to and exits from a facility. Entrances and exits must be recorded from both indoor and outdoor vantage points.

(D) Rooms with exterior windows, exterior walls, roof hatches, or skylights and storage rooms, including those that may contain seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, and safes.

(E) Twenty feet from the exterior of the perimeter of the facility.

(ii) Auxiliary power sufficient to maintain operation for [at least] no less than 48 hours following a power outage.

(iii) The ability to operate under the normal lighting conditions of each area under surveillance.

(iv) The ability to immediately produce a clear, color, still photograph in a digital format that meets the requirements of this subsection.

(3) The ability to clearly and accurately display the date and time. The date and time must be synchronized and set correctly and may not significantly obscure the picture.

(4) The ability to record and store all images captured by each surveillance camera for a minimum of [2 years] 180 days, unless otherwise required for investigative or litigation purposes, in a format that may be easily accessed for investigative purposes. The recordings must be kept:

(i) At the facility:

(A) In a locked cabinet, closet or other secure place to protect it from tampering or theft.

(B) In a limited access area or other room to which access is limited to authorized individuals.

(ii) At a secure location other than the location of the facility if approved in writing by the Department.

(5) A security alarm system separate from the facility's primary security system covering the limited access area or other room where the recordings under paragraph (4) are stored. The separate security alarm system must meet the same requirements as the facility's primary security alarm system.

(b) The following requirements regarding the inspection, servicing or alteration of, and the upgrade to, the site's and facility's security and surveillance systems apply:

(1) The systems shall be inspected and all devices tested once every year by a qualified alarm system vendor and a qualified surveillance system vendor.

(2) The grower/processor shall conduct maintenance inspections once every month to ensure that any repairs, alterations or upgrades to the security and surveillance systems are made for the proper operation of the systems.

(3) The grower/processor shall retain at the facility, for [at least] 4 years, in paper or electronic form, records of all inspections, servicing, alterations and upgrades performed on the systems and shall make the records available to the Department and its authorized agents within 2 business days following the Department's request or the request of the Department's authorized agents.

(4) In the event of a mechanical malfunction of the security or surveillance system that a grower/processor anticipates will exceed an 8-hour period, the grower/processor shall notify the Department immediately and, with Department approval, provide alternative security measures that may include closure of the facility.

(5) The grower/processor shall designate employees to continuously monitor the security and surveillance systems at the facility.

(6) The following apply regarding records retention:

(i) Within 2 business days following a request, a grower/processor shall provide up to four screen captures of an unaltered copy of a video surveillance recording to the Department or its authorized agents, law enforcement or other Federal, State or local government officials if necessary to perform the governmental officials' functions and duties.

(ii) If a grower/processor has been notified in writing by the Department or its authorized agents, law enforcement or other Federal, State or local government officials of a pending criminal or administrative investigation for which a recording may contain relevant information, the grower/processor shall retain an unaltered copy of the recording for 4 years or until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the grower/processor that it is not necessary to retain the recording, whichever is longer.

(c) The grower/processor shall install commercial-grade, nonresidential steel doors and door locks on each room where seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products are stored, and on each external door of the facility. Keys or key codes for all doors shall remain in the possession of designated authorized individuals.

(d) At all times, all entrances to and exits from a site and a facility must be securely locked.

(e) The grower/processor shall have an electronic back-up system for all electronic records.

(f) The grower/processor shall install lighting to ensure proper surveillance inside and outside of a facility.

(g) A grower/processor shall limit access to a room in a facility containing security and surveillance monitoring equipment to persons who are essential to maintaining security and surveillance operations; Federal, State and local law enforcement; security and surveillance system service employees; the Department or its authorized agents; and other persons with the prior written approval of the Department. The following requirements apply:

(1) A grower/processor shall make available to the Department or the Department's authorized agents, upon request, a current list of authorized employees and service employees or contractors who have access to any security and surveillance areas.

(2) A grower/processor facility shall keep security and surveillance rooms locked at all times and may not use these rooms for any other purpose or function.

### **§ 1151a.27. Requirements for growing and processing medical marijuana.**

(a) [A grower/processor shall use only a pesticide, fungicide or herbicide that is approved by the Department of Agriculture for use on medical marijuana plants and listed in Appendix A (relating to acceptable pesticide active ingredients for use). The Department will periodically publish a notice in the *Pennsylvania Bulletin* updating the list of approved pesticides, fungicides and herbicides.] A grower/processor may use a pesticide that is registered by the Department of Agriculture under the act of March 1, 1974 (P.L.90, No.24), known as the Pennsylvania Pesticide Control Act of 1973, and designated by the Secretary of Agriculture in consultation with the secretary for use by a grower/processor.

(1) The Secretary of Agriculture will publish the list of approved pesticides by notice in the *Pennsylvania Bulletin*.

(2) The list shall be posted on the Department's publicly accessible Internet website and shall be reviewed and updated by the Secretary of Agriculture, in consultation with the secretary, at least once annually and transmitted to the Legislative Reference Bureau for publication in the *Pennsylvania Bulletin*.

(b) A grower/processor shall use [a] an approved pesticide[, fungicide or herbicide listed in Appendix A] in a manner that is approved by the Department of Agriculture on the basis of Federal law and regulations.

(c) A grower/processor shall maintain a log of all actions taken to detect pests or pathogens, and the measures taken for control.

(d) A grower/processor shall:

(1) Use appropriate nutrient practices.

(2) Use a fertilizer or hydroponic solution of a type, formulation and at a rate to support healthy growth of plants.

(3) Maintain records of the type and amounts of fertilizer and any growth additives used.

(e) A grower/processor shall perform visual inspections of growing plants and harvested plant material to ensure there is no visible mold, mildew, pests, rot, or grey or black plant material [that is greater than an acceptable level as determined by the Department].

(f) A grower/processor may not use any added substance that alters the dosage level, color, appearance, smell, taste, effect or weight of the medical marijuana unless the grower/processor has first obtained the prior written approval of the Department. Excipients must be pharmaceutical grade, unless otherwise approved by the Department. In determining whether to approve an added substance, the Department will consider:

(i) Whether the added substance is permitted by the United States Food and Drug Administration for use in food or is Generally Recognized as Safe (GRAS) under Federal guidelines.

(ii) Whether the added substance constitutes a known hazard such as, but not limited to, diacetyl, CAS number 431-03-8, and pentanedione, CAS number 600-14-6.

(iii) Whether the added substance is permitted by the United States Food and Drug Administration for the applicable route of administration and dosage.

(iv) Whether the added substance has known drug interactions.

(g) A grower/processor shall have a separate and secure area for temporary storage of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products that are awaiting disposal by the grower/processor.

(h) A grower/processor may only process the parts of the medical marijuana plant that:

(1) Are free of seeds and stems.

(2) Are free of dirt, sand, debris or other foreign matter.

(3) Do not contain a level of mold, rot or other fungus or bacterial diseases higher than the minimum levels contained in the standards for testing under § 1171a.30 (relating to standards for testing)[acceptable to the Department].

(i) A grower/processor shall process the medical marijuana plants in a safe and sanitary manner. The following requirements apply:

(1) Medical marijuana plants, raw material and other product used in the processing of medicalmarijuana shall be handled on food-grade stainless steel benches or tables.

(2) Proper sanitation shall be maintained.

(3) Proper rodent, bird and pest exclusion practices shall be employed.

(j) A grower/processor shall install a system to monitor, record and regulate:

(1) Temperature.

(2) Humidity.

(3) Ventilation.

(4) Lighting.

(5) Water supply.

## **§ 1151a.28. Forms of medical marijuana.**

(a) A grower/processor may only process medical marijuana for dispensing to a patient or caregiver in the following forms:

(1) Pill.

(2) Oil.

(3) Topical forms, including gel, creams or ointments.



(4) A form medically appropriate for administration by vaporization or nebulization, including dry leaf or plant form for administration by vaporization.

(5) Tincture.

(6) Liquid.

(b) A grower/processor may not manufacture, produce or assemble any medical marijuana product, instrument or device without the prior written approval of the Department.

#### **§ 1151a.29. Limit on medical marijuana processing.**

(a) In the form intended to be sold to another medical marijuana organization, medical marijuana or a medical marijuana product must have a specific concentration of total THC and total CBD and must have a consistent cannabinoid profile. The concentration of the following cannabinoids[, at a minimum,] shall be reported to the Department by an approved laboratory and include the following on the label (CAS numbers need not be displayed on the label):

(1) THC.

(2) THCA, if greater than 0.0%.

(3) THCV, if greater than 0.0%.

(4) CBD.

(5) CBDA, if greater than 0.0%.

(6) CBDV, if greater than 0.0%.

(7) CBN, if greater than 0.0%.

(8) CBG, if greater than 0.0%.

(9) CBC, if greater than 0.0%.

(10) D8, if greater than 0.0%.

(11) Any other cannabinoid component at 0.1%.

(b) Within the first 6 months after the Department determines the grower/processor to be operational, the grower/processor shall provide the Department with a forecast of the amount of medical marijuana products it projects it will produce and in what form. The grower/processor shall notify the Department in writing [promptly] within 48 hours upon becoming aware of a potential increase or decrease in the forecasted amount occurring within any subsequent 6-month period.

#### **§ 1151a.30. Inventory data.**

(a) A grower/processor shall maintain the following inventory data in its electronic tracking system which must include an accounting of and an identifying tracking number for:

(1) The number, weight and type of seeds.

(2) The number of immature medical marijuana plants.

(3) The number of medical marijuana plants.

(4) The number of medical marijuana products ready for sale.

(5) The number of damaged, defective, expired or contaminated seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products awaiting disposal.

(b) A grower/processor shall establish inventory controls and procedures to conduct inventory reviews and comprehensive inventories at its facility. The following requirements apply:

(1) Inventory reviews of medical marijuana plants in the process of growing, and medical marijuana and medical marijuana products that are being stored for future sale shall be conducted monthly.

(2) Comprehensive inventories of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products shall be conducted [at least] annually.

(c) A written or electronic record shall be created and maintained of each inventory conducted under subsection (b) that includes the date of the inventory, a summary of the inventory findings, and the employee identification numbers and titles or positions of the individuals who conducted the inventory.

#### **§ 1151a.31. Storage requirements.**

(a) A grower/processor shall ensure that a facility has separate and locked limited access areas for storage of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products that are expired, damaged, deteriorated, mislabeled, contaminated, recalled or whose containers or packaging have been opened or breached until the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products are destroyed or otherwise disposed of as required under § 1151a.40 (relating to management and disposal of medical marijuana waste).

(b) A grower/processor facility shall maintain all storage areas in a clean and orderly condition and free from infestation by insects, rodents, birds and pests.

#### **§ 1151a.32. Equipment, operation and maintenance.**

(a) A grower/processor shall ensure that a facility has a written process in place to maintain the sanitation and operation of equipment that comes into contact with seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products to prevent contamination. The grower/processor shall provide a copy of the written process to the Department upon request.

(b) As part of the written process required under subsection (a), a grower/processor shall:

(1) [Routinely] Annually, or more frequently if recommended by the manufacturer, calibrate, check and inspect the following to ensure accuracy:

(i) Automatic, mechanical or electronic equipment.

(ii) Scales, balances or other measurement devices used in the grower/processor's operations.

(2) Maintain an accurate log recording the following:

(i) Maintenance of equipment.

(ii) Cleaning of equipment.

(iii) Calibration of equipment.

### **§ 1151a.33. Sanitation and safety in a facility.**

(a) A grower/processor shall maintain a facility in a sanitary condition to limit the potential for contamination or adulteration of the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products grown and processed in the facility and any medical marijuana product produced at a facility. The following requirements apply:

(1) Equipment and surfaces, including floors, counters, walls and ceilings, shall be cleaned and sanitized as frequently as necessary to protect against contamination, using a sanitizing agent registered by the United States Environmental Protection Agency, in accordance with the instructions printed on the label. Equipment and utensils shall be so designed and of such material and workmanship as to be capable of being adequately cleaned.

(2) Trash shall be properly removed.

(3) Floors, walls and ceilings shall be kept in good repair.

(4) Equipment, counters and surfaces for processing must be food grade quality and may not react adversely with any solvent being used.

(5) Adequate protection against pests shall be provided through the use of integrated pest management practices and techniques that identify and manage plant pathogens and pest problems, and the regular disposal of trash to prevent infestation.

(6) Toxic cleaning compounds, sanitizing agents, solvents used in the growing and processing of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, and pesticide chemicals must be labeled and stored in a manner that prevents contamination and that otherwise complies with other applicable laws and regulations.

(b) An employee working in direct contact with medical marijuana is subject to the restrictions on food handlers in 28 Pa. Code § 27.153 (relating to restrictions on food handlers). An employee shall otherwise conform to sanitary practices while on duty, including the following:

(1) Maintaining adequate personal hygiene.

(2) Wearing proper clothing, including gloves.

(3) Washing hands thoroughly in an adequate hand-washing area before starting work and at any other time when hands may have become soiled or contaminated.

(c) A grower/processor shall provide adequate and convenient hand-washing facilities furnished with running water at a temperature suitable for sanitizing hands. The following requirements apply:

(1) A grower/processor shall locate hand-washing facilities in processing areas and where good sanitary practices require employees to wash and sanitize their hands.

(2) A grower/processor shall provide effective nontoxic sanitizing cleansers and sanitary

towel service or suitable drying devices.

(d) A grower/processor shall provide adequate, readily accessible lavatories that are maintained in a sanitary condition and in good repair.

(e) A grower/processor shall provide a facility with a water supply sufficient for the facility's operations, which shall be derived from a source that is a public water system, or a nonpublic system that is capable of providing a safe, potable and adequate supply of water to meet the operational needs of the facility.

(f) A grower/processor shall comply with all other applicable State and local building code requirements.

#### **§ 1151a.34. Packaging and labeling of medical marijuana products.**

(a) A grower/processor shall package and label at its facility each form of medical marijuana products prepared for sale. The original seal of a package may not be broken, except for quality control testing at an approved laboratory, for adverse loss investigations conducted by the Department or by a dispensary that purchased the medical marijuana products.

(b) A grower/processor shall package the medical marijuana products in a package that minimizes exposure to oxygen and that [is]:

(1) [Child-resistant] is child-resistant.

(2) [Tamper-proof] is tamper-proof or tamper-evident.

(3) [Opaque] is opaque. This requirement does not apply to packages containing dry leaf.

(4) [Resealable] is resealable.

(5) clearly distinguishes the contents of the package from the contents of any other package of similar appearance.

(6) lists all product ingredients and includes a warning for known allergens, such as tree nuts.

(c) A grower/processor shall identify each process lot of medical marijuana with a unique identifier.

(d) A grower/processor shall obtain the prior written approval of the Department of all packaging and the content of any label to be affixed to a medical marijuana product package. Each label must meet the following requirements:

(1) Be easily readable.

(2) Be made of weather-resistant and tamper-resistant materials.

(3) Be conspicuously placed on the package.

(4) Include the name, address and permit number of the grower/processor.

(5) List the form, quantity and weight of medical marijuana included in the package.

(6) List the number of individual doses contained within the package, the species and percentage of THC and CBD and other cannabinoids as enumerated in § 1151a.29 (relating to limit on medical marijuana processing), and the individual terpenes and corresponding percentages, if

greater than 0.0%. CAS numbers need not be displayed on the label.

(7) Contain an identifier that is unique to a particular harvest batch of medical marijuana, including the number assigned to each harvest lot or process lot in the harvest batch.

(8) Include the date the medical marijuana product was packaged.

(9) State the employee identification number of the employee preparing the package and packaging the medical marijuana product.

(10) State the employee identification number of the employee shipping the package, if different than the employee described in paragraph (9).

(11) Contain the name and address of the dispensary to which the package is to be sold, except where a clinical registrant sells medical marijuana products to another grower processor and the intended dispensary is not known. In such case, the grower processor selling to a dispensary is required to affix a label bearing the dispensary name and address to the outer packaging, notwithstanding subsection (d)(17).

(12) List the date of expiration of the medical marijuana product.

(13) Include instructions for proper storage of the medical marijuana product in the package.

(14) Contain the following warning stating: This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the practitioner who issued the certification and, in the case of breastfeeding, the infant's pediatrician. This product might impair the ability to drive or operate heavy machinery. Keep out of reach of children.

(15) Contain a warning that the medical marijuana product must be kept in the original container in which it was dispensed.

(16) Contain a warning that unauthorized use is unlawful and will subject the purchaser to criminal penalties.

(17) Be firmly affixed to the container directly holding medical marijuana product, except when the product is being used for a blinded research program, and be firmly affixed to outer packaging if used.

(18) List THC as the first number when THC and CBD are listed on a label as a ratio.

(e) Labeling by a grower/processor of any medical marijuana product may not bear:

(1) Any resemblance to the trademarked, characteristic or product-specialized packaging of any commercially available food or beverage product.

(2) Any statement, artwork or design that could reasonably lead an individual to believe that the package contains anything other than medical marijuana.

(3) Any seal, flag, crest, coat of arms or other insignia that could reasonably mislead an individual to believe that the product has been endorsed, manufactured or approved for use by any state, county or municipality or any agency thereof.

(4) Any cartoon, color scheme, image, graphic or feature that might make the package attractive to children.

## **§ 1151a.35. Transportation of medical marijuana.**

(a) A grower/processor may transport and deliver seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products to a medical marijuana organization or an approved laboratory in this Commonwealth in accordance with this section. The following requirements apply:

(1) Unless otherwise approved by the Department, a grower/processor may deliver seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products to a medical marijuana organization or an approved laboratory only between 7 a.m. and 9 p.m.

(2) A grower/processor may contract with a third-party contractor for delivery so long as the contractor complies with this section.

(3) A grower/processor may not transport seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, postharvest plant material, or medical marijuana products to any location outside of this Commonwealth.

(4) A grower/processor shall use a global positioning system to ensure safe, efficient delivery of the seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products to a medical marijuana organization or an approved laboratory.

(b) Vehicles permitted to transport seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products must:

(1) Be equipped with a secure lockbox or locking cargo area.

(2) Have no markings that would either identify or indicate that the vehicle is being used to transport seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products.

(3) Be capable of being temperature-controlled for perishable seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products, as appropriate.

(4) Maintain current State inspection and vehicle registrations.

(5) Be insured in an amount that is commercially reasonable and appropriate.

(c) A transport vehicle must be staffed with a delivery team consisting of [at least] two or more individuals and comply with the following:

(1) [At least one] One delivery team member shall remain with the vehicle at all times that the vehicle contains seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products.

(2) Each delivery team member shall have access to a secure form of communication with the grower/processor, such as a cellular telephone, at all times that the vehicle contains seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products.

(3) Each delivery team member shall carry an identification badge or card at all times and shall, upon demand, produce it to the Department or its authorized agents, law enforcement, or

other Federal, State or local government officials if necessary to perform the government officials' functions and duties.

(4) Each delivery team member shall have a valid driver's license.

(5) While on duty, a delivery team member may not wear any clothing or symbols that may indicate ownership or possession of seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products.

(d) Seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products stored inside the transport vehicle must be placed inside a secure lockbox or locking cargo area and may not be visible from the outside of the transport vehicle.

(e) Except as provided in subsection (h), a delivery team shall proceed in a transport vehicle from a grower/processor facility, where the seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products are loaded, directly to a medical marijuana organization facility or approved laboratory, where the seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products are unloaded, without unnecessary delays. Notwithstanding the foregoing, a transport vehicle may make stops at multiple medical marijuana organization facilities or approved laboratories, as appropriate, to deliver seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products.

(f) A grower/processor shall immediately report to the Department, either through a designated phone line established by the Department or by electronic communication with the Department [in a manner prescribed by the Department], vehicle accidents, diversions, losses or other reportable events that occur during transport of seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products.

(g) A grower/processor shall notify the Department daily of its delivery schedule, including routes and delivery times, either through a designated phone line established by the Department or by electronic communication with the Department [in a manner prescribed by the Department].

(h) A transport vehicle is subject to inspection by the Department or its authorized agents, law enforcement, or other Federal, State or local government officials if necessary to perform the government officials' functions and duties. A transport vehicle may be stopped and inspected along its delivery route or at any medical marijuana organization or approved laboratory.

### **§ 1151a.36. Transport manifest.**

(a) A grower/processor shall generate a printed or electronic transport manifest that accompanies every transport vehicle and contains the following information:

(1) The name, address and permit number of the grower/processor and the name of and contact information for a representative of the grower/processor who has direct knowledge of the transport.

(2) The name, address and permit number of the medical marijuana organization facility or approved laboratory receiving the delivery and the name of and contact information for a representative of the medical marijuana organization facility or approved laboratory.

(3) The quantity, by weight or unit, of each seed, immature medical marijuana plant, medical marijuana plant, medical marijuana harvest batch, harvest lot or process lot, [medical marijuana] postharvest plant material, and medical marijuana product contained in the transport, along with the identification number for each batch or lot.

(4) The date and approximate time of departure.

(5) The date and approximate time of arrival.

(6) The transport vehicle's make and model and license plate number.

(7) The identification number of each member of the delivery team accompanying the transport.

(b) When a delivery team delivers seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products to multiple medical marijuana organizations or approved laboratories, the transport manifest must correctly reflect the specific seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products in transit. Each recipient shall provide the grower/processor with a printed receipt for the seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products received.

(c) All seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products being transported shall be packaged in shipping containers and labeled in accordance with § 1151a.34 (relating to packaging and labeling of medical marijuana products).

(d) A grower/processor shall provide a copy of the transport manifest to the recipient receiving the seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products described in the transport manifest. To maintain confidentiality, a grower/processor may prepare separate manifests for each recipient.

(e) A grower/processor shall, if requested, provide a copy of the printed transport manifest, and any printed receipts for seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, and medical marijuana products being transported, to the Department or its authorized agents, law enforcement, or other Federal, State or local government officials if necessary to perform the government officials' functions and duties.

### **§ 1151a.37. Transportation of seeds, immature medical marijuana plants, [and] medical marijuana plants, and postharvest plant material.**

(a) A grower/processor may transport seeds, immature medical marijuana plants, [and] medical marijuana plants, and postharvest plant material within this Commonwealth for the growing and processing of medical marijuana.

(b) A grower/processor may not transport seeds, immature medical marijuana plants, [or] medical marijuana plants, or postharvest plant material to a location outside of this Commonwealth.

(c) A grower/processor's authorization to transport seeds, immature medical marijuana plants, [or] medical marijuana plants, or postharvest plant material shall be subject to §§ 1151a.35, 1151a.36 and 1151a.38 (relating to transportation of medical marijuana; transport manifest; and evidence of adverse loss during transport).



### **§ 1151a.38. Evidence of adverse loss during transport.**

(a) If a grower/processor receiving a delivery of seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, or medical marijuana products from a medical marijuana organization discovers a discrepancy in the transport manifest that remains unresolved upon delivery, the grower/processor shall refuse acceptance of the delivery and immediately report the discrepancy to the Department either through a designated phone line established by the Department or by electronic communication with the Department [in a manner prescribed by the Department], and to the appropriate law enforcement authorities.

(b) If a grower/processor discovers evidence of, or reasonably suspects, a theft or diversion of seeds, immature medical marijuana plants, medical marijuana plants, [medical marijuana] postharvest plant material, or medical marijuana products during transport, the grower/processor shall immediately report its findings or suspicions to the Department either through a designated phone line established by the Department or by electronic communication with the Department [in a manner prescribed by the Department], and to law enforcement.

(c) If a grower/processor discovers a discrepancy in the transport manifest, the grower/processor shall:

(1) Conduct an investigation.

(2) Amend the grower/processor's standard plan of operation, if necessary, to prevent future discrepancies between the quantity or description of inventory listed in the transport manifest and the quantity or description of inventory delivered.

(3) Submit a report of the investigation to the Department. The following requirements apply:

(i) The grower/processor shall submit a written preliminary report of the investigation to the Department within 7 days of discovering the discrepancy.

(ii) The grower/processor shall submit a final written report of the investigation to the Department within 30 days of discovering the discrepancy.

### **§ 1151a.39. Electronic tracking system.**

A grower/processor shall use the electronic tracking system prescribed by the Department containing the requirements in section 701 of the act (35 P.S. § 10231.701). The electronic tracking system prescribed by the Department shall allow for two-way communication, automation and secure application-programming interface with a medical marijuana organization's enterprise resource planning, inventory, accounting and point-of-sale software. The electronic tracking system prescribed by the Department shall include a secure application program interface capable of accessing all data required to be transmitted to the Department to ensure compliance with the operational reporting requirements of the act and these regulations.

### **§ 1151a.40. Management and disposal of medical marijuana waste.**

(a) Medical marijuana waste generated by a grower/processor or an approved laboratory shall be stored, collected and transported in accordance with 25 Pa. Code Chapter 285 (relating to storage, collection and transportation of municipal waste), provided the medical marijuana waste is not hazardous.

(b) The following types of medical marijuana waste shall be rendered unusable and unrecognizable prior to being transported from a grower/processor or an approved

laboratory:

(1) Unused, surplus, returned, recalled, contaminated or expired medical marijuana.

(2) Any medical marijuana plant material that is not used in the growing, harvesting or processing of medical marijuana, including flowers, stems, trim, leaves, seeds, dead medical marijuana plants, dead immature medical marijuana plants, unused medical marijuana plant parts, unused immature medical marijuana plant parts or roots.

(c) Medical marijuana waste is unusable and unrecognizable if all components of the waste are indistinguishable and incapable of being ingested, inhaled, injected, swallowed or otherwise used for certified medical use. Acceptable methods of rendering the waste unusable and unrecognizable include thermal treatment or melting; shredding, grinding or tearing; and incorporating the medical marijuana waste with other municipal waste.

(d) Unusable and unrecognizable medical marijuana waste identified in subsection (b) and other solid or semi-solid medical marijuana waste that is not hazardous shall be disposed of at a permitted municipal waste landfill or processed at a permitted resource recovery facility or incinerator.

(e) Wastewater or spent hydroponic nutrient solution generated or produced from the growing, harvesting or processing of immature medical marijuana plants or medical marijuana plants shall be managed in accordance with one of the following:

(1) Discharged into a permitted sewage treatment system in accordance with local, Federal and State requirements, including The Clean Streams Law (35 P.S. §§ 691.1—691.1001) and 25 Pa. Code Chapter 92a (relating to National Pollutant Discharge Elimination System permitting, monitoring and compliance).

(2) Treated and discharged into waters of the Commonwealth under a National Pollutant Discharge Elimination System permit or water quality management permit in accordance with the requirements of The Clean Streams Law, including 25 Pa. Code Chapter 91 (relating to general provisions) and 25 Pa. Code Chapter 92a.

(3) Disposed in a municipal waste landfill if placed in a container that is less than one gallon in size.

(f) Hazardous waste shall be managed in accordance with Federal and State law, rules and regulations related to hazardous waste, including sections 3001—3024 of the Resource Conservation and Recovery Act of 1976 (42 U.S.C.A. §§ 6921—6939g), the Solid Waste Management Act (35 P.S. §§ 6018.101—6018.1003) and regulations promulgated thereunder.

(g) The type of medical marijuana waste identified in subsection (b)(2) may be composted and beneficially used at the grower/processor facility through a permit-by-rule provided the requirements of 25 Pa. Code § 271.103(d)(1)—(3) and (5) (relating to permit-by-rule for municipal waste processing facilities other than for regulated medical or chemotherapeutic waste; qualifying facilities; general requirements) are satisfied, and the compost is beneficially used at the grower/processor facility as a soil substitute, soil conditioner, soil amendment, fertilizer or mulch. The notice required under 25 Pa. Code § 271.103(d)(5) shall be submitted to the Solid Waste Manager of the Department of Environmental Protection's regional office having jurisdiction over the grower/processor facility within 15 days of initiating the composting activity.

## **§ 1151a.42. Complaints about or recall of medical marijuana products.**

(a) A dispensary shall notify the Department and the grower/processor from which it obtained the medical marijuana product in question immediately upon becoming aware of any

complaint made to the dispensary by a patient, caregiver or practitioner who reports an adverse event from using medical marijuana products purchased by the dispensary from the grower/processor. A grower/processor shall investigate the report. The following requirements apply:

(1) A grower/processor shall immediately investigate a complaint to determine if a voluntary or mandatory recall of seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products is necessary or if any further action is required.

(2) If a grower/processor determines that further action is not required, the grower/processor shall notify the Department of its decision and, within 24 hours, submit a written report to the Department stating its rationale for not taking further action.

(b) The following requirements apply to voluntary recalls:

(1) A grower/processor may voluntarily recall seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products from the market at its discretion for reasons that do not pose a risk to public health and safety.

(2) If a grower/processor initiates a recall for a reason that does not pose a risk to public health and safety, the grower/processor shall notify the Department at the time the grower/processor begins the recall.

(c) The following requirements apply to mandatory recalls:

(1) If a grower/processor discovers that a condition relating to the seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products grown or processed at its facility poses a risk to public health and safety, the grower/processor shall:

(i) Immediately notify the Department by phone.

(ii) Secure, isolate and prevent the distribution of the seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products that may have been affected by the condition and remains in its possession. The grower/processor may not dispose of affected seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products prior to notifying the Department and coordinating the disposal with the Department.

(2) If a grower/processor fails to cooperate with the Department in a recall, or fails to immediately notify the Department of a need for a recall under paragraph (1), the Department may seek a cease and desist order under § 1141a.47 (relating to general penalties and sanctions) and the grower/processor may be subject to any other penalties or sanctions provided for in the act or this part.

(d) A grower/processor's recall plan must include the following:

(1) Designation of one or more employees to serve as the recall coordinators. A recall coordinator shall be responsible for, among other duties, accepting the recalled seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products.

(2) Procedures for identifying and isolating the affected seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products to prevent or minimize its distribution to patients, caregivers and other

medical marijuana organizations and approved laboratories.

(3) Procedures to retrieve and dispose of the affected seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products.

(4) A communications plan to notify those affected by the recall, including:

(i) The manner in which the grower/processor will notify other medical marijuana organizations or approved laboratories in possession of seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products subject to the recall.

(ii) The use of press releases and other appropriate notifications to ensure that patients and caregivers are notified of the recall if affected medical marijuana products were dispensed to patients and caregivers.

(5) Procedures for notifying the Department.

(6) Procedures for entering information relating to the recall into the grower/processor's electronic tracking system.

(e) A grower/processor shall follow the procedures outlined in its recall plan, unless the grower/processor obtains the prior written approval of the Department. The grower/processor shall conduct recall procedures in a manner that maximizes the recall of affected seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products and minimizes risks to public health and safety.

(f) A grower/processor shall coordinate the disposal of recalled seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products with the Department. The Department or its authorized agents may oversee the disposal to ensure that the recalled seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products are disposed of in a manner that will not pose a risk to public health and safety.

(g) The grower/processor shall enter information relevant to the recall into the electronic tracking system as part of the daily inventory, including:

(1) The total amount of recalled seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products, including types, forms, harvest batches, harvest lots and process lots, if applicable.

(2) The amount of recalled seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products received by the grower/processor, including types, forms, harvest batches, harvest lots and process lots, if applicable, by date and time.

(3) The total amount of recalled seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products returned to the grower/processor, including types, forms, harvest batches, harvest lots and process lots, if applicable.

(4) The names of the recall coordinators.

(5) From whom the recalled seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products were received.

(6) The means of transport of the recalled seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products.

(7) The reason for the recall.

(8) The number of recalled samples or test samples, types, forms, harvest batches, harvest lots and process lots, if applicable, sent to approved laboratories, the names and addresses of the approved laboratories, the dates of testing and the results by sample or test sample.

(9) The manner of disposal of the recalled seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products, including:

(i) The name of the individual overseeing the disposal of the recalled seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products.

(ii) The name of the disposal company, if applicable.

(iii) The method of disposal.

(iv) The date of disposal.

(v) The amount disposed of by types, forms, harvest batches, harvest lots and process lots, if applicable. [

(10) Any other information required by the Department.]

(h) The Department may initiate a mandatory recall upon receipt of information that a condition relating to the seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products grown, processed or dispensed by a medical marijuana organization poses a risk to public health and safety.

### **§ 1151a.43. Pesticides.**

(a) The use of a pesticide by a grower/processor in the growing or processing of seeds, immature medical marijuana plants, postharvest plant material, medical marijuana plants or medical marijuana shall be in accordance with the Pennsylvania Pesticide Control Act of 1973 (Pesticide Control Act) (3 P.S. §§ 111.21— 112) and this part.

(b) The Department and the Department of Agriculture will cooperate to inspect for and enforce the requirements of this section.

(c) The following apply regarding recordkeeping requirements for pesticide applications:

(1) The grower/processor shall maintain a record of each application of a pesticide. The record must include the following information:

(i) The date of application. For a pesticide requiring a re-entry time, the date of application must include the hour completed.

(ii) The place of application, including the specific block, section, or immature medical marijuana plants or medical marijuana plants treated.

(iii) The size of the area treated.

(iv) The product name of every pesticide used.

(v) The United States Environmental Protection Agency product registration number. This requirement is unnecessary for products exempted under section 25 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C.A. § 136w).

(vi) The total amount of every pesticide used in pounds, ounces, gallons or liters applied to a treated area.

(vii) The dosage or rate of application of every pesticide used.

(viii) If applicable, the employee identification numbers of the individuals involved in making the pesticide and the permit or certification numbers of the individuals making or supervising the application.

(ix) Copies of pesticide labels and Safety Data Sheets for the pesticides used at the facility.

(2) A record required to be kept under this section shall be completed within 24 hours of the completion of the application and maintained for [at least] 4 years. A record shall be made immediately available to the Department or its authorized agents and medical personnel or first responders in an emergency. A record shall be made available to the Department of Agriculture upon request.

(d) For purposes of enforcement, the Pesticide Control Act and 7 Pa. Code Chapter 128 (relating to pesticides) are incorporated by reference and adopted as standards for use by the Department of Agriculture, in coordination with the Department, in enforcing this section.

(e) A grower/processor shall only use the pesticide active ingredients [in Appendix A] approved pursuant to § 1151a.27 in the growing and processing of seeds, immature medical marijuana plants, postharvest plant material, medical marijuana plants or medical marijuana.

(f) The following words and terms, when used in this section, have the following meanings, unless the context clearly indicates otherwise:

*Defoliant*—A substance or mixture of substances intended for causing the leaves or foliage to drop from a plant, with or without causing abscission.

*Desiccant*—A substance or mixture of substances intended for artificially accelerating the drying of plant tissue.

*Pesticide*—A substance or mixture of substances intended for preventing, destroying, repelling or mitigating a pest, and a substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant.

*Plant regulator*—

(i) A substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but may not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants and soil amendments.

(ii) The term does not include any of the nutrient mixtures or soil amendments commonly known as vitamin-hormone horticultural products, which are intended for improvement, maintenance, survival, health and propagation of plants, and are not for pest destruction and are nontoxic, nonpoisonous in the undiluted packaged concentration.

## **§ 1151a.44. Treatment and quarantine orders.**

(a) If a grower/processor fails or refuses to eradicate a plant pest that is found at its facility, the Department, in cooperation with the Department of Agriculture, may issue and enforce a treatment order against the grower/processor, including an order to eradicate, for any immature medical marijuana plants or medical marijuana plants that may carry or harbor the plant pest. The order will be issued in writing and set forth the necessary treatment, control or eradication measures required. If the grower/processor fails or refuses to comply with the order, the Department, acting in cooperation with the Department of Agriculture, may carry out the control measures established in the treatment order with all expenses associated with the measures accruing to the grower/processor.

(b) The Department of Agriculture, acting with the cooperation of the Department, may establish a quarantine to prevent the dissemination of plant pests within this Commonwealth or to prevent or delay the introduction of a plant pest into this Commonwealth from any country, state or territory. The following requirements apply:

(1) Upon finding a plant pest in a facility that has the potential to cause serious damage to other grower/processors or to agriculture in general, the geographic area in which the plant pest was found and any adjacent areas as the Department of Agriculture deems necessary may be quarantined.

(2) The quarantine order will establish conditions and restrictions determined by the Department of Agriculture to be necessary to prevent or reduce the movement of the plant pest from the quarantined area. Vehicles or any means of conveyance suspected of carrying the plant pest may also be subject to quarantine and a treatment order under subsection (a) may be issued as necessary to eradicate the plant pest.

(3) The quarantine order may regulate the planting, growing or harvesting of any immature medical marijuana plants or medical marijuana plants that serve as a host or reservoir for the plant pest within the quarantined area and may include prohibiting the processing of a specific harvest batch or harvest lot of medical marijuana within a specific geographic area or during a specified time period. An immature medical marijuana plant or medical marijuana plant suspected of harboring the plant pest may be ordered to be treated or destroyed.

## **CHAPTER 1161a. DISPENSARIES**

Sec.

1161a.22. Dispensaries generally.

1161a.23. Dispensing medical marijuana products.

1161a.24. Limitations on dispensing.

1161a.25. Licensed medical professionals at facility.

1161a.26. Dispensary facilities.

1161a.27. Items and services provided at a dispensary.

1161a.28. Labels and safety inserts.

1161a.29. Plans of operation.

1161a.30. Access to dispensary facilities.

1161a.31. Security and surveillance.

1161a.32. Inventory data.

1161a.33. Storage requirements.

1161a.34. Sanitation and safety in a facility.

1161a.35. Transportation of medical marijuana products.

1161a.36. Transport manifest.

1161a.37. Evidence of adverse loss during transport.

1161a.38. Complaints about or recall of medical marijuana products.

1161a.39. Electronic tracking system.

1161a.40. [Application for additional] Additional dispensary locations.

## **§ 1161a.22. Dispensaries generally.**

(a) The qualifications that a dispensary shall meet to receive a permit are continuing qualifications to maintain the permit.

(b) In addition to any other requirements in the act or this part, a dispensary shall comply with the following:

(1) A dispensary may not engage in the business of possessing, dispensing, selling or offering to dispense or sell medical marijuana products to a patient or caregiver in this Commonwealth without first being issued a permit by the Department and without first being determined operational by the Department as required under § 1141a.42 (relating to failure to be operational).

(2) A dispensary may not employ an individual at a facility who is under 18 years of age.

(3) A dispensary may not permit a patient to self-administer medical marijuana products at the facility unless the patient is also an employee of the dispensary, and the dispensary permits self-administration of medical marijuana products at the facility by the employees.

## **§ 1161a.23. Dispensing medical marijuana products.**

(a) A dispensary may only dispense medical marijuana products to a patient or caregiver who presents a valid identification card to an employee [at the facility] who is authorized to dispense medical marijuana products at the facility. The valid identification card must be presented in-person at the facility or from within a vehicle on the dispensary's site.

(b) Prior to dispensing medical marijuana products to a patient or caregiver, the [dispensary] dispensary's medical professional shall:

(1) Verify the validity of the patient or caregiver identification card using the electronic tracking system.

(2) Review the information on the patient's most recent certification by using the electronic tracking system to access the Department's database. The following requirements apply:

(i) If a practitioner sets forth recommendations, requirements or limitations as to the form or dosage of a medical marijuana product on the patient certification, the medical marijuana product dispensed to a patient or a caregiver by a dispensary must conform to those recommendations, requirements or limitations.

(ii) If a practitioner does not set forth recommendations, requirements or limitations as to the form or dosage of a medical marijuana product on the patient certification, the physician, pharmacist, physician assistant or certified registered nurse practitioner employed by the dispensary and working at the facility shall consult with the patient or the caregiver regarding the appropriate form and dosage of the medical marijuana product to be dispensed.

(iii) The dispensary shall update the patient certification in the electronic tracking system by entering any recommendation as to the form or dosage of medical marijuana product that is



dispensed to the patient.

(c) Prior to the completion of the transaction, the employee conducting the transaction at the dispensary shall prepare a receipt of the transaction, and file the receipt information with the Department utilizing the electronic tracking system. A dispensary shall provide a copy of the receipt to the patient or the caregiver, unless the patient or the caregiver declines the receipt. The receipt must include all of the following information:

- (1) The name, address and any permit number assigned to the dispensary by the Department.
- (2) The name and address of the patient and, if applicable, the patient's caregiver.
- (3) The date the medical marijuana product was dispensed.
- (4) Any requirement or limitation noted by the practitioner on the patient's certification as to the form of medical marijuana product that the patient should use.
- (5) The form and the quantity of medical marijuana product dispensed.

(d) Except as provided in sections 2001—2003 of the act (35 P.S. §§ 10231.2001—10231.2003) and this part, a dispensary shall destroy any paper copy of the patient certification or delete any electronically recorded patient certification stored on the dispensary's network, server or computer system as the result of a transaction after the receipt relating to that transaction has been filed under subsection (c).

#### **§ 1161a.24. Limitations on dispensing.**

(a) A dispensary may not dispense to a patient or caregiver:

- (1) A quantity of medical marijuana product that is greater than the amount indicated on the patient's certification.
- (2) A form or dosage of medical marijuana product that is listed as a restriction or limitation on the patient certification.
- (3) A form of medical marijuana products not permitted by the act or this part, unless otherwise [provided in regulations] adopted [by the Department] under section 1202 of the act (35 P.S. § 10231.1202).

(b) A dispensary may not dispense an amount of medical marijuana product greater than a [30] 90-day supply, 192 medical marijuana units, to a patient or caregiver until the patient has exhausted all but a 7-day supply of medical marijuana units provided pursuant to the patient certification currently on file with the Department.

#### **§ 1161a.25. Licensed medical professionals at facility.**

(a) Except as provided in subsection (b), a dispensary shall ensure that a physician or a pharmacist is [present at the facility] available, either in person or by synchronous interaction, to verify patient certifications and to consult with patients and caregivers at all times during the hours the facility is open to dispense or to offer to dispense medical marijuana products to patients and caregivers.

(b) If a dispensary is authorized to operate more than one facility under its permit, a physician assistant or a certified registered nurse practitioner may be [present onsite] available, either in person or by synchronous interaction, to verify patient certifications and to consult with patients

and caregivers at each of the other locations instead of a physician or pharmacist. The physician, pharmacist, physician assistant or certified registered nurse practitioner may rotate coverage of the facilities, provided that a physician or pharmacist is always [present] available, either in person or by synchronous interaction, at one of the facilities. Furthermore, no less than one dedicated medical professional must be present either, physically or by synchronous interaction, for each distinct dispensary facility location and shall not cover more than one dispensary facility location regardless of whether in-person coverage or synchronous interaction is used.

(c) As required under the act, a physician, a pharmacist, a physician assistant or a certified registered nurse practitioner shall, prior to assuming any duties at a facility, successfully complete a 4-hour training course developed by the Department. The course must provide instruction in the latest scientific research on medical marijuana, including the risks and benefits of medical marijuana, and other information deemed necessary by the Department.

(d) Successful completion of the course required under subsection (c) shall be approved as continuing education credits as determined by:

- (1) The State Board of Medicine and the State Board of Osteopathic Medicine.
- (2) The State Board of Pharmacy.
- (3) The State Board of Nursing.

(e) A practitioner or a physician, while at the facility, may not issue a patient certification to a patient.

#### **§ 1161a.26. Dispensary facilities.**

(a) A dispensary may only dispense medical marijuana products to a patient or caregiver in an indoor, enclosed, secure facility [as approved] that has been inspected and deemed operational by the Department, or to a patient or caregiver who is in a vehicle on the dispensary's operational site.

(b) A dispensary may not be located:

(1) Within 1,000 feet of a public, private or parochial school, or a day-care center providing services to children under 18 years of age, measured from the property line of the public, private or parochial school, or day-care center nearest to the dispensary to the nearest physical wall of the dispensary.

(2) At the same site used for growing and processing medical marijuana.

(3) In the same office space as a practitioner or other physician.

(c) The Department may waive or amend the prohibition under subsection (b)(1) if it is shown by clear and convincing evidence that the waiver or amendment is necessary to provide patients with adequate access to medical marijuana. A waiver or amendment by the Department under this subsection may require additional security measures, changes to the physical plant of a facility or other conditions necessary to protect individuals under 18 years of age and to prevent unauthorized access to medical marijuana.

(d) No one under 18 years of age is permitted to enter a dispensary unless the individual is a patient or accompanied by a parent, guardian or caregiver. If a dispensary facility is located adjacent to a commercial operation, the facility shall provide additional means of security satisfactory to the Department to prevent individuals under 18 years of age from entering the facility from the commercial operation unless the individual is accompanied by an adult.

(e) The following areas of a dispensary facility must be clearly marked with proper signage:

(1) *Limited access areas.* All areas of ingress and egress to a limited access area must be clearly identified by the posting of a sign which shall be not less than 12 inches wide and 12 inches long, composed of letters not less than 1/2 inch in height, which must state: Do Not Enter—Limited Access Area—Access Limited to Authorized Personnel and Escorted Individuals.

(2) Areas that are open to patients and caregivers.

(f) A dispensary shall ensure that a facility has an enclosed, secure area out of public sight for the loading and unloading of medical marijuana products into and from a transport vehicle.

### **§ 1161a.27. Items and services provided at a dispensary.**

(a) A dispensary shall dispense the form of medical marijuana products under § 1161a.23(b)(2)(relating to dispensing medical marijuana products).

(b) A dispensary shall purchase medical marijuana products only from a grower/processor.

(c) A dispensary may sell, offer for sale or provide at a facility, with the prior written approval of the Department, instruments, devices and services related to the use of medical marijuana products.

(d) A dispensary may dispense a medical marijuana product with a THC concentration of 0.3% or less so long as the dispensary purchases it from a grower/processor [and the grower/processor obtained Department approval under § 1151.28(b) (relating to forms of medical marijuana)].

(e) A dispensary may not:

(1) Provide medical marijuana products at no cost or free, unless the patient is approved for financial assistance by the Department.

(2) Make the dispensing of medical marijuana products to a patient or caregiver conditional upon:

(i) The purchase of a medical device, instrument or service provided at a dispensary facility.

(ii) The purchase of a medical device, instrument or service provided at a location other than a dispensary facility.

(3) Deliver, or contract to a third party the delivery of, medical marijuana products to a patient or caregiver at the patient's or caregiver's home or any other location.

(4) Sell, offer for sale or provide at a facility, items and services unrelated to the use of medical marijuana products.

### **§ 1161a.28. Labels and safety inserts.**

(a) Medical marijuana products dispensed by a dispensary must only be identified by the name of the grower/processor, the name of the dispensary, the form and species of medical marijuana, the percentage of THC and CBD contained in the medical marijuana product, and any other labeling required by the Department.

(b) A dispensary shall dispense medical marijuana products to a patient or caregiver in a sealed and properly labeled package.

(c) The dispensary shall inspect the label to ensure that the label:

(1) Is easily readable.

(2) Is conspicuously placed on the package.

(3) Includes the name, address and permit number of the grower/processor.

(4) Lists the form and quantity of medical marijuana.

(5) Contains the following warning stating: This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the practitioner who issued the certification and, in the case of breastfeeding, the infant's pediatrician. This product might impair the ability to drive or operate heavy machinery. Keep out of reach of children.

(6) Lists the number of individual doses contained within the package and the species and percentage of THC and CBD and other cannabinoids enumerated in § 1151a.29 (relating to limit on medical marijuana processing), and the individual terpenes and corresponding percentages.

(7) Contains a warning that the medical marijuana product must be kept in the original container in which it was dispensed.

(8) Contains a warning that unauthorized use is unlawful and will subject the purchaser or user to criminal penalties.

(9) Includes the name and address of the dispensary.

(10) Includes the identification number of the sales clerk dispensing the medical marijuana products to the patient or caregiver and the patient identification number.

(11) Lists a use by or expiration date.

(12) Lists the packaging date.

(13) Includes instructions for proper storage of the medical marijuana product in the package.

(14) Contains [any other information required by the Department] a process lot identification number.

(15) Is firmly affixed to the container directly holding medical marijuana [and] or is firmly affixed to outer packaging if used.

(d) The dispensary shall inspect the label to ensure that the label does not bear:

(1) Any resemblance to the trademarked, characteristic or product-specialized packaging of any commercially available food or beverage product.

(2) Any statement, artwork or design that could reasonably lead an individual to believe that the package contains anything other than medical marijuana.

(3) Any seal, flag, crest, coat of arms or other insignia that could reasonably mislead an individual to believe that the product has been endorsed, manufactured or approved for use by any state, county or municipality or any agency thereof.

(4) Any cartoon, color scheme, image, graphic or feature that might make the package attractive to children.

(e) When a dispensary dispenses medical marijuana products to a patient or caregiver, the dispensary shall also provide the patient or caregiver with a safety insert developed and approved by the Department that includes the following information:

- (1) The method or methods for administering individual doses of medical marijuana products.
- (2) Any potential dangers stemming from the use of medical marijuana products.
- (3) How to recognize what may be problematic usage of medical marijuana products and how to obtain appropriate services or treatment for problematic usage.
- (4) The side effects and contraindications associated with medical marijuana products, if any, which may cause harm to the patient.
- (5) How to prevent or deter the misuse of medical marijuana products by an individual under 18 years of age or others.[]
- (6) Any other information determined by the Department to be relevant to enhance patient safety.]

#### **§ 1161a.29. Plans of operation.**

(a) At the time the Department determines a dispensary to be operational, the dispensary shall provide the Department with a full and complete plan of operation for review that includes the following:

- (1) Employment policies and procedures.
- (2) Security policies and protocols, including:
  - (i) Staff identification measures.
  - (ii) Monitoring of attendance of staff and individuals requiring access to the facility.
  - (iii) Alarm systems.
  - (iv) Video surveillance.
  - (v) Monitoring and tracking inventory.
  - (vi) Personnel security.
- (3) A process for receiving, packaging, labeling, handling, tracking, transporting, storing, disposing, returning and recalling medical marijuana products in accordance with all applicable laws, rules and regulations.
- (4) Workplace safety.
- (5) Maintenance, cleaning and sanitation of the site or facility, or both.
- (6) Inventory maintenance and reporting procedures.
- (7) The investigation of complaints and potential adverse events from other medical marijuana organizations, patients, caregivers or practitioners.
- (8) The use of the electronic tracking system prescribed by the Department.

(b) A dispensary shall make the full and complete plan of operation available to the Department upon request and during any inspection of the site and facility.

(c) A dispensary shall comply with its plan of operation.

### **§ 1161a.30. Access to dispensary facilities.**

(a) A dispensary shall post a sign in a conspicuous location at each entrance of the facility that reads:

THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE. [ONLY EMPLOYEES, PATIENTS AND CAREGIVERS MAY ENTER.] NO ONE UNDER THE AGE OF 18 IS PERMITTED TO ENTER UNLESS THE INDIVIDUAL IS A PATIENT [AND] OR IS ACCOMPANIED BY A PARENT, GUARDIAN OR CAREGIVER.

(b) Except as provided in [subsection] subsections (a) and (c), or in § 1161a.26(d), only patients, caregivers, and authorized employees of a dispensary may enter a limited access area.

(c) When an individual who is not approved to enter the facility requires access to a limited access area in the dispensary facility to provide goods or services to the facility, to assist a patient with product selection as the certifying practitioner or for potential investment or employment when patients and caregivers are not at the dispensary, a dispensary shall require the individual to present government-issued identification, to sign a log for that specific facility, detailing the need for entry, and to wear a temporary identification badge that is visible to others at all times while in a limited access area. The identification of a certifying practitioner must match the name and medical credentials documented on the accompanied patient's certification.

(d) When admitting an individual under subsection (c) to a limited access area, a dispensary shall:

(1) Require the individual to sign a log and detail the need for entry upon entering and sign the log when leaving the limited access area.

(2) Check the individual's government-issued identification to verify that the name on the identification provided matches the name in the log. A photocopy of the identification must be retained with the log.

(3) Issue a temporary identification badge with the individual's name and company, if applicable, and a badge number.

(4) Escort the individual while the individual remains in a limited access area.

(5) Ensure that the individual does not touch any medical marijuana products located in a limited access area.

(e) The following requirements apply regarding the log required under subsections (c) and (d):

(1) The dispensary shall maintain the log for [4 years] 1 year, either in paper or electronic form, and make the log available to the Department, State or local law enforcement and other State or local government officials upon request if necessary to perform the government officials' functions and duties.

(2) The log must include the full name of each individual granted access to the facility's limited access area, the temporary identification badge number, the date and time of arrival, the date and time of departure and the purpose of the visit, including the areas visited and the name of each employee visited.

(f) This section does not limit the right of the Department or its authorized agents, State or local law enforcement or other Federal, State or local government officials, from entering any area of a dispensary if necessary to perform the government officials' functions and duties that pertain to the act or this part.

(g) A principal, financial backer, operator or an employee of a dispensary may not receive any type of consideration or compensation for allowing an individual to enter a limited access area.

### **§ 1161a.31. Security and surveillance.**

(a) A dispensary shall have security and surveillance systems, utilizing commercial-grade equipment, to prevent unauthorized entry and to prevent and detect an adverse loss. The security and surveillance systems must include all of the following:

(1) A professionally-monitored security alarm system that includes the following:

(i) Coverage of all facility entrances and exits; rooms with exterior windows, exterior walls, roof hatches or skylights; storage rooms, including those that contain medical marijuana and safes; and the perimeter of the facility.

(ii) A silent security alarm system signal, known as a duress alarm, generated by the entry of a designated code into an arming station to signal that the alarm user is being forced to turn off the system.

(iii) An audible security alarm system signal, known as a panic alarm, generated by the manual activation of a device intended to signal a life-threatening or emergency situation requiring law enforcement response.

(iv) A silent alarm signal, known as a holdup alarm, generated by the manual activation of a device intended to signal a robbery in progress.

(v) An electrical, electronic, mechanical or other device capable of being programmed to send a prerecorded voice message requesting dispatch, when activated, over a telephone line, radio or other communication system to a law enforcement, public safety or emergency services agency.

(vi) A failure notification system that provides an audible, text or visual notification of any failure in the systems. The failure notification system must provide by telephone, e-mail or text message an alert to a designated security person within the facility within 5 minutes after the failure.

(vii) Smoke and fire alarms.

(viii) Auxiliary power sufficient to maintain security and surveillance systems for [at least] no less than 48 hours following a power outage.

(ix) The ability to ensure all access doors are not solely controlled by an electronic access panel to prevent locks from becoming released during a power outage.

(x) Motion detectors.

(2) A professionally-monitored security and surveillance system that is operational 24 hours per day, 7 days per week and records [all activity] continuously in images capable of clearly revealing facial detail. The security and surveillance system must include all of the following:

(i) Fixed camera placement that allows for a clear image of all individuals and activities in and around the following:

(A) Any area of a facility where medical marijuana products are loaded or unloaded into or from transport vehicles.

(B) Entrances to and exits from a facility. Entrances and exits must be recorded from both indoor and outdoor vantage points.

(C) Rooms with exterior windows, exterior walls, roof hatches or skylights and storage rooms, including those that may contain medical marijuana products and safes.

(D) Five feet from the exterior of the perimeter of a facility.

(E) All limited access areas.

(ii) Auxiliary power sufficient to maintain security and surveillance systems for [at least] no less than 48 hours following a power outage.

(iii) The ability to operate under the normal lighting conditions of each area under surveillance.

(iv) The ability to immediately produce a clear, color, still photograph in a digital format that meets the requirements of this subsection.

(3) The ability to clearly and accurately display the date and time. The date and time must be synchronized and set correctly and may not significantly obscure the picture.

(4) The ability to record and store all images captured by each surveillance camera for a minimum of [2 years] 180 days, unless otherwise required for investigative or litigation purposes, in a format that may be easily accessed for investigative purposes. The recordings must be kept:

(i) At the facility:

(A) In a locked cabinet, closet or other secure place to protect it from tampering or theft.

(B) In a limited access area or other room to which access is limited to authorized individuals.

(ii) At a secure location other than the location of the facility if approved by the Department.

(5) A security alarm system separate from the facility's primary security system covering the limited access area or other room where the recordings under paragraph (4) are stored. The separate security alarm system must meet the same requirements as the facility's primary security alarm system.

(b) The following apply regarding the inspection, servicing or alteration of, and the upgrade to, the dispensary facility's security and surveillance systems:

(1) The systems shall be inspected and all devices tested once every year by a qualified alarm system vendor and a qualified surveillance system vendor.

(2) The dispensary shall conduct maintenance inspections once every month to ensure that any repairs, alterations or upgrades to the security and surveillance systems are made for the proper operation of the systems.

(3) The dispensary shall retain at the facility, for [at least] 4 years, in paper or electronic form, records of all inspections, servicing, alterations and upgrades performed on the systems and shall make the records available to the Department and its authorized agents within 2 business days following a request.



(4) In the event of a mechanical malfunction of the security or surveillance system that the dispensary anticipates will exceed a 4-hour period, the dispensary shall notify the Department immediately and, with Department approval, provide alternative security measures that may include closure of the facility.

(5) The dispensary shall designate an employee or employees to continuously monitor the security and surveillance systems at the facility.

(6) The following requirements apply regarding records retention:

(i) Within 2 business days following a request, a dispensary shall provide up to four screen captures of an unaltered copy of a video surveillance recording to the Department or its authorized agents, law enforcement, or other Federal, State or local government officials if necessary to perform the government officials' functions and duties.

(ii) If a dispensary has been notified in writing by the Department or its authorized agents, law enforcement, or other Federal, State or local government officials of a pending criminal or administrative investigation for which a recording may contain relevant information, the dispensary shall retain an unaltered copy of the recording for 4 years or until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the dispensary that it is not necessary to retain the recording, whichever is longer.

(c) A dispensary shall install commercial-grade, nonresidential steel doors and door locks on each room where medical marijuana products are stored and shall install commercial grade, nonresidential doors and door locks on each external door of the facility. Keys or key codes for all doors shall remain in the possession of designated authorized individuals.

(d) At all times, all entrances to and exits from the facility must be securely locked.

(e) A dispensary shall have an electronic back-up system for all electronic records.

(f) A dispensary shall install lighting to ensure proper surveillance inside and outside of the facility.

(g) A dispensary shall limit access to a room in a facility containing security and surveillance monitoring equipment to persons who are essential to maintaining security and surveillance operations; Federal, State and local law enforcement; security and surveillance system service employees; the Department or its authorized agents; and other persons with the prior written approval of the Department. The following requirements apply:

(1) A dispensary shall make available to the Department or the Department's authorized agents, upon request, a current list of authorized employees and service employees or contractors who have access to any security and surveillance areas.

(2) A dispensary facility shall keep security and surveillance rooms locked at all times and may not use these rooms for any other purpose or function.

## **§ 1161a.32. Inventory data.**

(a) A dispensary shall maintain the following inventory data in its electronic tracking system:

(1) Medical marijuana products received from a grower/processor.

(2) Medical marijuana products dispensed to a patient or caregiver.

(3) Damaged, defective, expired or contaminated medical marijuana products awaiting return

to a grower/processor or awaiting disposal.

(b) A dispensary shall establish inventory controls and procedures to conduct monthly inventory reviews and annual comprehensive inventories of medical marijuana products at its facility.

(c) A written or electronic record shall be created and maintained of each inventory which includes the date of the inventory, a summary of the inventory findings, and the employee identification numbers and titles or positions of the individuals who conducted the inventory.

### **§ 1161a.33. Storage requirements.**

(a) A dispensary shall have separate and locked limited access areas for storage of medical marijuana products that are expired, damaged, deteriorated, mislabeled, contaminated, recalled, or whose containers or packaging have been opened or breached until the medical marijuana products are returned to a grower/processor, destroyed or otherwise disposed of as required under § 1151a.40 (relating to management and disposal of medical marijuana waste).

(b) A dispensary shall maintain all storage areas in a clean and orderly condition and free from infestation by insects, rodents, birds and pests.

### **§ 1161a.34. Sanitation and safety in a facility.**

(a) A dispensary shall maintain a facility in a sanitary condition to limit the potential for contamination or adulteration of the medical marijuana products stored in or dispensed at the facility. The following requirements apply:

(1) Trash shall be properly removed.

(2) Floors, walls and ceilings shall be kept in good repair.

(3) Adequate protection against pests shall be provided through the use of integrated pest management practices and techniques that identify and manage pest problems, and the regular disposal of trash to prevent infestation.

(4) Toxic cleaning compounds, sanitizing agents, solvents and pesticide chemicals must be labeled and stored in a manner that prevents contamination of medical marijuana products and in a manner that otherwise complies with other applicable laws and regulations.

(b) An employee working in direct contact with medical marijuana products is subject to the restrictions on food handlers in 28 Pa. Code § 27.153 (relating to restrictions on food handlers). An employee shall otherwise conform to sanitary practices while on duty, including the following:

(1) Maintaining adequate personal hygiene.

(2) Washing hands thoroughly in an adequate hand-washing area before starting work and at any other time when hands may have become soiled or contaminated and at all times before dispensing medical marijuana products to a patient or caregiver.

(c) A dispensary shall provide adequate and convenient hand-washing facilities furnished with running water at a temperature suitable for sanitizing hands. The following requirements apply:

(1) A dispensary shall locate hand-washing facilities where good sanitary practices

require employees to wash and sanitize their hands.

(2) A dispensary shall provide effective nontoxic sanitizing cleansers and sanitary towel service or suitable hand drying devices.

(d) A dispensary shall provide adequate, readily accessible lavatories that are maintained in a sanitary condition and in good repair.

(e) A dispensary shall comply with all other applicable State and local building code requirements.

### **§ 1161a.35. Transportation of medical marijuana products.**

(a) A dispensary may transport and deliver medical marijuana products to a medical marijuana organization in this Commonwealth in accordance with this section. The following apply:

(1) Unless otherwise approved by the Department, a dispensary may deliver medical marijuana products to a medical marijuana organization only between 7 a.m. and 9 p.m. for the purposes of transporting medical marijuana products among the permittee's dispensary locations and returning medical marijuana products to a grower/processor.

(2) A dispensary may contract with a third-party contractor for delivery so long as the contractor complies with this section.

(3) A dispensary may not transport medical marijuana products to any location outside of this Commonwealth.

(4) A dispensary shall use a global positioning system to ensure safe, efficient delivery of the medical marijuana products to a medical marijuana organization.

(b) Vehicles permitted to transport medical marijuana products must:

(1) Be equipped with a secure lockbox [located within a] or locking cargo area.

(2) Have no markings that would either identify or indicate that the vehicle is being used to transport medical marijuana products.

(3) Be capable of being temperature-controlled for perishable medical marijuana products, as appropriate.

(4) Maintain current State inspection and vehicle registrations.

(5) Be insured in an amount that is commercially reasonable and appropriate.

(c) A transport vehicle shall be staffed with a delivery team consisting of [at least] two or more individuals and comply with the following:

(1) [At least one] One delivery team member shall remain with the vehicle at all times that the vehicle contains medical marijuana products.

(2) Each delivery team member shall have access to a secure form of communication with the dispensary, such as a cellular telephone, at all times that the vehicle contains medical marijuana products.

(3) Each delivery team member shall carry an identification badge or card at all times and shall, upon demand, produce it to the Department or its authorized agents, law enforcement or other Federal, State or local government officials if necessary to perform the government officials' functions and duties.

(4) Each delivery team member shall have a valid driver's license.

(5) While on duty, a delivery team member may not wear any clothing or symbols that may indicate ownership or possession of medical marijuana products.

(d) Medical marijuana products stored inside the transport vehicle must be placed inside a secure lockbox or locking cargo area and may not be visible from the outside of the transport vehicle.

(e) Except as provided in subsection (h), a delivery team shall proceed in a transport vehicle from the dispensary facility, where the medical marijuana products are loaded, directly to the medical marijuana organization facility, where the medical marijuana products are unloaded, without unnecessary delays. Notwithstanding the foregoing, a transport vehicle may make stops at multiple facilities, as appropriate, to deliver medical marijuana products.

(f) A dispensary shall immediately report to the Department, either through a designated phone line established by the Department or by electronic communication with the Department [in a manner prescribed by the Department], any vehicle accidents, diversions, losses or other reportable events that occur during transport of medical marijuana products.

(g) A dispensary shall notify the Department daily of its delivery schedule, including routes and delivery times, either through a designated phone line established by the Department or by electronic communication with the Department [in a manner prescribed by the Department].

(h) A transport vehicle is subject to inspection by the Department or its authorized agents, law enforcement, or other Federal, State or local government officials if necessary to perform the government officials' functions and duties. A transport vehicle may be stopped and inspected along its delivery route or at any medical marijuana organization.

### **§ 1161a.36. Transport manifest.**

(a) A dispensary shall generate a printed or electronic transport manifest that accompanies every transport vehicle and contains the following information:

(1) The name, address and permit number of the dispensary, and the name of and contact information for a representative of the dispensary who has direct knowledge of the transport.

(2) The name, address and permit number of the medical marijuana organization receiving the delivery, and the name of and contact information for a representative of the medical marijuana organization.

(3) The quantity, by weight or unit, of each medical marijuana harvest batch, harvest lot or process lot contained in the transport, along with the identification number for each harvest batch, harvest lot or process lot.

(4) The date and approximate time of departure.

(5) The date and approximate time of arrival.

(6) The transport vehicle's make and model and license plate number.

(7) The identification number of each member of the delivery team accompanying the transport.

(b) When a delivery team delivers medical marijuana products to multiple facilities, the transport manifest must correctly reflect the specific medical marijuana products in transit. Each recipient shall provide the dispensary with a printed receipt for the medical marijuana products received.

(c) All medical marijuana products being transported shall be labeled in accordance with §§ 1151a.34 and 1161a.28 (relating to packaging and labeling of medical marijuana products; and labels and safety inserts) and shall be transported in a secure lockbox [located within a] or locking cargo area.

(d) A dispensary shall provide a copy of the transport manifest to the recipient receiving the medical marijuana products described in the transport manifest. To maintain confidentiality, a dispensary may prepare separate manifests for each recipient.

(e) A dispensary shall, if requested, provide a copy of the printed transport manifest, and any printed receipts for medical marijuana products being transported, to the Department or its authorized agents, law enforcement, or other Federal, State or local government officials if necessary to perform the government officials' functions and duties.

### **§ 1161a.37. Evidence of adverse loss during transport.**

(a) If a dispensary receiving a delivery of medical marijuana products from a medical marijuana organization discovers a discrepancy in the transport manifest that remains unresolved upon delivery, the dispensary shall refuse acceptance of the delivery and immediately report the discrepancy to the Department either through a designated phone line established by the Department or by electronic communication with the Department [in a manner prescribed by the Department], and to the appropriate law enforcement authorities.

(b) If a dispensary discovers evidence of, or reasonably suspects, a theft or diversion of medical marijuana products during transport, the dispensary shall immediately report its findings or suspicions to the Department either through a designated phone line established by the Department or by electronic communication with the Department [in a manner prescribed by the Department], and to law enforcement.

(c) If a dispensary discovers a discrepancy in the transport manifest, the dispensary shall:

(1) Conduct an investigation.

(2) Amend the dispensary's standard plan of operation, if necessary, to prevent future discrepancies between the quantity or description of inventory listed in the transport manifest and the quantity or description of inventory delivered.

(3) Submit a report of the investigation to the Department. The following requirements apply:

(i) The dispensary shall submit a written preliminary report of the investigation to the Department within 7 days of discovering the discrepancy.

(ii) The dispensary shall submit a final written report of the investigation to the Department within 30 days of discovering the discrepancy.

### **§ 1161a.38. Complaints about or recall of medical marijuana products.**

(a) A dispensary shall notify the Department and the grower/processor from which it received the medical marijuana product in question immediately upon becoming aware of any complaint made to the dispensary by a patient, caregiver or practitioner who reports an adverse event from

using medical marijuana products dispensed by the dispensary.

(b) Upon notification by the grower/processor under § 1151a.42 (relating to complaints about or recall of medical marijuana products), the dispensary shall cease dispensing the affected medical marijuana products immediately.

(c) A dispensary shall coordinate the return of the recalled medical marijuana products with the grower/processor.

### **§ 1161a.39. Electronic tracking system.**

A dispensary shall use the electronic tracking system prescribed by the Department containing the requirements in section 701 of the act (35 P.S. § 10231.701). The system shall allow for two-way communication, automation and secure application-programming interface of a medical marijuana organization's enterprise resource planning, inventory, accounting and point-of-sale software and allow for accessing all data required to be transmitted to the Department to ensure compliance with the operational reporting requirements of the act and these regulations.

### **§ 1161a.40. [Application for additional] Additional dispensary locations.**

(a) An applicant for a dispensary permit shall include a primary dispensary facility location, and may include up to two additional dispensary facility locations, in its initial permit application. A permittee may file an application under this section for additional dispensary facility locations at a later date.

(b) A dispensary shall submit an application for additional dispensary locations on a form prescribed by the Department.

(c) A dispensary submitting an application for additional dispensary locations shall include with the application the following fees:

(1) An application fee of \$5,000, which is nonrefundable.

(2) A permit fee of \$30,000 for each dispensary location being proposed. The permit fee shall be submitted with the application for additional dispensary locations and will be refunded if the permit is not granted.

(d) A dispensary may not begin operations at an additional location until the Department approves the application for additional dispensary locations, in writing, under this section.

(e) A dispensary submitting an application for additional dispensary locations shall follow the requirements in § 1141a.29 (relating to initial permit application) and this part.

(f) A dispensary may interchange the designation of a primary, secondary or tertiary location at any time, including the period before a location becomes operational, by providing written notice to the department at least 14 days before the change in designation. A change in designation under this subsection may not be subject to approval of the Department.

## **CHAPTER 1171a. LABORATORIES**

Sec.

1171a.22. Laboratories generally.

- 1171a.23. Approval of laboratories.
- 1171a.24. Suspension or revocation of an approval issued to a laboratory.
- 1171a.25. Renewal of an approval issued to a laboratory.
- 1171a.26. Stability testing and retention of samples.
- 1171a.27. Sampling procedures for testing.
- 1171a.28. Selection protocol for samples.
- 1171a.29. Testing requirements.
- 1171a.30. Standards for testing.
- 1171a.31. Test results and reporting.
- 1171a.32. Quality assurance program.
- 1171a.33. Transporting samples.
- 1171a.34. Department request for testing.
- 1171a.35. Laboratory reporting.
- 1171a.36. Advertising.
- 1171a.37. Ownership prohibitions.
- 1171a.38. Appeals.

#### **§ 1171a.22. Laboratories generally.**

(a) A laboratory may not identify, collect, handle or conduct tests on samples from a grower/processor or conduct tests on test samples for the Department unless the laboratory has been approved by the Department under § 1171a.23 (relating to approval of laboratories) and has entered into a written contract with the grower/processor under § 1171a.29 (relating to testing requirements).

(b) The Department will post on its website a current list of approved laboratories.

(c) An approved laboratory shall employ [at least one] a director to oversee and be responsible for the identification, collection, handling and testing operations of the approved laboratory. A director shall have earned, from a college or university accredited by a National or regional accrediting authority, [at least] one or more of the following:

(1) A doctorate of science or an equivalent degree in chemistry, biology, or a subdiscipline of chemistry or biology.

(2) A master's level degree in a chemical or biological science and a minimum of 2 years post-degree laboratory experience related to testing of medicinal or pharmaceutical products or other experience as approved by the Department.

(3) A bachelor's degree in a biological science and a minimum of 4 years post-degree laboratory experience related to testing of medicinal or pharmaceutical products or other experience as approved by the Department.

(d) A principal or employee of a medical marijuana organization may not also own, be employed by or be affiliated with an approved laboratory that has a contract with that medical marijuana organization.

(e) An approval issued by the Department to a laboratory under this part is valid for 2 years from the date of issuance and is valid only for the laboratory named and the location specified in the approval.

(f) An approval issued by the Department to a laboratory under this part is not transferable to any other person or any other location unless the laboratory obtains the prior written consent of the Department.

(g) Notwithstanding the definitions of “harvest batch”, “harvest lot”, “medical marijuana extract”, “process lot”, “processing”, “sample”, and “test sample”, §§ 1171a.22 – 1171a.28 shall also apply to an approved laboratory’s testing of harvested hemp.

### **§ 1171a.23. Approval of laboratories.**

(a) A laboratory wishing to identify, collect, handle and conduct tests on samples and test samples and other items used by a grower/processor in the growing and processing of medical marijuana and medical marijuana products as required under the act and this part shall submit an application for approval to the Department [on a form and in a manner prescribed by the Department]. The application is available on the Department’s public website.

(b) An application submitted under this section must include the following information:

- (1) The name and address of the laboratory applicant or its authorized agent.
- (2) The name and address of the owner of the laboratory applicant, and, if applicable, the medical or pharmacy licensure information regarding the owner.
- (3) The name of the laboratory applicant's proposed director and technical personnel who are or will be employed by the laboratory at the location to be approved.
- (4) A copy of the laboratory applicant's most recent certificate of accreditation.
- (5) Copies of the standard operating procedures and sampling procedures adopted by the laboratory applicant and approved by the accreditation body that issued the certificate of accreditation to the laboratory applicant.
- (6) A list of the specialized laboratory equipment utilized or to be utilized by the laboratory applicant in its testing operations, including the manufacturer's name and the serial and model number of the equipment, and other specifications as may be required by the Department.
- (7) A description of the tests which are capable of being conducted by the laboratory applicant at the location to be approved.
- (8) A description of the laboratory applicant's quality assurance program, which must be in compliance with § 1171a.32 (relating to quality assurance program).
- (9) The procedures to be followed to establish chain of custody when collecting samples or test samples.
- (10) A copy of the evaluation process that the laboratory applicant uses or will use to monitor, evaluate and document the competency of employees when testing samples and test samples and overseeing quality assurance controls.
- (11) Other information required by the Department.

(c) By submitting an application for approval to the Department, a laboratory applicant consents to an investigation of any person, information or physical location the Department or its authorized



agents deem appropriate for the Department to make a determination of the laboratory applicant's ability to meet the requirements under the act and this part.

(d) An application for approval submitted under this chapter must include a statement that a false statement made in the application is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).

(e) The Department may issue an approval under this chapter if the Department determines that the laboratory applicant is financially and professionally suitable to conduct the testing required under the act and this part.

#### **§ 1171a.24. Suspension or revocation of an approval issued to a laboratory.**

(a) An approval issued by the Department under this chapter may be suspended or revoked if the Department determines that the approved laboratory has engaged in unethical practices or has failed to do any of the following:

- (1) Maintain proper standards of accuracy.
- (2) Comply with the requirements of the act or this part applicable to the approved laboratory.

(b) An approval issued by the Department under this chapter may be revoked if the Department determines that the approved laboratory has engaged in any of the following conduct:

- (1) Dishonest reporting.
- (2) Repeated errors in conducting the required testing.
- (3) Allowing unauthorized individuals to perform testing or to sign reports.
- (4) Inclusion of false statements in the application for approval or renewal.
- (5) Advertising of medical marijuana testing services to the general public.
- (6) Knowingly accepting a sample from an individual other than a grower/processor or a test sample from an individual other than the Department or an authorized agent of the Department.
- (7) Failure to maintain standard operating procedures approved by the accreditation body that issued the certificate of accreditation to the approved laboratory.
- (8) Failure to properly enter test results into the electronic tracking system.
- (9) Loss by the approved laboratory of its certificate of accreditation.

#### **§ 1171a.25. Renewal of an approval issued to a laboratory.**

An approved laboratory wishing to renew its approval under this chapter shall, not more than 6 months nor less than 4 months prior to the expiration of the approval, submit an application under § 1171a.23 (relating to approval of laboratories) and update the information required to be submitted with the application as necessary.

#### **§ 1171a.26. Stability testing and retention of samples.**

- (a) A grower/processor shall [request that a sample be identified and collected by an approved

laboratory from each harvest batch] retain a sample from each process lot to ensure product potency and purity and provide support for expiration dating sufficient to perform stability testing [at 6-month intervals for a 1-year period].

(b) The stability test shall be performed at six-month intervals for the duration of the expiration date period as listed on the medical marijuana product and once within six months of the expiration date if the medical marijuana product is still in inventory at a dispensary in this Commonwealth as determined by the seed-to-sale system [to ensure product potency and purity and provide support for expiration dating].

(c) [An approved laboratory] A grower/processor shall retain a sample from each [harvest batch sufficient to provide for stability testing and properly store the sample for 1 year] process lot for subsequent stability testing, in an amount equivalent to the sample size initially identified and collected by an approved laboratory, for the duration of the expiration date period as listed on the medical marijuana product.

### **§ 1171a.27. Sampling procedures for testing.**

(a) An approved laboratory shall ensure that its employees prepare all samples in accordance with policies and procedures that include appropriate information necessary for identifying, collecting and transporting samples in a manner that does not endanger the integrity of the samples for any testing required by this part.

(b) The sampling policies must[, at a minimum, meet the following requirements]:

- (1) Be appropriate to the matrix being sampled.
- (2) [Be in accordance with guidance provided by the Department]Require samples to be representative of the harvest batch, harvest lot or process lot.
- (3) Require the amount being removed to be based on applicable statistical criteria.

(c) The sampling procedures must include the following procedures:

- (1) Surveying the conditions in which the sample is being stored.
- (2) Using appropriate sampling equipment and consistent procedures.
- (3) Selecting and removing equal portions for each sample.
- (4) Random or systematic taking of samples throughout the harvest batch or harvest lot.
- (5) Obtaining a minimum number of samples based on harvest batch or harvest lot size.
- (6) Checking all parts of the harvest batch when harvest lots are created from that harvest batch.
- (7) Recording on a form prescribed by the Department all observations and procedures used when collecting the sample.
- (8) Creating a unique sample identification number that will be linked to the harvest batch or harvest lot number assigned by the grower/processor in the electronic tracking system.
- (9) Entering all required information into the electronic tracking system.

## **§ 1171a.28. Selection protocols for samples.**

(a) An employee of an approved laboratory may [only] enter a grower/processor facility for the purpose of identifying and collecting samples and shall only have access to limited access areas in the facility for these purposes.

(b) An employee identifying and collecting samples under subsection (a) shall follow the chain of custody procedures included in the approved laboratory's application and approved by the Department.

(c) While at a grower/processor facility, an employee of an approved laboratory shall identify and collect the following for testing:

- (1) Samples at the time of harvest.
- (2) Samples of medical marijuana product before being sold or provided to a dispensary.
- (3) Test samples at other times when requested by the Department.
- (4) Samples for stability testing.

## **§ 1171a.29. Testing requirements.**

(a) Prior to conducting any testing of a sample at the request of a grower/processor, an approved laboratory shall enter into a written contract with the grower/processor for testing services. The approved laboratory shall provide a copy of the contract to the Department within 2 days following the Department's request.

(b) A grower/processor shall submit through the electronic tracking system a request to the approved laboratory with which it has a written contract under subsection (a) for each test to be conducted.

(c) [At a minimum, testing, as prescribed by the Department,] Testing shall be performed as follows:

(1) An approved laboratory shall test samples from a harvest batch or harvest lot prior to using the harvest batch or harvest lot to produce a medical marijuana product.

(2) An approved laboratory other than the one that tested the harvest batch or harvest lot shall test samples from each process lot before the medical marijuana is sold or offered for sale to another medical marijuana organization.

(3) An approved laboratory may test other samples and test samples at the request of a grower/processor or the Department.

(d) The samples identified in subsection (c) shall be tested[, at a minimum,] for the following:

- (1) Pesticides.
- (2) Solvents.
- (3) Water activity and moisture content.

(4) THC and CBD concentration.

(5) Microbiological contaminants.

(6) Terpenes.

(7) Heavy metals.

(8) Mycotoxins.

(e) Sampling and testing under this chapter shall be conducted with a statistically significant number and size of samples and with approved methodologies [acceptable to the Department] to ensure that all harvest batches, harvest lots and medical marijuana products are adequately tested for contaminants and that the cannabinoid profile is consistent throughout the harvest batch, harvest lot or medical marijuana products. All testing methods must be fully validated to address the accuracy, precision, specificity, linearity, range, and sensitivity of the testing method.

(e.1) PCR testing is not an approved methodology.

(f) An approved laboratory may not test any samples when there is evidence of improper collection, improper preservation, apparent spoilage, excessive time lapse between collection of the sample and testing, or any other [factor sufficient to render the findings of questionable validity] obvious circumstance that compromises the sample.

(g) An approved laboratory shall enter test results for samples collected under § 1171a.28(c)(1) and (2) [(relating to selection protocols for samples)] into the electronic tracking system and, under § 1151a.40 (relating to management and disposal of medical marijuana waste), properly dispose of all tested and untested samples and test samples.

### **§ 1171a.30. Standards for testing.**

(a) An approved laboratory shall follow the methodologies, ranges and parameters [acceptable to the Department that are contained in] that are consistent with [and] the scope of the certificate of accreditation issued to the laboratory and in accordance with this chapter.

(b) Testing methods used by an approved laboratory shall meet or exceed the minimum standards under the American Herbal Pharmacopeia's "Cannabis Inflorescence Standards of Identity, Analysis and Quality Control", 2014 Revision Edition.

### **§ 1171a.31. Test results and reporting.**

(a) Only the results of the following tests are in compliance with the testing requirements of this chapter:

(1) Tests conducted on harvest batch samples or harvest lot samples requested by a grower/processor under § 1171a.29 (relating to testing requirements) and identified and collected by an employee of an approved laboratory.

(2) Tests conducted on process lot samples requested by a grower/processor under § 1171a.29 and identified and collected by [either an employee of a grower/processor or] an employee of an approved laboratory.

(b) The test results for each sample collected under § 1171a.28(c)(1) and (2) (relating to selection

protocols for samples) shall be entered into the electronic tracking system and shall only be accessible to the grower/processor submitting the sample and to the Department.

(c) If a sample fails any test required under § 1171a.29, the following apply to the sample:

(1) The approved laboratory that performed the initial test may re-test the sample upon a request from the grower/processor in accordance with subsection (d).

(1.1) If the re-tested sample fails, the lot shall be disposed of under § 1151a.40 unless the lot failed only for yeast or mold and the grower/processor chooses to process the lot into a topical form under § 702(a)(3) of the act. 35 P.S. § 10231.702(a)(3).

(2) If the sample passes the re-test, another approved laboratory shall sample the same harvest batch, harvest lot or process lot to confirm the passing test result.

(2.1) Following the confirming test, and to determine whether to accept the confirming result, the Department may require any or all of the following:

(i) the grower/processor to provide a root cause analysis for the initially failed result;

(ii) documentation from the grower/processor and the confirming laboratory that required testing procedures were followed and detailing chain of custody;

(iii) an affirmation by the grower/processor that the sample was not modified in any manner and was not subjected to any form of decontamination or remediation between the initially failed and confirming passing results;

(iv) an additional confirming test by an approved laboratory other than the two who conducted the first and second tests.

(3) If the Department does not agree to accept the confirming results from the approved laboratory, the sample shall be disposed of by the approved laboratory under § 1151a.40 (relating to management and disposal of medical marijuana waste).

(d) A grower/processor shall notify the Department and the approved laboratory through the electronic tracking system of its intent to re-test the sample or test another sample from the same harvest batch, harvest lot or process lot that failed a test.

(e) An approved laboratory shall issue to a grower/processor a certificate of analysis, including the supporting data, for each harvest batch, harvest lot or process lot sample that was tested at the request of the grower/processor. The certificate of analysis must include the following information:

(1) Whether the chemical profile of the harvest batch, harvest lot or process lot conforms to the approved chemical profile of the strain [as determined by the Department] for the following compounds:

(i) THC.

(ii) THCA.

(iii) CBD.

(iv) CBDA.

(v) CBC.

(vi) CBN.

(vii) THCV.

(viii) CBDV.

(ix) CBG.

(x) D8.

(2) That the presence of the following contaminants within the harvest batch, harvest lot or process lot does not exceed the approved maximum levels [as determined by the Department] for the following:

(i) Heavy metals, mercury, lead, cadmium or arsenic.

(ii) Foreign material such as hair, insects, or any similar or related adulterant.

(iii) Any microbiological impurity, including:

(A) Total aerobic microbial count.

(B) Total yeast mold count.

(C) *P. aeruginosa*.

(D) *Aspergillus spp.*

(E) *S. aureus*.

(F) Aflatoxin B1, B2, G1 and G2.

(G) Ochratoxin A.

(H) Pesticide residue.

(I) E. coli.

(J) Salmonella.

(iv) Whether the harvest batch, harvest lot or process lot is within the specification for the strain for the characteristics of:

(A) Odor.

(B) Appearance.

(C) Fineness.

(D) Moisture content, when applicable for process lot.

(f) If an approved laboratory detects an amount of a pesticide that exceeds normal or acceptable

limits, the approved laboratory shall notify the Department immediately. If an approved laboratory detects a prohibited pesticide or a pesticide within the National Institute of Standards and Technology (NIST) library during the testing process, the approved laboratory shall notify the Department. An approved laboratory shall report whether any residual pesticides are detected above the limit of detection and shall report the results to the Department. The Department may obtain test samples from a grower/processor to conduct pesticide residue testing.

(1) An approved laboratory shall establish a limit of quantification of 0.1 ug/g or lower for all pesticides.

(2) An approved laboratory shall analyze at minimum 0.5 grams of the representative sample of medical marijuana to determine whether residual pesticides are present.

(g) The Department will maintain oversight of testing methods and sampling standards under this chapter. The Department may conduct onsite visits and review certificates of analysis submitted by an approved laboratory.

### **§ 1171a.32. Quality assurance program.**

(a) An approved laboratory shall establish and implement a quality assurance program to ensure that measurements are accurate, errors are controlled, and devices used for testing are [routinely and] properly calibrated annually or more frequently if recommended by the manufacturer.

(b) The quality assurance program required under subsection (a) must include the following components:

(1) An organizational chart that includes the testing responsibilities of each employee of the approved laboratory named in the chart.

(2) A description of sampling procedures to be utilized.

(3) Appropriate chain of custody protocols.

(4) Analytical procedures.

(5) Data reduction and validation procedures.

(6) A plan for implementing corrective action, when necessary.

(7) A requirement for the provision of quality assurance reports to management.

(8) A description of the internal and external quality control systems.

### **§ 1171a.33. Transporting samples.**

(a) An employee of an approved laboratory, grower/processor or third-party contractor shall follow the transportation requirements under §§ 1151a.35 and 1151a.36 (relating to transportation of medical marijuana; and transport manifest) when transporting a sample or test sample under this part.

(b) An employee of an approved laboratory, grower/processor or third-party contractor who transports [process lot] samples from a grower/processor to an approved laboratory shall:

(1) Protect the physical integrity of the sample.

(2) Keep the composition of the sample intact.

(3) Protect the sample against factors that interfere with the validity of testing results, including the factors of time, temperature and [other environmental factors that may work to jeopardize the integrity of the sample] any other circumstance that [obviously compromises] appears to have compromised the sample.

#### **§ 1171a.34. Department request for testing.**

(a) The Department, in its sole discretion, may identify and collect a test sample from a grower/processor at any time and request an approved laboratory to conduct proficiency testing, conduct quality assurance measures and perform tests under this chapter.

(b) The approved laboratory shall provide the Department with a written report of the test results from a test sample tested under subsection (a) within 7 days of the collection of the test sample, or sooner if requested by the Department.

#### **§ 1171a.35. Laboratory reporting.**

(a) An approved laboratory shall enter into the electronic tracking system the following information for each sample collected under § 1171a.28(c)(1) and (2) (relating to selection protocols for samples) and each test conducted:

- (1) The unique sample identification number the approved laboratory assigns to the sample.
- (2) The name of the grower/processor that supplied the sample.
- (3) The employee identification number of the employee of the approved laboratory who identified and collected the sample at the request of the grower/processor.
- (4) The date and time the sample was collected from the grower/processor.
- (5) The date and time the sample was received by the approved laboratory.
- (6) The date the test was completed.
- (7) The condition of the sample when it was received by the approved laboratory.
- (8) A description of each test performed.
- (9) The results from the certificate of analysis issued under § 1171a.31 (relating to test results and reporting).
- (10) The date the testing results were provided to the grower/processor under § 1171a.31 or the Department under § 1171a.34 (relating to Department request for testing).

(b) An approved laboratory shall keep for 4 years a paper or electronic copy of the certificate of analysis performed on samples submitted by a grower/processor or test samples submitted by the Department including test results not required to be entered into the electronic tracking system under § 1171a.29 (relating to testing requirements).

(1) Regarding tests results not entered into the electronic tracking system, the approved laboratory shall immediately provide to the Department by email an electronic copy of the certificate



of analysis.

(2) Regarding test results entered into the electronic tracking system, the approved laboratory shall provide a copy of a certificate of analysis to the Department within 2 days of a request made by the Department.

(c) The Department may conduct an investigation based on the results shown on any certificate of analysis.

### **§ 1171a.36. Advertising.**

(a) An approved laboratory may not advertise, market or otherwise promote its medical marijuana testing services to the general public.

(b) An approved laboratory may only promote its medical marijuana testing services to a grower/processor. An approved laboratory may use advertising, marketing and promotional materials directed at a grower/processor to promote its medical marijuana testing services. The advertising, marketing and promotional materials proposed to be used by an approved laboratory under this section shall be reviewed and approved by the Department prior to circulation or other use.

(c) Personal solicitation by an employee, representative or agent of an approved laboratory to a grower/processor is considered advertising, marketing or otherwise promoting its medical marijuana testing services for the purposes of this section.

(d) An approved laboratory may only advertise, market or otherwise promote its medical marijuana testing services that are performed onsite at the location designated in the laboratory's application.

(e) A sign installed at the location of an approved laboratory that is designed to identify the laboratory or access to the laboratory is permissible as long as the sign meets local zoning requirements and does not violate the provisions of this section.

### **§ 1171a.37. Ownership prohibition.**

The following individuals may not have a management, a direct or indirect financial, or other ownership interest in an approved laboratory:

(1) A principal, owner, financial backer or employee of a medical marijuana organization.

(2) A practitioner.

(3) A physician, pharmacist, physician assistant or certified registered nurse practitioner who is currently employed by a medical marijuana organization.

(4) Any other person, other than a patient, who may receive a direct or indirect financial benefit from the growing, processing, transporting, dispensing or selling of seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products.

### **§ 1171a.38. Appeals.**

Chapter 5, Subchapter A of 2 Pa.C.S. (relating to practice and procedure of Commonwealth agencies) and the accompanying regulations, as modified by Chapter 1230a (relating to practice and

procedure), apply to all actions of the Department under this chapter constituting an adjudication as defined in 2 Pa.C.S. § 101 (relating to definitions).

## **CHAPTER 1181a. PHYSICIANS AND PRACTITIONERS**

Sec.

1181a.22. Practitioners generally.

1181a.23. Medical professionals generally.

1181a.24. [Physician]Practitioner registration.

1181a.25. Practitioner registry.

1181a.26. Denial, revocation or suspension of a practitioner registration.

1181a.27. Issuing patient certifications.

1181a.28. Modifying a patient certification.

1181a.29. Revocation of a patient certification.

1181a.30. Prescription drug monitoring program.

1181a.31. Practitioner prohibitions.

1181a.32. Training.

1181a.33. Appeals.

### **§ 1181a.22. Practitioners generally.**

(a) The qualifications that a physician shall meet to be registered with the Department and approved as a practitioner are continuing qualifications.

(b) A physician may not issue a patient certification without being registered by the Department as a practitioner in accordance with § 1181a.24 (relating to physician registration).

(c) A practitioner shall notify a dispensary by telephone of a patient's adverse reaction to medical marijuana products dispensed by that dispensary immediately upon becoming aware of the reaction.

(d) A practitioner may petition the Medical Marijuana Advisory Board (Board) for the Board to review on a continuing basis, and recommend to the Secretary for approval, that serious medical conditions be changed, reduced or added to those conditions for which medical marijuana is likely to provide therapeutic or palliative benefit to a patient.

### **§ 1181a.23. Medical professionals generally.**

(a) The qualifications that a medical professional shall meet to be employed by a dispensary are continuing qualifications.

(b) A medical professional may not assume any duties at a dispensary until the training required under § 1181a.32 (relating to training) and any other requirements for medical professionals under the act and this part are completed.

(c) A medical professional shall notify by telephone the practitioner listed on a patient certification of a patient's adverse reaction to medical marijuana products dispensed by that dispensary immediately upon becoming aware of the reaction.

### **§ 1181a.24. [Physician] Practitioner registration.**

(a) A physician who has an active and unrestricted medical license in this Commonwealth in accordance with the Medical Practice Act of 1985 (63 P.S. §§ 422.1—422.51a) or the Osteopathic Medical Practice Act (63 P.S. §§ 271.1—271.18) may file an application for registration with the

Department as a practitioner on a form prescribed by the Department.

(b) An application for registration must include[, at a minimum,] the following requirements:

(1) The physician's full name, business address, professional e-mail address, telephone numbers and, if the physician owns or is affiliated with a medical practice, the name of the medical practice.

(2) The physician's credentials, education, specialty, training and experience, and supporting documentation when available.

(3) The physician's medical license number.

(4) A certification by the physician that states:

(i) That the physician's Pennsylvania license to practice medicine is active and in good standing.

(ii) Whether the physician has been subject to any type of professional disciplinary action that would prevent the physician from carrying out the responsibilities under the act and this part, together with, if applicable, an explanation of the professional disciplinary action.

(iii) That the physician does not hold a direct or economic interest in a medical marijuana organization.

(5) A statement that a false statement made by a physician in an application for registration is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).

(c) Based on the information provided by the physician under subsection (b), the Department will determine whether to approve the physician to issue patient certifications.

(d) The Department may list a physician on the practitioner registry only after the physician has successfully completed the training course required under § 1181a.32 (relating to training) and any other requirements for registration under the act and this part.

### **§ 1181a.25. Practitioner registry.**

(a) The Department will maintain a practitioner registry for use by a patient or caregiver registered by the Department. The practitioner registry will include only the practitioner's name, business address and medical credentials.

(b) The inclusion of a physician in the practitioner registry will be subject to annual review by the Department to determine if the physician's license is inactive, expired, suspended, revoked, limited or otherwise restricted by the applicable Medical Board, or if the physician has been subject to professional disciplinary action.

### **§ 1181a.26. Denial, revocation or suspension of a practitioner registration.**

(a) A practitioner registration will be denied, revoked or suspended if the practitioner's medical license is inactive, expired, suspended, revoked, limited or otherwise restricted by the applicable Medical Board.

(b) A practitioner registration may be denied, revoked or suspended if the practitioner is or has been the subject of professional disciplinary action, including an immediate temporary action.

(c) A physician who has been denied registration or whose practitioner registration has been revoked or suspended may reapply to the Department for inclusion in the practitioner registry in accordance with § 1181a.24 (relating to physician registration) if the event that led to the physician's denial, revocation or suspension has been resolved and the physician's medical license is designated as active without limitation by the applicable Medical Board. The physician's application for registration under this subsection must include evidence of the resolution.

(d) A physician who has been denied registration or whose practitioner registration has been revoked or suspended may not do any of the following:

(1) Have electronic access to a patient certification.

(2) Issue or modify a patient certification.

(3) Provide a copy of an existing patient certification to any person, including a patient or a caregiver, except [in accordance with applicable law] where a patient is entitled by law to obtain copies of their own medical records, such as in 42 Pa.C.S. § 6155(b)(1).

(e) The Department may revoke or suspend the registration of a practitioner for any of the following:

(1) A violation of the act or this part.

(2) A violation of an order issued under the act or this part.

(3) A violation of a regulation promulgated under the act.

(4) For conduct or activity that would have disqualified the practitioner from receiving a registration.

(5) Pending the outcome of a hearing in a case which the practitioner's registration could be suspended or revoked.

## **§ 1181a.27. Issuing patient certifications.**

(a) A practitioner may issue a patient certification to a patient if the following conditions are met:

(1) The practitioner has determined, based upon a patient consultation [and any other factor deemed relevant by the practitioner,] that the patient has a serious medical condition and has included that condition in the patient's health care record.

(1.5) The patient is under the practitioner's continuing care for the serious medical condition.

(2) The practitioner has determined the patient is likely to receive therapeutic or palliative medical benefit from the use of medical marijuana based upon the practitioner's professional opinion and review of the following:

(i) The patient's prior medical history as documented in the patient's health care records if the records are available for review.

(ii) The patient's controlled substance history if the records are available in the Prescription Drug Monitoring Program.

(b) Notwithstanding subsection (a), the following requirements apply:

(1) A practitioner who is not board-eligible or board-certified in pediatrics or a pediatric specialty, neurology with special qualifications in child neurology, child and adolescent psychiatry, or adolescent medicine (whether through pediatrics, internal medicine or family practice) may not issue a patient certification to a minor patient.

(2) Paragraph (1) will be effective upon the registration of a sufficient number of eligible practitioners to ensure adequate access for minor patients needing services under the act and this part based on location, serious medical condition and number of patients, specialty, and number and availability of practitioners. The Department will publish a notice in the *Pennsylvania Bulletin* 1 month before paragraph (1) becomes effective, stating that a sufficient number of eligible practitioners have registered to effectuate this subsection.

(c) A patient certification that is issued by a practitioner must include[, at a minimum,] all of the following:

(1) The patient's name, home address, telephone number, date of birth and e-mail address, if available.

(2) The practitioner's name, business address, telephone numbers, professional e-mail address, medical license number, area of specialty, if any, and signature.

(3) The date of the patient consultation for which the patient certification is being issued.

(4) The patient's specific serious medical condition.

(5) A statement by the practitioner that the patient has a serious medical condition, and the patient is under the practitioner's continuing care for the condition.

(6) A statement as to the length of time, not to exceed 1 year, for which the practitioner believes the use of medical marijuana by the patient would be therapeutic or palliative.

(7) A statement by the practitioner that includes one of the following:

(i) The recommendations, requirements or limitations as to the form or dosage of medical marijuana product.

(ii) The recommendation that only a medical professional employed by the dispensary and working at the dispensary facility consult with the patient or the caregiver regarding the appropriate form and dosage of the medical marijuana product to be dispensed.

(8) A statement by the practitioner that the patient is terminally ill, if applicable.

(9) Any other information that the practitioner believes may be relevant to the patient's use of medical marijuana products.

(10) A statement that the patient is homebound or an inpatient during the time for which the patient certification is issued due to the patient's medical and physical condition and is unable to visit a dispensary to obtain medical marijuana products.

(11) A statement that the practitioner has explained the potential risks and benefits of the use of medical marijuana products to the patient and has documented in the patient's health care record that the explanation has been provided to the patient and informed consent has been obtained.

(12) A statement that a false statement made by the practitioner in the patient certification is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).

(d) Upon completion of a patient certification, a practitioner shall:

(1) Provide a copy of the patient certification to the patient or the patient's caregiver, if the patient is a minor, and to an adult patient's caregiver if authorized by the patient.

(2) Provide the patient certification with the original signature to the Department, which may be submitted electronically.

(3) File a copy of the patient certification in the patient's health care record.

### **§ 1181a.28. Modifying a patient certification.**

(a) A practitioner may [not] modify [the form of medical marijuana products on] a patient certification [for 30 days from the date the receipt is entered into the electronic tracking system by the dispensary unless the practitioner notifies the Department of the intent to modify the patient certification] at any time after issuance and before expiration.

(b) After modifying a patient certification, a practitioner shall do the following:

(1) Provide a copy of the patient certification to the patient or the patient's caregiver, if the patient is a minor, and to an adult patient's caregiver if authorized by the patient.

(2) Provide the patient certification with the original signature to the Department, which may be submitted electronically.

(3) File a copy of the patient certification in the patient's health care record.

### **§ 1181a.29. Revocation of a patient certification.**

(a) A practitioner shall immediately notify the Department in writing if the practitioner knows or has reason to know that any of the following events are true with respect to a patient for whom the practitioner issued a patient certification:

(1) The patient no longer has the serious medical condition for which the patient certification was issued.

(2) The use of medical marijuana products by the patient would no longer be therapeutic or palliative.

(3) The patient has died.

(b) The Department will revoke a patient certification upon receiving notification of the occurrence of an event listed in subsection (a).

(c) Notwithstanding subsection (a), a practitioner may withdraw the issuance of a patient certification at any time by notifying, in writing, both the patient and the Department.

(d) The Department will immediately notify a medical marijuana cardholder upon the revocation of a patient certification and the information shall be entered into the electronic tracking system.

### **§ 1181a.30. Prescription Drug Monitoring Program.**

(a) A practitioner shall review the Prescription Drug Monitoring Program prior to issuing or modifying a patient certification to determine the controlled substance history of the patient to determine whether the controlled substance history of the patient would impact the patient's use of medical marijuana products.

(b) A practitioner may access the Prescription Drug Monitoring Program to do any of the following:

(1) Determine whether a patient may be under treatment with a controlled substance by another physician or other person.

(2) Allow the practitioner to review the patient's controlled substance history as deemed necessary by the practitioner.

(3) Provide to the patient, or caregiver if authorized by the patient, a copy of the patient's controlled substance history.

### **§ 1181a.31. Practitioner prohibitions.**

(a) A practitioner may not accept, solicit or offer any form of remuneration from or to any individual, prospective patient, patient, prospective caregiver, caregiver or medical marijuana organization, including an employee, financial backer or principal, to certify a patient, other than accepting a fee for service with respect to a patient consultation of the prospective patient to determine if the prospective patient should be issued a patient certification to use medical marijuana products.

(b) A practitioner may not hold a direct or economic interest in a medical marijuana organization.

(c) A practitioner may not advertise the practitioner's services as a practitioner who can certify a patient to receive medical marijuana products.

(d) A practitioner may not issue a patient certification for the practitioner's own use or for the use of a family or household member.

(e) A practitioner may not be a designated caregiver for a patient that has been issued a patient certification by that practitioner.

(f) A practitioner may not receive or provide medical marijuana product samples.

(g) A practitioner may not excessively charge a patient for any expense related to the certification and follow-up process.

### **§ 1181a.32. Training.**

(a) Within the time specified, the following individuals shall complete a 4-hour training course approved by the Department:

(1) A physician prior to being included in the practitioner registry under § 1181a.24 (relating to physician registration).

(2) A medical professional prior to assuming any duties at a dispensary under § 1161a.25 (relating to licensed medical professionals at facility).

(b) The requirements of the training course required under subsection (a) must include[, at a minimum,] all of the following:

(1) The provisions of the act and this part relevant to the responsibilities of a practitioner or medical professional.

(2) General information about medical marijuana under Federal and State law.

(3) The latest scientific research on the endocannabinoid system and medical marijuana, including the risks and benefits of medical marijuana.

(4) Recommendations for medical marijuana as it relates to the continuing care of a patient in the following areas:

(i) Pain management, including opioid use in conjunction with medical marijuana.

(ii) Risk management, including drug interactions, side effects and potential addiction from medical marijuana use.

(iii) Palliative care.

(iv) The misuse of opioids and medical marijuana.

(v) Recommendations for use of medical marijuana and obtaining informed consent from a patient.

(vi) Any other area determined by the Department.

(5) Use of the Prescription Drug Monitoring Program.

(6) Best practices for recommending the form and dosage of medical marijuana products based on the patient's serious medical condition and the practitioner's or medical professional's medical specialty and training.

(c) Successful completion of the course required under subsection (a) shall be approved as continuing education credits as determined by:

(1) The State Board of Medicine and the State Board of Osteopathic Medicine.

(2) The State Board of Pharmacy.

(3) The State Board of Nursing.

(d) The individuals listed in subsection (a) shall [submit] ensure that the training provider submits documentation of the completion of the 4-hour training course to the Department within the time specified in subsection (a).

(e) The Department will maintain on its publicly-accessible web site a list of approved training providers that offer the 4-hour training course.

(f) An application for approval to become an approved training provider is available on the Department's public website. Any application meeting the requirements of subsections (b) and (c) will be approved.



## **§ 1181a.33. Appeals.**

Chapter 5, Subchapter A of 2 Pa.C.S. (relating to practice and procedure of Commonwealth agencies) and the accompanying regulations, as modified by Chapter 1230a (relating to practice and procedure), apply to all actions of the Department under this chapter constituting an adjudication as defined in 2 Pa.C.S. § 101 (relating to definitions).

## **CHAPTER 1191a. PATIENTS AND CAREGIVERS**

Sec.

- 1191a.22. Patient and caregiver registry.
- 1191a.23. Patients and caregivers generally.
- 1191a.24. Medical marijuana cardholder responsibilities.
- 1191a.25. Application for, and issuance or denial, of identification cards.
- 1191a.26. Application fees.
- 1191a.27. Criminal background checks.
- 1191a.28. Identification cards.
- 1191a.29. Renewing an identification card.
- 1191a.30. Revocation or suspension of identification card.
- 1191a.31. Obtaining medical marijuana products from a dispensary.
- 1191a.32. Medical marijuana patient authorization letters.
- 1191a.33. Appeals.

### **§ 1191a.22. Patient and caregiver registry.**

- (a) The Department will maintain a patient and caregiver registry.
- (b) Patient and caregiver information maintained by the Department is confidential and not subject to public disclosure, including disclosure under the Right-to-Know Law (65 P.S. §§ 67.101—67.3104). Patient and caregiver information must include the following:
  - (1) Information provided in an identification card application.
  - (2) Information in a patient certification issued by a practitioner.
  - (3) Criminal history record check information provided as part of an identification card application submitted by a caregiver under § 1191a.27 (relating to criminal background checks).
  - (4) Information encoded in the 2D barcode of an identification card.
  - (5) Information relating to a patient's serious medical condition.
- (c) A caregiver who is listed in the patient and caregiver registry may waive in writing the caregiver's right to confidentiality and consent to the caregiver's name and contact information being provided to a patient who has obtained a patient certification from a practitioner.

### **§ 1191a.23. Patients and caregivers generally.**

- (a) The qualifications that a patient or caregiver shall meet to be included in the patient and caregiver registry and to obtain an identification card or a medical marijuana patient authorization letter are continuing qualifications.
- (b) Except with respect to a minor patient as provided in § 1191a.32 (relating to medical

marijuana patient authorization letters), the Department may issue an identification card to an applicant who meets the qualifications in the act and this part.[

(c) The Department may issue an identification card to an individual who is under 21 years of age to serve as a caregiver when a sufficient showing is made to the Department that the individual should be permitted to serve as a caregiver, as determined by the Department].

(d) A minor patient shall have a caregiver who is one of the following:

(1) A parent or legal guardian.

(2) An individual designated by a parent or legal guardian.[

(3) An appropriate individual approved by the Department upon a sufficient showing that a parent or legal guardian is not appropriate or available.]

#### **§ 1191a.24. Medical marijuana cardholder responsibilities.**

(a) A medical marijuana cardholder shall immediately contact the Department upon the occurrence of any of the following:

(1) A change of the medical marijuana cardholder's name or address.

(2) The withdrawal of a patient certification by a practitioner under § 1181a.29 (relating to revocation of a patient certification).

(3) A decision by a patient or the patient's legal guardian to discontinue the services of a caregiver.

(4) A decision by a caregiver to no longer serve as a caregiver for a patient.

(5) A decision by a patient, the patient's legal guardian or a parent on behalf of a patient to discontinue obtaining medical treatment from the practitioner who issued the patient certification.

(b) A medical marijuana cardholder shall apply to the Department for a replacement identification card within 10 business days of discovering the loss or defacement of the identification card.

#### **§ 1191a.25. Application for, and issuance or denial of, identification cards.**

(a) An applicant shall submit an identification card application [on a form prescribed by the Department]. The application will be made available on the Department's publicly-accessible web site and in hard copy upon request.

(b) An identification card application submitted by or on behalf of a patient must include[, at a minimum,] the following information:

(1) The name, address, telephone number, e-mail address, if available, and date of birth of the patient.

(2) The patient's Pennsylvania driver's license number, a Department of Transportation State-issued identification card, if applicable, or other documentation acceptable to the Department evidencing the patient's identification and residency in this Commonwealth.

(3) The name, address and telephone number of the practitioner who issued the patient

certification.

(4) The name, birth date, address, telephone number and e-mail address, if applicable, of up to two individuals designated by the applicant to serve as caregivers, if applicable.

(5) The patient certification issued by the patient's practitioner, which shall be provided by the practitioner to the Department under § 1181a.27(d)(2) (relating to issuing patient certifications).

(6) The appropriate fee or proof of financial hardship as provided for in § 1191a.26 (relating to application fees).

(7) The signature of the applicant and the date signed.

(8) A statement that a false statement made in the application is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation). [

(9) Any other information deemed necessary by the Department.]

(c) For an application submitted under this section that designates an individual as a caregiver who is not authorized under the act or this part to serve as a caregiver, the following apply:

(1) The Department may deny that portion of the application and approve the balance of the application. In that case, an identification card may be issued to the patient but the designated caregiver will not be authorized to serve in that capacity.

(2) If the application is submitted on behalf of a minor patient but does not include the designation of another individual as a caregiver who is authorized under the act or this part to serve as a caregiver, the Department will deny the entire application unless and until the applicant designates an individual who is authorized to serve.

(3) An individual designated as a caregiver may not serve as a caregiver unless and until the individual submits an application under subsection (d) and the individual is issued an identification card by the Department.

(d) An identification card application submitted by a caregiver must include[, at a minimum,] the following information:

(1) The name, address, telephone number, e-mail address, if available, and date of birth of the caregiver.

(2) The caregiver's Pennsylvania driver's license number[, or a Department of Transportation State-issued identification card, if applicable, [or other documentation acceptable to the Department] evidencing the caregiver's identification.

(3) The name, address and telephone number of the practitioner who issued the patient certification.

(4) The patient certification issued by the patient's practitioner, which will be provided by the practitioner to the Department under § 1181a.27(d)(2).

(5) A copy of the criminal history record information required under § 1191a.27 (relating to criminal background checks), except when not required pursuant to § 1191a.29(c).

(6) The name, address, telephone number and e-mail address, if available, of [up to five patients] any patient for which the caregiver wishes to be approved by the Department as a caregiver.

(7) The appropriate fee or proof of financial hardship as provided for in § 1191a.26 (relating to application fees).

(8) The signature of the applicant and the date signed.

(9) A statement that a false statement made in the application is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49. [

(10) Any other information deemed necessary by the Department.]

(e) The Department will review the criminal history record information obtained by a caregiver under § 1191a.27 and the Prescription Drug Monitoring Program database before approving the issuance of an identification card to the caregiver. The Department will deny the issuance of an identification card to a caregiver if the caregiver has been convicted of a criminal offense relating to the sale or possession of drugs, narcotics or controlled substances that occurred within the 5 years immediately preceding the submission of the application. The Department may deny the issuance of an identification card to a caregiver if the caregiver has a history of drug abuse or of diverting controlled substances or illegal drugs.

(f) The Department will [promptly] notify [an] a caregiver applicant in writing if an identification card application is incomplete or factually inaccurate and provide the applicant with an explanation as to what documents or information are necessary for the Department to consider the identification card application to be complete and accurate.

(g) [An] A caregiver applicant shall have 60 days from [receipt] mailing of a notification under subsection (f) to submit to the Department the documents or information requested. If [an] a caregiver applicant fails to submit the requested documents or information within 60 days, the Department may deny the identification card application.

(h) The Department will notify [an] a caregiver applicant in writing of the reasons for the denial of an identification card application.

(i) [An] A caregiver applicant whose identification card application is denied may submit a new identification card application. The Department may decline to consider a new application that does not correct the deficiencies in the initial application leading to a prior denial.

### **§ 1191a.26. Application fees.**

(a) An applicant shall pay no more than one fee of \$50 in a 12-month period for an identification card with an identification card application.

(b) Notwithstanding subsection (a):

(1) An applicant shall submit a fee of \$25 if the Department issues a replacement identification card as a result of a lost, stolen, destroyed, defaced or illegible identification card.

(2) An applicant shall pay a second fee of \$50 in the same 12-month period with an identification card renewal application.

(c) The Department may establish higher fees for issuance of a second and subsequent replacement identification cards by publishing notice of those fees in the *Pennsylvania Bulletin*.

(d) [Subject to § 1191a.32 (relating to medical marijuana patient authorization letters), the] The

Department may waive or reduce the fee for an identification card application or identification card renewal application for an applicant who demonstrates financial hardship. The Department will post on its publicly-accessible web site the qualifications for financial hardship that an applicant requesting a waiver or reduction of the application fee shall submit with an identification card application or identification card renewal application. The Department will publish notice of the qualifications for financial hardship in the *Pennsylvania Bulletin*.

#### **§ 1191a.27. Criminal background checks.**

(a) An individual applying for an identification card to serve as a caregiver, who has not previously been approved by the Department to serve as a caregiver, shall submit fingerprints to the Pennsylvania State Police, or an authorized agent, for the purpose of obtaining a criminal history record check. The Pennsylvania State Police, or an authorized agent, will submit the fingerprints to the Federal Bureau of Investigation for the purpose of verifying the identity of the caregiver and obtaining a current record of any criminal arrests and convictions.

(b) The Department may only review the criminal history record information received under subsection (a) to determine the caregiver's character, fitness and suitability to serve as a caregiver under the act and this part.

#### **§ 1191a.28. Identification cards.**

(a) The Department will issue an identification card to a patient or caregiver as soon as reasonably practicable after approving an identification card application.

(b) An identification card will contain all of the following information:

(1) The full name of the medical marijuana cardholder.

(2) The address of the medical marijuana cardholder.

(3) A designation of the medical marijuana cardholder as a patient or a caregiver.

(4) The date of issuance and the date of expiration of the identification card.

(5) A unique identification number for the medical marijuana cardholder.

(6) A photograph of the medical marijuana cardholder unless the patient or caregiver provides the Department with a statement in accordance with subsection (c).

(7) Any requirement or limitation on the patient certification concerning the recommended form of medical marijuana products or limitation on the duration of use, if applicable.[]

(8) Any other information deemed necessary by the Department.[]

(c) Notwithstanding subsection (b)(6), the Department may not require a photograph on an identification card if a statement is provided to the Department in an identification card application that a photograph cannot be provided due to religious beliefs.

(d) An identification card issued to a patient will expire on the earlier to occur of the following:

(1) The date occurring 1 year from the date of issuance.

(2) The date, if any, contained in the patient certification issued to the patient beyond which the

practitioner does not believe the use of medical marijuana by the patient would be therapeutic or palliative.

(3) The date the patient dies.

(e) An identification card issued to a caregiver will expire on the earlier to occur of the following:

(1) The date that occurs 1 year from the date of issuance.

(2) Any of the events listed under subsection (d)(2) or (3).

(3) The date the caregiver dies.

### **§ 1191a.29. Renewing an identification card.**

(a) A medical marijuana cardholder shall submit an identification card renewal application to the Department no later than 30 days prior to the expiration date on the card. The form of the renewal application will be prescribed by the Department and will be made available on the Department's publicly-accessible web site and in hard copy upon request. If a medical marijuana cardholder's patient certification is expired, the cardholder shall obtain a new or updated patient certification issued by the patient's practitioner, which will be provided by the practitioner to the Department under § 1181a.27(d)(2) (relating to issuing patient certifications).

(b) If the Department denies an identification card renewal application or if the Department does not receive a complete identification card renewal application by the expiration date on the identification card, the identification card will no longer be valid beyond the expiration date and the Department may remove a medical marijuana cardholder from the patient and caregiver registry.

(c) Section 1191a.27 shall not apply to an applicant who has been previously approved by the Department to serve as a caregiver.

### **§ 1191a.30. Revocation or suspension of identification card.**

(a) The Department may revoke or suspend a medical marijuana cardholder's identification card upon the occurrence of any of the following:

(1) The Department receives written notice from a practitioner under § 1181a.29(a) (relating to revocation of a patient certification).

(2) A caregiver notifies the Department in writing that the caregiver is no longer acting as a caregiver.

(3) The patient or caregiver has intentionally, knowingly or recklessly violated the act or regulations [as determined by the Department]. The suspension or revocation will be in addition to any criminal or other penalty that may apply.

(4) Except for good cause shown, a medical marijuana cardholder does not visit a dispensary within 60 days from the issuance date on an identification card.

(5) A patient notifies the Department in writing that the patient has elected to withdraw from participation in the medical marijuana program or that the patient has removed or changed a current caregiver. If the caregiver is not serving as a caregiver for any other patient, the Department will issue a notification to the caregiver that the caregiver's identification card is invalid [and shall be promptly returned to the Department].

(b) The Department will [promptly] notify a medical marijuana cardholder in writing of any action taken by the Department regarding the medical marijuana cardholder as a result of information received under subsection (a).

(c) If a patient's practitioner's registration has been revoked or suspended under § 1181a.26 (relating to denial, revocation or suspension of a practitioner registration) or if a patient's practitioner withdraws the patient's patient certification under § 1181a.29(c), a medical marijuana cardholder shall obtain a new patient certification within 90 days of receiving written notice from the Department or prior to the expiration date on the identification card, whichever is sooner.

### **§ 1191a.31. Obtaining medical marijuana products from a dispensary.**

(a) A medical marijuana cardholder may only obtain medical marijuana products from a dispensary in accordance with § 1161a.24 (relating to limitations on dispensing).

(b) A medical marijuana cardholder may only obtain medical marijuana products from a dispensary based upon the recommendation in a patient certification that has not been revoked under § 1181a.29 (relating to revocation of a patient certification) and that may be accessed by a dispensary through the electronic tracking system.

### **§ 1191a.32. Medical marijuana patient authorization letters.**

(a) The Department will issue a medical marijuana patient authorization letter to a minor patient instead of issuing an identification card to the minor patient. Upon reaching 18 years of age, a minor patient who has been issued a medical marijuana patient authorization letter will be entitled to receive an identification card upon application under § 1191a.25 (relating to application for, and issuance or denial of, identification cards).

(b) The Department may issue a medical marijuana patient authorization letter to an adult patient only when the patient's illness or infirmity permanently prevents the patient from visiting a dispensary.

(c) A patient who has been issued a medical marijuana patient authorization letter by the Department under this section shall have all of the rights and obligations of a medical marijuana cardholder under this chapter, except that an identification card shall be required for entry into a dispensary.

(d) A medical marijuana patient authorization letter is subject to the same terms and conditions, including expiration, revocation and suspension requirements, as an identification card under this chapter.

(e) A patient who has been issued a medical marijuana patient authorization letter by the Department under this section will not be required to pay an identification card application fee or an identification card renewal application fee.

### **§ 1191a.33. Appeals.**

Chapter 5, Subchapter A of 2 Pa.C.S. (relating to practice and procedure of Commonwealth agencies) and the accompanying regulations, as modified by Chapter 1230a (relating to practice and procedure), apply to all actions of the Department under this chapter constituting an adjudication as defined in 2 Pa.C.S. § 101 (relating to definitions).

## **CHAPTER 1211a. CLINICAL REGISTRANTS AND ACADEMIC RESEARCH**

## CENTERS

Sec.

- 1211a.22. Clinical registrants generally.
- 1211a.23. Limitations on permits.
- 1211a.24. Capital requirements.
- 1211a.25. Certifying ACRCs.
- 1211a.26. Revocation of a certification of an ACRC.
- 1211a.27. Application for approval of a clinical registrant.
- 1211a.27a. Research contracts.
- 1211a.28. Request for conversion of an existing permit.
- 1211a.29. Practices and procedures of research programs, projects or studies.
- 1211a.29a. Research initiative.
- 1211a.30. Approval or denial of an application for approval of a clinical registrant.
- 1211a.31. Renewal of approval of a clinical registrant.
- 1211a.32. Revocation of approval of a clinical registrant.
- 1211a.33. Dispensing and tracking medical marijuana products.
- 1211a.34. Prohibition.
- 1211a.35. Reporting requirements.
- 1211a.36. Sale or exchange.
- 1211a.37. Appeals.

### **§ 1211a.22. Clinical registrants generally.**

(a) The qualifications that a clinical registrant shall meet to be approved by the Department are continuing qualifications.

(b) An applicant that has already been issued a grower/processor permit or a dispensary permit by the Department under sections 601—616 of the act (35 P.S. §§ 10231.601—10231.616) who wishes to become an approved clinical registrant shall:

(1) Submit a request to the Department under § 1211a.28 (relating to request for conversion of an existing permit) with the application for approval of a clinical registrant.

(2) Not be required to apply for, or be eligible to receive, an additional grower/processor permit or dispensary permit under the act, this chapter, Chapter 1141a, Chapter 1151a or Chapter 1161a (relating to general provisions; growers/processors; and dispensaries), as applicable.

(c) The Department will not approve more than [eight] ten clinical registrants.

(d) An approved clinical registrant may not dispense or offer to dispense, as a clinical registrant, any medical marijuana products at the clinical registrant dispensary location until:

(1) The [Department has determined that an approved clinical registrant is ready, willing and able to operate as a] clinical registrant's grower/processor and [a] dispensary facilities have been inspected and deemed operational by the Department.

(2) The approved clinical registrant demonstrates to the satisfaction of the Department that it will be able to begin an approved research program or research study within 6 months following the date the Department determines the approved clinical registrant's dispensary to be operational.

(e) An approved clinical registrant may dispense medical marijuana products to a patient or caregiver who presents a valid identification card to an employee who is authorized to dispense



medical marijuana products at a dispensary location operated by an approved clinical registrant under this chapter regardless of whether the patient is a participant in a research study.

### **§ 1211a.23. Limitation on permits.**

(a) An approved clinical registrant may not hold more than one grower/processor permit and one dispensary permit.

(b) A dispensary permit held by an approved clinical registrant for use under this chapter may be used to dispense medical marijuana products at no more than six separate locations as approved [by the Department] in its application or under § 1161a.40, each of which shall be dispensing medical marijuana for the purpose of conducting research.

(c) An approved clinical registrant may not locate more than three of its approved dispensaries in the same medical marijuana region or in the same county.

### **§ 1211a.24. Capital requirements.**

An applicant shall provide all of the following information with its application under § 1211a.27 (relating to application for approval of a clinical registrant):

(1) An affidavit, on a form prescribed by the Department, stating that the applicant has at least \$15 million in capital, which must include evidence that the applicant meets the capital requirements of a medical marijuana organization under § 1141a.30 (relating to capital requirements).

(2) A release sufficient to obtain information from a state governmental agency, financial institutions, an employer or any other person to verify the requirements of paragraph (1). Failure to provide a release will result in the rejection of the application for approval of a clinical registrant.

### **§ 1211a.25. Certifying ACRCs.**

(a) The qualifications that an ACRC shall meet to be approved by the Department are continuing qualifications.

(b) An accredited medical school may file an application with the Department to be certified as an ACRC using a form prescribed by the Department. The Department will publish a notice in the *Pennsylvania Bulletin* announcing the availability of the application and the time period during which the Department will accept applications.

(c) An application submitted under subsection (b) must include all of the following information:

(1) The legal name, address and telephone number of the accredited medical school and the name, telephone number and professional e-mail address of an individual at the accredited medical school who will be the primary contact for the Department during the Department's review of the application.

(2) The legal name, address and telephone number of the acute care hospital that is operated by or partnered with the accredited medical school and the name, telephone number and professional e-mail address of an individual at the accredited medical school who will be the primary contact for the Department during the Department's review of the application.

(3) An affidavit, on a form prescribed by the Department, disclosing any payments to the accredited medical school or any of its affiliates made by a person with whom the accredited medical school intends to enter into a research contract for purposes of operating as an approved clinical

registrant or by any principal or financial backer of the person, up to and including the date of the submission of the application. The affidavit must include the amount and purpose of each payment made.

(4) A statement that the accredited medical school is currently accredited by the Liaison Committee of Medical Education or the Commission on Osteopathic College Accreditation.

(5) A statement that the acute care hospital designated by the accredited medical school under paragraph (2) holds a valid license from the Department.

(6) The State and Federal tax identification numbers of the accredited medical school.

(7) A statement that a false statement made by the accredited medical school submitting the application is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).]

(8) Any other information deemed necessary by the Department.]

(d) The Department will publish a list containing the name and address of each ACRC on its publicly-accessible web site and in the *Pennsylvania Bulletin*.

#### **§ 1211a.26. Revocation of a certification of an ACRC.**

(a) The certification of an ACRC will be revoked by the Department upon the occurrence of any of the following:

(1) The ACRC is no longer accredited by the Liaison Committee of Medical Education or the Commission on Osteopathic College Accreditation, as applicable.

(2) The ACRC no longer operates or is partnered with the acute care hospital listed in its application for certification.

(3) The ACRC is no longer located in this Commonwealth.

(b) If the Department intends to revoke the certification of an ACRC under this section, the Department will provide written notice of its intention to the ACRC. Upon receipt of a notice under this subsection, the ACRC shall have 90 days from the date of the notice to provide the Department with evidence satisfactory to the Department that it has received reaccreditation by the Liaison Committee of Medical Education or the Commission on Osteopathic College Accreditation, as applicable, that it operates or is partnered with another acute care hospital or that it has relocated within this Commonwealth. If the ACRC does not comply with this subsection within 90 days from the date of the notice, the Department may revoke the certification of the ACRC.

#### **§ 1211a.27. Application for approval of a clinical registrant.**

(a) An applicant shall file an application for approval of a clinical registrant with the Department on a form prescribed by the Department. The Department will publish a notice in the *Pennsylvania Bulletin* announcing the availability of applications and the time period during which the Department will accept applications.

(b) An application for approval of a clinical registrant submitted under this section must include all of the following information:

(1) The legal name, address and telephone number of the applicant and the name, telephone

number and professional e-mail address of an individual who will be the primary contact for the Department during the Department's review of the application.

(2) The name of the ACRC under § 1211a.25 (relating to certifying ACRCs).

(3) The applicant's State and Federal tax identification numbers.

(4) An affidavit, on a form prescribed by the Department, disclosing any payments made by the applicant, a principal or financial backer of the applicant to an ACRC or any affiliates of an ACRC, up to and including the date of the submission of the application. The affidavit must include the amount and purpose of each payment made.

(5) The name of an institution of higher education, if any, that will be participating in an approved research program or research study.

(6) An affidavit and release under § 1211a.24 (relating to capital requirements).

(7) Evidence that the applicant is responsible and capable of successfully operating as an approved clinical registrant, including all of the following:

(i) A copy of the research contract between the applicant and the ACRC.

(ii) A description of the research program or research study the applicant and the ACRC intend to conduct.

(iii) A statement that the applicant may not engage in the business of selling, dispensing or offering to dispense medical marijuana products at an applicant's dispensary as a clinical registrant until the [clinical registrant dispensary is ready, willing and able to dispense medical marijuana products] clinical registrant's grower/processor and dispensary facilities have been inspected and deemed operational by the Department.

(8) Except as provided in § 1211a.28 (relating to request for conversion of an existing permit), an application for a grower/processor permit under Chapters 1141a and 1151a (relating to general provisions; and growers/processors).

(9) Except as provided in § 1211a.28, an application for a dispensary permit under Chapter 1141a and Chapter 1161a (relating to dispensaries).

(10) A statement that a false statement made by the applicant is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).[

(11) Any other information deemed necessary by the Department.]

(c) An applicant may only include one ACRC in its application for approval of a clinical registrant.

(d) The following documents provided to the Department under this chapter are confidential and not subject to disclosure under the Right-to-Know Law (65 P.S. §§ 67.101—67.3104):

(1) A research contract.

(2) A description of a research program or research study.

(3) An ACRC's intellectual property.

(4) An approved clinical registrant's intellectual property.

**§ 1211a.27a. Research contracts.**

(a) An applicant for approval as a clinical registrant shall provide, with its application, either an executed agreement or a letter of intent to enter into an agreement, with an ACRC, the effective date of which shall be on or after the effective date of the ACRC certification.

(b) A clinical registrant applicant may submit more than one application, with separate applications identifying distinct ACRCs.

(c) An ACRC may enter into a letter of intent with more than one clinical registrant applicant but may only execute a research contract with one approved clinical registrant.

(d) If more than one applicant for approval as a clinical registrant submits an application that includes a letter of intent with the same ACRC, the Department shall follow the following process in approving the applications:

(1) Determine initially that the CR application meets the following qualifications:

(i) Is complete;

(ii) Complies with the act and this part, and

(iii) Meets the following minimum scoring requirements in each of the following application sections:

<b>Grower Processor Application</b>	<b>Max Points/Section</b>	<b>Minimum Acceptable Score</b>
8—Operational Timetable	75	31
9—Employee Qualifications, Description of Duties and Training	25	11
10—Security and Surveillance	50	21
11—Transportation of Medical Marijuana	25	11
12—Storage of Medical Marijuana	25	11
13—Packaging and Labeling of Medical Marijuana	25	11
14—Inventory Management	25	11
15—Management and Disposal of Medical Marijuana Waste	25	11
16—Diversion Prevention	50	21
17—Growing Practice	100	41
18—Nutrient and Additive Practices	100	41
19—Processing and Extraction	100	41
20—Sanitation and Safety	25	11
22—Recordkeeping	25	11
24—Business History and Capacity to Operate	75	31
Attachment D: Site and Facility Plan	50	21
<b>Dispensary Application</b>	<b>Max Points/Section</b>	<b>Minimum Acceptable Score</b>
8—Operational Timetable	100	41
9—Employee Qualifications, Description of Duties and Training	50	21
10—Security and Surveillance	100	41
11—Transportation of Medical Marijuana	50	21
12—Storage of Medical Marijuana	75	31
14—Inventory Management	75	31
15—Diversion Prevention	100	41
16—Sanitation and Safety	50	21
17—Recordkeeping	75	31
19—Business History and Capacity to Operate	75	31
Attachment D: Site and Facility Plan	50	21

(2) The Department shall approve clinical registrant applicants that meet the standards of paragraph (1) in the following order:

(i) A clinical registrant applicant that holds a grower/processor permit and a dispensary permit, both of which are in good standing, and both medical marijuana organizations have been deemed operational by the Department. In applying this preference, the Department will look at the clinical registrant's primary dispensary location only.

(ii) A clinical registrant applicant that holds a grower/processor permit only that is in good standing and the applicant's medical marijuana organization has been deemed operational by the Department.

(iii) A clinical registrant applicant that holds a dispensary permit only that is in good standing and the applicant's primary dispensary location has been deemed operational by the Department.

(iv) A clinical registrant applicant that holds a grower/processor permit only that is in good standing, but has not been deemed operational by the Department.

(v) A clinical registrant applicant that holds a dispensary permit only that is in good standing, but has not had its primary location deemed operational by the Department.

(vi) A clinical registrant applicant that is applying for both a grower/processor permit and dispensary permit under this chapter. Awarding of approval to these clinical registrant applications shall be prioritized by ranking the sum of the grower/processor permit and dispensary permit application scores highest to lowest.

#### **§ 1211a.28. Request for conversion of an existing permit.**

(a) An applicant holding a grower/processor permit or a dispensary permit, or both, under sections 601—616 of the act (35 P.S. §§ 10231.601—10231.616), shall submit a request for conversion of an existing permit under this section on a form prescribed by the Department when submitting an application for approval of a clinical registrant under § 1211a.27 (relating to application for approval of a clinical registrant).

(b) Upon approval of a clinical registrant under subsection (a), the clinical registrant shall surrender its grower/processor permit or dispensary permit, or both, previously issued under sections 601—616 of the act.

(c) A grower/processor permit or dispensary permit, or both, surrendered under subsection (b) will increase the number of grower/processor permits or dispensary permits, as applicable, available to other persons applying for permits under sections 601—616 of the act, Chapter 1141a (relating to general provisions) and Chapter 1151a or Chapter 1161a (relating to growers/processors; and dispensaries), as applicable.

(d) An applicant may include additional dispensary locations in its request for conversion of an existing permit or may request additional dispensary locations at a later date under § 1161a.40 (relating to application for additional dispensary locations).

## **§ 1211a.29. Practices and procedures of research programs, projects or studies.**

(a) Medical marijuana dispensed as part of a research program shall be dispensed only in a form permitted by the act or this part and only from a dispensary to a patient or to a caregiver.

(b) Marijuana dispensed under a research project or study may be dispensed, in any form deemed medically safe by an IRB, from a clinical registrant dispensary directly to an ACRC.

(c) A RAC or IRB shall adopt research procedures and shall review and approve each research program in accordance with the RAC or IRB established practices and procedures.

(d) An IRB shall review each proposed research project or study in accordance with the IRB's practices, procedures and protocols.

(e) A RAC or IRB shall[, at a minimum,] ensure that each research program, project or study addresses all of the following:

(1) Protecting the rights and welfare of patients involved in research programs conducted under this chapter.

(2) Minimizing the risk to patients by using procedures that are consistent with sound research design and that do not unnecessarily expose patients to risk being performed on subjects for diagnosis or treatment purposes.

(3) Determining that the risks to patients involved in research programs are reasonable in relation to the anticipated benefits (if any) to the patients, and the importance of the knowledge that may be expected to result from the research program.

(4) Guaranteeing that informed consent will be sought from each prospective patient or the patient's legally authorized representative and is properly documented.

(5) Protecting the privacy of every patient.

### **§ 1211a.29a. Research initiative.**

(a) An academic clinical research center, in coordination with its contracted clinical registrant, may conduct a research initiative on the antimicrobial effects of applying solvent-based extraction methods and processes to microbial contamination of immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products.

(b) An academic clinical research center shall submit to the Department for approval a completed written research protocol of the planned research initiative. The Department shall grant approval or denial of the protocol within 15 days of its submission. The following apply:

(1) The research initiative shall commence no later than 30 days from the date the Department issues approval and shall be completed no later than six months from the start date of the research initiative.

(2) Research initiative findings shall be provided to the Department by the academic clinical research center within 15 days of the research initiative's conclusion.

(3) An academic clinical research center and its contracted clinical registrant shall present research initiative findings to the medical marijuana advisory board and the board's research subcommittee for the board's review and consideration under sections 1201 and 1202 of the act. The board shall issue a

written report, with recommendations and findings regarding the use of solvent-based extraction methods and processes on microbial contamination by a clinical registrant or grower/processor. The secretary may approve the board's recommendation in accordance with section 1202.

(4) Prior to implementing a recommendation of the board under paragraph (3), as approved by the secretary, a clinical registrant or grower/processor shall seek approval from the Department for a change in its grower/processor extraction process. The Department shall inspect the site and facility equipment. Upon approval, the Department shall issue a notice of final approval to implement the process.

### **§ 1211a.30. Approval or denial of an application for approval of a clinical registrant.**

(a) An applicant shall be an approved clinical registrant upon the Department's approval of an application under § 1211a.27 (relating to application for approval of a clinical registrant).

(b) The Department may deny the application for approval of a clinical registrant if the payments disclosed in the affidavit submitted under § 1211a.27(b)(4) violate the prohibition in § 1211a.34 (relating to prohibition).

(c) Before the Department denies an application for approval of a clinical registrant under subsection (b), the Department will provide the applicant with written notice specifying the violation. The applicant may submit to the Department, within 10 days following receipt of the Department's written notice, a supplemental affidavit indicating that the ACRC or its affiliate has refunded to the applicant or a principal or financial backer of the applicant that portion of payments in violation of § 1211a.34. Upon receipt of the supplemental affidavit, the Department may approve the application for approval of a clinical registrant. If the applicant fails to provide a supplemental affidavit within 10 days of the Department's written notice, the Department will deny the application for approval of a clinical registrant.

(c.1) The Department shall not approve an applicant for a grower/processor permit if the applicant has previously had a contractual relationship with an academic clinical research center whereby the academic clinical research center or its affiliate provided advice to the applicant regarding, among other areas, patient health and safety, medical applications and dispensing and management of controlled substances and the applicant subsequently sold or assigned for profit to another entity their responsibility under the contractual relationship.

(d) An approved clinical registrant shall have the same rights and obligations as a medical marijuana organization that holds a grower/processor permit or a dispensary permit under sections 601—616 of the act (35 P.S. §§ 10231.601—10231.616) and Chapters 1141a, 1151a and 1161a (relating to general provisions; growers/processors; and dispensaries), as applicable, subject to any modifications or limitations in sections 2001—2003 of the act (35 P.S. §§ 10231.2001—10231.2003) and this chapter.

(e) A grower/processor permit and a dispensary permit issued to an approved clinical registrant will expire upon the nonrenewal, revocation or suspension by the Department of the approved clinical registrant's approval.

### **§ 1211a.31. Renewal of approval of a clinical registrant.**

(a) The term of an approval of a clinical registrant will coincide with the term of the clinical registrant's grower/processor permit and dispensary permit.

(b) An approved clinical registrant shall renew its approval as part of the renewal for a



grower/processor permit and a dispensary permit under § 1141a.36 (relating to permit renewal applications). The renewal application must be on a form prescribed by the Department and include all of the following:

- (1) A copy of the research contract.
- (2) A list of the approved research programs or research studies that are continuing or, if any of them are concluded, the dates they were concluded.
- (3) A report of the current status of active research programs or research studies being conducted under the research contract, including preliminary findings, if applicable, and any expectations and projections the approved clinical registrant and the ACRC have for future research programs or research studies over the course of the 2 years following the date of submission of the report.
- (4) A description of proposed research programs or research studies covered by the research contract that the approved clinical registrant intends to conduct within the next year following submission of the renewal application including evidence of IRB approval for each research program or research study.
- (5) A statement that a false statement made by the approved clinical registrant or the ACRC is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).]
- (6) Any other information deemed necessary by the Department.]

(c) The Department will not renew an approval for a clinical registrant under this section if the Department determines that none of the dispensary locations under the dispensary permit held by the approved clinical registrant are participating in an approved research program or research study and the approved clinical registrant does not intend to begin any additional approved research programs or research studies within the first six months following the approval of its application for renewal.

### **§ 1211a.32. Revocation of approval of a clinical registrant.**

(a) The approval of a clinical registrant will be revoked immediately by the Department upon the occurrence of any of the following:

- (1) The Department revokes, suspends or does not renew the grower/processor permit or dispensary permit held by the approved clinical registrant.
- (2) Subject to subsection (b), the Department revokes the certification of the ACRC listed in the clinical registrant's application under § 1211a.27 (relating to application for approval of a clinical registrant).
- (3) The research contract between the approved clinical registrant and the ACRC expires without being renewed or is terminated by either party.

(b) If the Department intends to revoke the certification of the ACRC under subsection (a)(2), the Department will provide written notice of its intention to the approved clinical registrant. Upon receipt of a notice under this subsection, the approved clinical registrant shall have 90 days from the date of the notice to contract with another ACRC that is not already a party to a research contract with another approved clinical registrant and to provide the Department with all relevant information relating to the ACRC. If the approved clinical registrant does not comply with this subsection within 90 days from the date of the notice, the Department may revoke the clinical registrant's approval.

### **§ 1211a.33. Dispensing and tracking medical marijuana products.**

In addition to the information to be entered in the electronic tracking system under § 1161a.39 (relating to electronic tracking system) with respect to medical marijuana products dispensed to all patients and caregivers, the dispensary of an approved clinical registrant shall enter information into the electronic tracking system as required by the Department that identifies patients that are enrolled in an approved research program or research study.

### **§ 1211a.34. Prohibition.**

Except for reasonable remuneration specifically in a research contract for the services to be performed or costs to be incurred by an ACRC, an ACRC may not solicit or accept anything of value from an approved clinical registrant or a principal or financial backer of an approved clinical registrant. Reasonable remuneration may include up-front deposits or other payments to an ACRC under a research contract to defray start-up and ongoing costs of the ACRC in connection with the establishment of the contractual relationship in the research contract. This section does not apply to charitable contributions that are part of a history of giving to an ACRC established 1 year or more prior to the effective date of the act.

### **§ 1211a.35. Reporting requirements.**

(a) Except as provided in subsection (b), an approved clinical registrant shall provide a written report of the findings of its research program or research study to the Department within 365 days of the completion of an approved research program or research study.

(b) In the event the approved clinical registrant or its ACRC intends to submit a manuscript of the results of an approved research program or research study to a peer-reviewed medical journal for publication, the written report required under subsection (a) shall be provided to the Department within 30 days following publication.

(c) The Department may post the findings received under this section on its publicly-accessible web site and share them with other approved clinical registrants, ACRCs or any other person it determines would benefit from the findings.

### **§ 1211a.36. Sale or exchange.**

(a) The grower/processor of an approved clinical registrant may sell or exchange the following items to another grower/processor:

- (1) Seeds.
- (2) Immature medical marijuana plants.
- (3) Medical marijuana plants.
- (4) Medical marijuana products.

(b) The grower/processor of an approved clinical registrant may [only] sell its medical marijuana products to [either its own approved dispensaries or any other approved dispensaries of an approved clinical registrant] any dispensary. [

(c) Notwithstanding subsection (b), an approved clinical registrant may petition the Department, on a form prescribed by the Department, to sell its medical marijuana products to a dispensary holding a permit under sections 601—616 of the act (35 P.S. §§ 10231.601—10231.616).

(d) A petition filed under subsection (c) must include either the report or manuscript required under § 1211a.35 (relating to reporting requirements). If a clinical registrant fails to provide the report or manuscript required under § 1211a.35, the petition will be denied.]

### **§ 1211a.37. Appeals.**

Chapter 5 of 2 Pa.C.S. (relating to practice and procedure) and its accompanying regulations, as modified by Chapter 1230a (relating to practice and procedure), apply to actions of the Department under this chapter constituting an adjudication as defined in 2 Pa.C.S. § 101 (relating to definitions).

## **CHAPTER 1230a. PRACTICE AND PROCEDURE**

### **Subchapter A. Preliminary Provisions**

### **Subchapter B. Formal Proceedings**

## **SUBCHAPTER A. PRELIMINARY PROVISIONS**

Sec.

### **GENERAL**

1230a.21. Scope.

1230a.22. Definitions.

1230a.23. Docket.

1230a.24. Filing generally.

### **TIME**

1230a.25. Effective date of adjudication, actions or order.

1230a.26. Representation.

### **GENERAL**

### **§ 1230a.21. Scope.**

(a) This chapter governs practice and procedure before the Department in medical marijuana appeals and in any action taken by the Office under the act.

(b) This chapter is not applicable to a proceeding to the extent that the applicable statute governing or authorizing the proceeding sets forth inconsistent practice or procedure.

(c) Except when inconsistent with this chapter, 1 Pa. Code Part II (relating to General Rules of Administrative Practice and Procedure) is applicable insofar as it relates to adjudicatory proceedings.

(d) Subsections (a)—(c) supplement 1 Pa. Code § 31.1 (relating to scope of part).

## **§ 1230a.22. Definitions.**

(a) The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

*Act*—The Medical Marijuana Act (35 P.S. §§ 10231.101—10231.2110).

*Clerk*—The Department's Docket Clerk in the Office of Legal Counsel.

*Department*—The Department of Health.

*Office*—The Department's Office of Medical Marijuana.

*Person*—An individual, partnership, association, corporation, political subdivision, municipal authority or other entity.

(b) Subsection (a) supplements 1 Pa. Code § 31.3 (relating to definitions).

## **§ 1230a.23. Docket.**

(a) The Clerk has the following duties:

(1) Provide information as to practice and procedure before the Department, under this chapter.

(2) Receive and docket pleadings and other documents required by the Department to be filed with the Clerk.

(b) A filing shall be directed to the Clerk at the following address, by first class mail, postage prepaid: Department of Health, Office of Legal Counsel, ATTN: Docket Clerk Room 825, Health and Welfare Building, 625 Forster Street, Harrisburg, Pennsylvania 17120-0701.

(c) Pleadings, submittals or other documents required or permitted to be filed under this chapter, the regulations of the Department or any other provision of law shall be received for filing by the Clerk within the time limits, if any, for the filing. The date of receipt by the Clerk and not the date of deposit in the mail is determinative. Electronic submissions will not be accepted by the Clerk for filing, unless the electronic filing is specifically permitted by the Department.

(d) The Clerk shall maintain a docket of proceedings. Each proceeding as initiated will be assigned a docket number.

(e) The docket will be available for inspection and copying by the public, at the requestor's expense, during the office hours of the Department insofar as consistent with the proper discharge of the duties of the Department.

(f) Subsections (a)—(e) supersede 1 Pa. Code §§ 33.11 and 33.51 (relating to execution; and docket).

## **§ 1230a.24. Filing generally.**

(a) Pleadings and other documents filed with the Clerk must clearly designate the docket number, if one has been assigned, the application or permit number, if one has been assigned, and a short title identifying the pleading or other document. The identity of the individual or person filing the pleading or other document, including the name, mailing address and status (for example, party or attorney for a party) must appear on the pleading or other document being filed.

(b) If a pleading or other document tendered for filing does not comply with this chapter, does not sufficiently set forth required material or is otherwise deficient, the Department may decline to accept the pleading or other document for filing and may return it without filing, or the Department may accept the pleading or other document for filing and advise the individual or person tendering it of the deficiency and require that the deficiency be corrected within a reasonable period of time.

(c) The Department may require redundant, immaterial, obscene or otherwise inappropriate comments stricken from a pleading or other document before accepting it for filing.

## **TIME**

### **§ 1230a.25. Effective date of adjudication, actions or order.**

(a) An adjudication, action or order will be effective as of the date of mailing unless otherwise specifically provided.

(b) Subsection (a) supersedes 1 Pa. Code § 31.14 (relating to effective dates of agency orders).

### **§ 1230a.26. Representation.**

(a) A party, except an individual appearing on [his] their own behalf, shall be represented by an attorney at all stages of the proceedings subsequent to the filing of the Notice of Appeal or Order to Show Cause.

(b) A corporation shall be represented by an attorney of record admitted to practice before the Supreme Court of Pennsylvania. A corporation may also be represented by an attorney in good standing and admitted to practice before the highest court of another State on a motion pro hac vice filed by the Pennsylvania attorney of record.

(c) A group of individuals acting in concert, whether formally or informally, shall be represented by an attorney admitted to practice law before the Supreme Court of Pennsylvania or by an attorney in good standing admitted to practice before the highest court of another State who has made a motion to appear pro hoc vice and has agreed in that motion to abide by the rules and regulations of the Department and the Pennsylvania Rules of Professional Conduct.

(d) An individual may appear in person on his own behalf. The individual is encouraged to appear through counsel. If the Department determines that the individual is acting in concert with or as a representative of a group of individuals, the individual may be required to appear through counsel under subsection (c).

(e) Subsections (a)—(d) supersede 1 Pa. Code §§ 31.21—31.23 (relating to appearance in person; appearance by attorney; and other representation prohibited at hearings).

## **SUBCHAPTER B. FORMAL PROCEEDINGS**

Sec.

### **APPEALS**

1230a.38. Commencement, form and content of Notice of Appeal.

1230a.39. Timeliness of Notice of Appeal.

## **SPECIAL ACTIONS**

1230a.43. Orders to Show Cause, orders or petitions filed by the Office.

1230a.44. Answers to Orders to Show Cause, orders or petitions filed by the Office.

1230a.45. Verifications and affidavits.

1230a.46. Entry of default judgment.

## **APPEALS**

### **§ 1230a.38. Commencement, form and content of Notice of Appeal.**

(a) An appeal from an action of the Office shall start with the filing of a Notice of Appeal with the Department.

(b) The caption of a Notice of Appeal must be in the following form:

### **COMMONWEALTH OF PENNSYLVANIA DEPARTMENT OF HEALTH**

Name of Appellant	: Docket No.: _____
Address of Appellant	:
Telephone Number of Appellant,	:
Appellant/Petitioner,	:
v.	:
	:
The Pennsylvania Department of Health,	:
	:
Office of Medical Marijuana,	:
Appellee/Respondent.	:

### **NOTICE OF APPEAL**

(c) The Notice of Appeal must set forth the name, mailing address, e-mail address, permit number or application number, if one has been assigned, and telephone number of the appellant. If the appellant is represented by an attorney, the Notice of Appeal shall be signed by at least one attorney of record in the attorney's individual name.

(d) If the appellant has received written notification of an action of the Office, a copy of the action must be attached to the Notice of Appeal.

(e) The Notice of Appeal must set forth in separate numbered paragraphs the specific objections to the action of the Office. The objections may be factual or legal.

(f) The Notice of Appeal must be typewritten on letter-size paper (approximately 8 to 8 1/2 inches by 10 1/2 to 11 inches) and pages after the first must be numbered. Photocopies will be accepted as typewritten, provided that the copies are legible. Failure to comply with these requirements will not result in rejection or dismissal of the Notice of Appeal. The Department may request that the appellant file an amended version of the Notice of Appeal in proper form.

(g) The appellant shall, concurrent with or prior to the filing of a Notice of Appeal, serve two copies on the Department's Office of Legal Counsel in the same manner in which the Notice of Appeal is filed with the Department.

(h) Subsections (a)—(g) supersede 1 Pa. Code §§ 35.5—35.7 and 35.20 (relating to informal complaints; and appeals from actions of the staff).

### **§ 1230a.39. Timeliness of Notice of Appeal.**

(a) Jurisdiction of the Department will not attach to an appeal from an action of the Office unless the Notice of Appeal is in writing and is timely filed with the Department within 30 days after the mailing date on the written notice of the action.

(b) An untimely Notice of Appeal may be deemed an admission or may be dismissed with prejudice by the Department.

(c) The Office may file an answer and new matter to the Notice of Appeal within 30 days of its service on the Office but is not required to do so.

(d) Subsection (a) supersedes 1 Pa. Code §§ 35.5—35.7, 35.20 and 35.35 (relating to informal complaints; appeals from actions of the staff; and answers to complaints and petitions).

## **SPECIAL ACTIONS**

### **§ 1230a.43. Orders to Show Cause, orders or petitions filed by the Office.**

(a) The Office may start an action by filing an Order to Show Cause, order or other petition filed by the Office and a notice of a right to respond or defend. The action is begun when the Order to Show Cause, order or other petition of the Office is filed with the Clerk.

(b) Service of the Order to Show Cause, order or other petition filed by the Office shall be by personal service or by United States first class mail, postage prepaid. The date of service shall be the date specified on the certificate of service.

(c) An Order to Show Cause must set forth the authority under which the Department is authorized to act and must set forth in separate numbered paragraphs the specific facts and circumstances upon which the request for action is based.

(d) The notice of a right to respond or defend shall conform substantially to the following:

#### **[Case Caption]**

#### **NOTICE**

If you wish to defend against the claims set forth in the following pages, you must take action within thirty (30) days after this Order to Show Cause and notice are served by entering a written appearance personally or by attorney and filing in writing with the Clerk in accordance with § 1230a.23 your answers, defenses or objections to the claims set forth against you. You are warned that if you fail to do so, the case may proceed without you, and a judgment may be entered against you by the Department without further notice for any claim or relief requested by the Office. You should take this paper to your lawyer at once.

(e) Subsections (a)—(d) supersede 1 Pa. Code § 35.14 (relating to orders to show cause).

**§ 1230a.44. Answers to Orders to Show Cause, orders or other petitions filed by the Office.**

(a) Answers to Orders to Show Cause, orders or other petitions filed by the Office shall be filed with the Clerk within 30 days after the date of service of the Order to Show Cause, order or other petition filed by the Office, unless, for cause, the Department, with or without motion, prescribes a different time.

(b) Answers to Orders to Show Cause, orders or other petitions filed by the Office must set forth legal objections and any denial of facts in a single pleading.

(c) Answers must be in writing and drafted as to fully and completely advise the parties and the Department as to the nature of the defense, including affirmative defenses. Answers must admit or deny specifically and in detail each material allegation of the Order to Show Cause, order or petition filed by the Office, and state clearly and concisely the facts and matters of law relied upon.

(d) A Respondent failing to file an answer within the prescribed time will be deemed in default and, upon motion made as set forth in § 1232.46 (relating to entry of default judgment), all relevant facts in the Order to Show Cause, order or other petition filed by the Office may be deemed admitted, and default judgment may be entered.

(e) New matter or preliminary objections may not be filed. To the extent that new matter or preliminary objections are filed, new matter or preliminary objections will be deemed stricken.

(f) Subsections (a)—(e) supersede 1 Pa. Code § 35.37 (relating to answers to orders to show cause).

**§ 1230a.45. Verifications and affidavits.**

(a) Pleadings or other documents containing an averment of fact not appearing of record in the action or containing a denial of fact shall be personally verified by a party thereto or by an authorized officer of the party if a corporation or other business entity. Verification means a signed written statement of fact supported by oath or affirmation or made subject to the penalties of 18 Pa.C.S. § 4904 (relating to unsworn falsification to authorities). If verification is required, notarization is not necessary.

(b) The verification form must comply substantially with the following:



## VERIFICATION

I, \_\_\_\_\_, hereby state that the facts above set forth are true and correct (or are true and correct to the best of my knowledge, information and belief). I understand that the statements herein are made subject to the penalties of 18 Pa.C.S. § 4904 (relating to unsworn falsification to authorities).

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Printed Name

(c) When an affidavit is used, the form should comply substantially with the following:

## AFFIDAVIT

I, \_\_\_\_\_ (Affiant), being duly sworn (affirmed) according to law, depose and say that (I am authorized to make this affidavit on behalf of \_\_\_\_\_ corporation/business entity, being the holder of the office of \_\_\_\_\_ with that corporation/business entity, and that the facts above set forth are true and correct (or are true and correct to the best of my knowledge, information and belief).

\_\_\_\_\_  
(Signature of affiant)

Sworn and subscribed before me this

day of \_\_\_\_\_, 20\_\_\_\_.

\_\_\_\_\_  
(Signature of official administering oath)

### § 1230a.46. Entry of default judgment.

(a) The Department, on motion of the Office, may enter default judgment against the Respondent for failure to file within the required time an answer to an Order to Show Cause, order or other petition allowed for under these regulations that contains a notice of a right to respond or defend.

(b) The Respondent may answer the motion for default judgment and request a hearing. If a request for a hearing on the default judgment is made, the Department may not grant default judgment prior to a hearing and the filing of an answer

## **[28 Pa. Code § 1151 Appendix A**

### **§ 1151 Appendix A. Acceptable Pesticide Active Ingredients for Use**

The following pesticides can be used legally in the growing and processing of seeds, immature medical marijuana plants, medical marijuana plants or medical marijuana and in accordance with the Pennsylvania Pesticide Control Act of 1973 (3 P.S. §§ 111.21—112). Products containing the following active ingredients must also be labeled for use in greenhouses on food crops to qualify.

<b>EPA Status</b>	<b>Pesticide Type</b>	<b>Comments</b>	<b>Active Ingredient</b>
25(b)	Insecticide		Castor Oil
25(b)	Insecticide		Cedar Oil
25(b)	Insecticide		Cinnamon
25(b)	Fungicide, Insecticide		Cinnamon Oil
25(b)	Fungicide, Insecticide		Citric Acid
25(b)	Bactericide, Fungicide		Clove
25(b)	Insecticide		Clove Oil
25(b)	Fungicide		Corn Oil
25(b)	Insecticide		Cottonseed Oil
25(b)	Insecticide		Garlic
25(b)	Insect Repellent		Garlic Oil
25(b)	Fungicide		Geraniol
25(b)	Insecticide		Geranium Oil
25(b)	Fungicide, Insecticide		Lemon Grass Oil
25(b)	Insecticide		Peppermint Oil
25(b)	Insecticide		Peroxyacetic Acid
25(b)	Fungicide		Potassium Sorbate
25(b)	Insecticide		Rosemary
25(b)	Insecticide		Rosemary Oil
25(b)	Fungicide, Insecticide, Miticide		Sesame Oil
25(b)	Fungicide, Insecticide		Sodium Lauryl Sulfate
25(b)	Insecticide		Soybean Oil
25(b)	Fungicide		Thyme

25(b)	Fungicide, Insecticide, Miticide		Thyme Oil
25(b)	Insecticide		White Pepper
Sec 3 Products	Insecticide		Azadirachtin
Sec 3 Products	Fungicide		Bacillus Amyloliquefaciens Strain D747
Sec 3 Products	Fungicide	For use in protected growing environments only (for example, greenhouses).	Bacillus Pumilus Strain GHA 180
Sec 3 Products	Fungicide		Bacillus Subtilis QST713 Strain
Sec 3 Products	Insecticide		Bacillus Thuringiensis SSP. Aizawai
Sec 3 Products	Insecticide		Canola Oil
Sec 3 Products	Insect Repellent		Capsicum Oleoresin Extract
Sec 3 Products	Insecticide	Ground application only to nonblooming plants.	Chromobacterium Sub Strain PRAA4-1 Cells
Sec 3 Products	Fungicide, Insecticide		Clarified Hydrophobic Extract of Neem Oil
Sec 3 Products	Fungicide		Copper Octanoate
Sec 3 Products	PGR		Cytokinin (Kinetin)
Sec 3 Products	Insecticide		Diatomaceous Earth
Sec 3 Products	PGR		Gibberellins (Gibberellic Acid)
Sec 3 Products	PGR		Harpin Alpha Beta
Sec 3 Products	Antimicrobial, Fungicide	No foliar applications allowed.	Hydrogen Peroxide
Sec 3 Products	PGR	Applications allowed in furrow at planting or in hydroponics only.	IBA (Indole-3-Butyric Acid)
Sec 3 Products	Insecticide, PGR		Kaolin
Sec 3 Products	Insecticide		Mineral Oil
Sec 3 Products	Fungicide	Use only allowed prior to final transplant, unless grown in recirculating hydroponics systems.	Mono-Potassium and Di- Potassium Salts of Phosphorous Acid

Sec 3 Products	Insecticide		Monopotassium Phosphate
Sec 3 Products	Nematicide		Myrothecium Verrucaria
Sec 3 Products	Fungicide, Insecticide		Neem Oil, Cold Pressed
Sec 3 Products	Insecticide	Use allowed prior to final transplant.	Potassium Laurate
Sec 3 Products	Fungicide, Insecticide		Potassium Salts of Fatty Acids
Sec 3 Products	Insecticide		Pyrethrins
Sec 3 Products	Insecticide		Pyrethrins
Sec 3 Products	Molluscicide		Sodium Ferric EDTA
Sec 3 Products	Fungicide		Trichoderma Asperellum Strain ICC 012]

## 28 Pa. Code § 1141a Appendix A

### § 1141a Appendix A. Serious Medical Conditions.

Act 44 of 2021 amended the statutory definition of “serious medical condition” under the Medical Marijuana Act (Act), 35 P.S. §§ 10231.101—10231.2110, to include “other conditions that are recommended by the Advisory Board (Board) and approved by the Secretary under section 1202.” Section 1201 of the Act charges the Board with the responsibility to issue written reports, which include the Board’s recommendation on “whether to change, add or reduce the types of medical conditions which qualify as serious medical conditions....” See 35 P.S. § 10231.1201(j)(5)(ii). This amendment was given retroactive effect to May 18, 2016, codifying conditions added by the Board between the Act’s commencement and Act 44 of 2021’s passage.

At a public meeting on April 9, 2018, the Board adopted a final report recommending that a process be established for a subcommittee of the Board to review and approve additional serious medical conditions on a continuous basis. 35 P.S. § 1201(j)(6). The Secretary approved this recommendation at 48 Pa.B 2898 (May 12, 2018). The Department attaches this Appendix A to reflect all approved serious medical conditions. The Department will periodically, no less than annually if additional serious medical conditions have been recommended by the Board and approved by the Secretary, publish notice in the *Pennsylvania Bulletin* updating the list of serious medical conditions. The list will also be posted on the Department’s publicly accessible Internet website.

The following list is comprised of all medical conditions approved as a “serious medical condition” under the law:

- Cancer, including remission therapy.
- Positive status for Human Immunodeficiency Virus or Acquired Immune Deficiency Syndrome.
- Amyotrophic lateral sclerosis.
- Parkinson’s disease.
- Multiple sclerosis.
- Damage to the nervous tissue of the central nervous system (brain-spinal cord) with objective neurological indication of intractable spasticity, and other associated neuropathies.
- Epilepsy.
- Inflammatory bowel disease.
- Neuropathies.
- Huntington’s disease.
- Crohn’s disease.
- Post-traumatic stress disorder.

- Intractable seizures.
- Glaucoma.
- Sickle cell anemia.
- Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain.
- Autism.
- Neurodegenerative diseases.
- Terminal illness.
- Dyskinetic and spastic movement disorders.
- Opioid use disorder for which conventional therapeutic interventions are contraindicated or ineffective, or for which adjunctive therapy is indicated in combination with primary therapeutic interventions.
- Anxiety disorders.
- Tourette's Syndrome.



COMMONWEALTH OF PENNSYLVANIA  
OFFICE OF THE SECRETARY OF HEALTH

September 19, 2022

Mr. David Sumner  
Executive Director  
Independent Regulatory Review Commission  
14<sup>th</sup> Floor, 333 Market Street  
Harrisburg, PA 17101

Re: Department of Health – Final Regulation No. 10-219  
Medical Marijuana Regulations  
28 Pa. Code Part IXa

Dear Mr. Sumner:

Enclosed are final-form regulations for review by the Independent Regulatory Review Commission (IRRC) in accordance with the Regulatory Review Act (71 P.S. §§ 745.1—745.15). This final-form rulemaking transforms the current temporary regulations found in 28 Pa. Code Part IX to permanent regulations governing the medical marijuana program in a new Part IXa. These regulations further the purpose of the Medical Marijuana Act (35 P.S. §§ 10231.101—10231.2110) by providing access to medical marijuana for patients with serious medical conditions; ensuring a safe and effective method of distribution; and promoting high-quality research into the efficacy of medical marijuana.

The Act provides that upon completion of the agency's review of comments following proposed rulemaking, the agency is to submit to the Commission and the Standing Committees a copy of the agency's response to the comments received, the names and addresses of the commentators who have requested additional information relating to the final-form regulations, and the text of the final-form regulations which the agency intends to adopt. *See* 71 P.S. §§ 745.5a(a).

A list of the names and addresses of the commentators who requested a copy of the final-form regulations is enclosed. The Department previously forwarded these comments to the Commission.

The Act also provides that IRRC may have until its next scheduled meeting which occurs no less than 30 days after receipt of the final-form regulation to approve or disapprove the final-form regulation. 71 P.S. § 745.5a(e).

The Department will provide IRRC with any assistance it requires to facilitate a thorough review of the regulations. If you have any questions, please contact David Toth, Director of the Office of Legislative Affairs, at (717) 787-6436.

Sincerely,

A handwritten signature in dark ink, appearing to read "Denise Johnson", with a stylized flourish at the end.

Denise Johnson, MD  
Acting Secretary of Health

Enclosures



**Shani Shenk**

---

**From:** Bradbury, Joan <jbradbury@pasen.gov>  
**Sent:** Monday, September 19, 2022 10:48 AM  
**To:** Keefer, Lisa; Brooks, Senator Michele  
**Subject:** RE: Final-Form Medical Marijuana Regulation #10-219

Received Lisa, thank you.

*Joan Bradbury*  
Executive Director  
Senate Health & Human Services Committee  
717-787-1475 (direct)

**RECEIVED**

**SEP 19 2022**

Independent Regulatory  
Review Commission

---

**From:** Keefer, Lisa <likeefer@pa.gov>  
**Sent:** Monday, September 19, 2022 10:38 AM  
**To:** Brooks, Senator Michele <mbrooks@pasen.gov>  
**Cc:** Bradbury, Joan <jbradbury@pasen.gov>  
**Subject:** Final-Form Medical Marijuana Regulation #10-219  
**Importance:** High

---

© CAUTION : External Email ©

---

**Good Morning,**

**Attached is a final-form regulatory package from the Department of Health for medical marijuana.**

**The Regulatory Review Act requires delivery of the final-form regulatory package to the Standing Committees of the General Assembly and the Independent Regulatory Review Commission (IRRC) on the same day, with IRRC receiving the package last. Confirmation of receipt by the Standing Committees is required for delivery to IRRC.**

**Please respond as soon as possible to this email indicating that you have received the attached final-form regulatory package so that I can deliver the package to IRRC today, September 19, 2022.**

**Thank you!**

**Lisa M. Keefer | Legal Office Administrator 2**  
**Pennsylvania Department of Health**  
**Office of Legal Counsel**  
**Room 825 | Health and Welfare Building**  
**625 Forster Street | Harrisburg, PA 17120**  
**Ph: 717-783-2500 | Fax: 717-705-6042**  
**[www.health.pa.gov](http://www.health.pa.gov)**

**RECEIVED**

**SEP 19 2022**

**Independent Regulatory  
Review Commission**

**PRIVILEGED AND CONFIDENTIAL COMMUNICATION**

**The information transmitted is intended only for the person or entity to whom it is addressed and may contain confidential and/or privileged material. Any use of this information other than by the intended recipient is prohibited. If you received this message in error, please send a reply e-mail to the sender and delete the material from any and all computers. Unintended transmissions shall not constitute waiver of the attorney-client or any other privilege.**

## Shani Shenk

---

**From:** Freeman, Clarissa <Clarissa.Freeman@pasenate.com>  
**Sent:** Monday, September 19, 2022 12:58 PM  
**To:** Keefer, Lisa; Haywood, Art  
**Subject:** RE: Final-Form Medical Marijuana Regulation #10-219

Received.

Thank you,

**Clarissa L Freeman, Esq. (She/Her)**  
Health and Human Services Committee  
Senate of Pennsylvania  
Office of Senator Art Haywood

**10 East Wing, Main Capitol Building**  
Harrisburg, Pennsylvania 17120-3004  
717-787-1427 (P)  
717-772-0572 (F)

7106 Germantown Avenue  
Philadelphia, Pennsylvania 19119-1837  
215-242-8171 (P)  
215-242-6118 (F)

1168 Easton Road  
Abington, PA 19001  
215-517-1434 (P)  
215-517-1439 (F)



Our Philadelphia and Abington offices are open Monday through Friday, from 9:00am - 4:45pm. Notary services are only available in our Philadelphia office. Appointments are required. Please call us at 215-242-8171 or 215-517-1434 for assistance, or visit our [Self-Service](#) page.

You can also reach our team online Tuesday – Thursday, from 10:00am – 12:00pm & 2:00pm - 4:00pm via our **Live Chat tool** (real time text communications via computer or mobile phone with a District Representative) at [www.senatorhaywood.com](http://www.senatorhaywood.com).



**RECEIVED**

**SEP 19 2022**

**Independent Regulatory  
Review Commission**

From: Keefer, Lisa <likeefer@pa.gov>  
Sent: Monday, September 19, 2022 10:39 AM  
To: Haywood, Senator Art <art.haywood@pasenate.com>  
Cc: Freeman, Clarissa <clarissa.freeman@pasenate.com>  
Subject: Final-Form Medical Marijuana Regulation #10-219  
Importance: High

**RECEIVED**

SEP 19 2022

■ EXTERNAL EMAIL ■

Independent Regulatory  
Review Commission

**Good Morning,**

**Attached is a final-form regulatory package from the Department of Health for medical marijuana.**

**The Regulatory Review Act requires delivery of the final-form regulatory package to the Standing Committees of the General Assembly and the Independent Regulatory Review Commission (IRRC) on the same day, with IRRC receiving the package last. Confirmation of receipt by the Standing Committees is required for delivery to IRRC.**

**Please respond as soon as possible to this email indicating that you have received the attached final-form regulatory package so that I can deliver the package to IRRC today, September 19, 2022.**

**Thank you!**

**Lisa M. Keefer | Legal Office Administrator 2  
Pennsylvania Department of Health  
Office of Legal Counsel  
Room 825 | Health and Welfare Building  
625 Forster Street | Harrisburg, PA 17120  
Ph: 717-783-2500 | Fax: 717-705-6042  
[www.health.pa.gov](http://www.health.pa.gov)**

**PRIVILEGED AND CONFIDENTIAL COMMUNICATION**

**The information transmitted is intended only for the person or entity to whom it is addressed and may contain confidential and/or privileged material. Any use of this information other than by the intended recipient is prohibited. If you received this message in error, please send a reply e-mail**

**to the sender and delete the material from any and all computers. Unintended transmissions shall not constitute waiver of the attorney-client or any other privilege.**

This message and any attachment may contain privileged or confidential information intended solely for the use of the person to whom it is addressed. If the reader is not the intended recipient then be advised that forwarding, communicating, disseminating, copying or using this message or its attachments is strictly prohibited. If you receive this message in error, please notify the sender immediately and delete the information without saving any copies.

**RECEIVED**

**SEP 19 2022**

**Independent Regulatory  
Review Commission**

**Shani Shenk**

---

**From:** Michael Siget <Msiget@pahousegop.com>  
**Sent:** Monday, September 19, 2022 10:40 AM  
**To:** Keefer, Lisa; klrapp  
**Subject:** RE: Final-Form Medical Marijuana Regulation #10-219

Received. Thank you.

**RECEIVED**

SEP 19 2022

Independent Regulatory  
Review Commission

**From:** Keefer, Lisa <likeefer@pa.gov>  
**Sent:** Monday, September 19, 2022 10:37 AM  
**To:** Kathy Rapp <Klrapp@pahousegop.com>  
**Cc:** Michael Siget <Msiget@pahousegop.com>  
**Subject:** Final-Form Medical Marijuana Regulation #10-219  
**Importance:** High

**Good Morning,**

**Attached is a final-form regulatory package from the Department of Health for medical marijuana.**

**The Regulatory Review Act requires delivery of the final-form regulatory package to the Standing Committees of the General Assembly and the Independent Regulatory Review Commission (IRRC) on the same day, with IRRC receiving the package last. Confirmation of receipt by the Standing Committees is required for delivery to IRRC.**

**Please respond as soon as possible to this email indicating that you have received the attached final-form regulatory package so that I can deliver the package to IRRC today, September 19, 2022.**

**Thank you!**

**Lisa M. Keefer | Legal Office Administrator 2  
Pennsylvania Department of Health  
Office of Legal Counsel  
Room 825 | Health and Welfare Building  
625 Forster Street | Harrisburg, PA 17120**

**Ph: 717-783-2500 | Fax: 717-705-6042**

**[www.health.pa.gov](http://www.health.pa.gov)**

**PRIVILEGED AND CONFIDENTIAL COMMUNICATION**

**The information transmitted is intended only for the person or entity to whom it is addressed and may contain confidential and/or privileged material. Any use of this information other than by the intended recipient is prohibited. If you received this message in error, please send a reply e-mail to the sender and delete the material from any and all computers. Unintended transmissions shall not constitute waiver of the attorney-client or any other privilege.**

*The information transmitted is intended only for the person or entity to which it is addressed and may contain confidential and/or privileged material. Any review, retransmission, dissemination or other use of, or taking of any action in reliance upon, this information by persons or entities other than the intended recipient is prohibited. If you received this information in error, please contact the sender and delete the message and material from all computers.*

**RECEIVED**

**SEP 19 2022**

**Independent Regulatory  
Review Commission**

**Shani Shenk**

---

**From:** Fricke, Erika L. <EFricke@pahouse.net>  
**Sent:** Monday, September 19, 2022 12:27 PM  
**To:** Keefer, Lisa; Frankel Dan B.  
**Subject:** RE: Final-Form Medical Marijuana Regulation #10-219

Received

**From:** Keefer, Lisa <likeefer@pa.gov>  
**Sent:** Monday, September 19, 2022 10:35 AM  
**To:** Frankel, Dan <DFrankel@pahouse.net>  
**Cc:** Fricke, Erika L. <EFricke@pahouse.net>  
**Subject:** Final-Form Medical Marijuana Regulation #10-219  
**Importance:** High

**RECEIVED**

SEP 19 2022

Independent Regulatory  
Review Commission

**Good Morning,**

**Attached is a final-form regulatory package from the Department of Health for medical marijuana.**

**The Regulatory Review Act requires delivery of the final-form regulatory package to the Standing Committees of the General Assembly and the Independent Regulatory Review Commission (IRRC) on the same day, with IRRC receiving the package last. Confirmation of receipt by the Standing Committees is required for delivery to IRRC.**

**Please respond as soon as possible to this email indicating that you have received the attached final-form regulatory package so that I can deliver the package to IRRC today, September 19, 2022.**

**Thank you!**

**Lisa M. Keefer | Legal Office Administrator 2  
Pennsylvania Department of Health  
Office of Legal Counsel  
Room 825 | Health and Welfare Building  
625 Forster Street | Harrisburg, PA 17120**



**Ph: 717-783-2500 | Fax: 717-705-6042**

**[www.health.pa.gov](http://www.health.pa.gov)**

**PRIVILEGED AND CONFIDENTIAL COMMUNICATION**

**The information transmitted is intended only for the person or entity to whom it is addressed and may contain confidential and/or privileged material. Any use of this information other than by the intended recipient is prohibited. If you received this message in error, please send a reply e-mail to the sender and delete the material from any and all computers. Unintended transmissions shall not constitute waiver of the attorney-client or any other privilege.**

**RECEIVED**

**SEP 19 2022**

**Independent Regulatory  
Review Commission**