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RULES AND REGULATIONS

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

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

Medical Marijuana

[53 Pa.B. 1275]
[Saturday, March 4, 2023]

The Department of Health (Department) promulgates this final-form rulemaking by adding Part IXa (relating to medical marijuana) and deleting the current temporary regulations in Part IX, to read as set forth in Annex A.

Purpose of the Rulemaking

Under the authority of section 1107 of the Medical Marijuana Act (act) (35 P.S. § 10231.1107) regarding temporary regulations, the Department promulgated temporary regulations to facilitate the prompt implementation of the 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 and 74 (January 7, 2017); 47 Pa.B. 199, 217, 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, 2793, 2801, 2806, 2810 and 2814 (May 12, 2018). Section 1736-A.1 of the act of March 27, 2020 (P.L. 30, No. 10) (Act 10 of 2020), 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 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 The Department rescinded the initial Chapter 20 temporary regulations on July 28, 2018, at 48 Pa.B. 4493 (July 28, 2018), and promulgated revised Chapter 20 temporary regulations at 48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). The act of June 30, 2021 (P.L. 210, No. 44) (Act 44 of 2021) further extended the Department's authority to promulgate temporary regulations until May 31, 2022. See 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(b) of the act (35 P.S. § 10231.301(b)) authorizes the Department to promulgate all regulations neces-sary to carry out the act. 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; monitor 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 4-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 2-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 growers/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 final-form rulemaking transforms the current temporary regulations found in Part IX to permanent regulations governing the Medical Marijuana Program in Part IXa. These permanent 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 deleted in this final-form rulemaking.

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, the Independent Regulatory Review Commission (IRRC) requested more explanation, basis and rationale for each section because the temporary regulation upon which this final-form rulemaking is based was not subject to the Commonwealth Documents Law (45 P.S. §§ 1201—1208), the Regulatory Review Act (71 P.S. §§ 745.1—745.14) and the Commonwealth Attorneys Act (71 P.S. §§ 732-101—732-506). In response, the Department has included the explanation, basis and rationale for each section as follows, and has also gone into more depth regarding the changes from the temporary rulemaking to the proposed rulemaking to this final-form rulemaking. As an additional clarifying technique, the preamble will describe the changes from the temporary rulemaking to the proposed rulemaking 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 the temporary rulemaking to the proposed rulemaking.

In addition, IRRC requested the Department address whether the regulated community, in light of the enactment of Act 44 of 2021, had a chance to review the Act 44 of 2021 provisions in this final-form rulemaking. Because the Act 44 of 2021 provisions are self-executing, and the Department is mirroring this language in this 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 of 2021 to address questions and clarify implementation of certain self-executing provisions where practical.

B. *Requirements of the Regulation*

Chapter 1141a. General Provisions

This chapter in this 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 Chapters 1, 3, 6 and 13 of the act. This chapter is substantially similar to temporary Chapter 1141 (relating to general provisions—temporary regulations). Differences between the temporary rulemaking, the proposed rulemaking and this final-form rulemaking are discussed more fully as follows.

§ 1141a.21. Definitions

This section in this final-form rulemaking includes all terms that were contained in 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 in the temporary rulemakings. 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 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 in the proposed rulemaking are **underlined and bolded**; and the terms that were included for the first time in this final-form rulemaking are **CAPITALIZED and bolded**. There are no changes made in this final-form rulemaking to definitions included for the first time in the proposed rulemaking.

This final-form rulemaking includes the definitions for the following terms.

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 in §§ 1171.21, 1211.21 and 1230.22, and not carried over to the proposed rulemaking or final-form rulemaking are: "approved clinical registrant," "certified ACRC," "clerk" and "laboratory applicant." "immediate family" as defined in the temporary regulation in § 1141.21 is deleted from the proposed rulemaking to this final-form rulemaking.

The definition of "ACRC" was amended on proposed to mirror the definition of "academic clinical research center" in the act. The definition of "applicant" was amended in the proposed rulemaking to include persons who apply to become an approved laboratory, an ACRC or a clinical registrant.

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 3 Pa.C.S. Chapter 15 (relating to controlled plants and noxious weeds). See 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) (relating to requirements for growing and processing medical marijuana), 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) and (2) (declaring dedication to patient safety as part of the 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.

In the proposed rulemaking, due to amending the definition of "applicant," the definitions of "approved clinical registrant" and "certified ACRC" were deleted as unnecessary. To correspond to these changes, the definitions of "IRB," "RAC" and "research contract" were amended in the proposed rulemaking to delete the reference to "certified ACRC."

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

The definition of "caregiver" is amended in this final-form rulemaking to reflect statutory changes made by 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 growers/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 (relating to standards for environmental health services). As a result, the Department declined to make changes to the definition of "certificate of accreditation (COA)."

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 amended in this final-form rulemaking to include a sample taken for stability testing, and the definition of "chain of custody" is amended in this final-form rulemaking 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 amended in the proposed rulemaking to add subsection (iii) as the unnecessary definition of "approved clinical registrant" was deleted from the proposed rulemaking. Per comment from IRRC regarding use of the defined term within the definition, the phrase "as a clinical registrant" is deleted from the definition of "clinical registrant" in subsection (iii) of this final-form rulemaking.

The Department received comments seeking to amend the definition of "continuing care" to delete 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 novel coronavirus (COVID-19) response could be made permanent in these regulations. 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 in the proposed rulemaking to reflect the definition in the act by adding "including an in-person consultation with the patient." However, "in-person" is deleted in this final-form rulemaking from the definition, pursuant to the statutory change made in Act 44 of 2021. See 35 P.S. § 10231.103.

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

The definition of "de-identified data" was added in this final-form rulemaking in response to comments from IRRC and other commentators seeking clarification on § 1141a.22(f) (relating to records subject to disclosure; confidentiality).

One commentator requested that the Department amend 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 temporary § 1161.27(c) (relating to items and services provided at a dispensary), as safe and suitable for use.

One commentator, though not referencing a specific provision, sought to amend the definition of "diverse participant" to delete 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. See 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. See 35 P.S. § 10231.701(c.1).

The definition of "harvested hemp" is added in this final-form rulemaking due to Act 44 of 2021 amending section 702 of the act (35 P.S. § 10231.702) to allow growers/processors to obtain harvested hemp from hemp growers or cultivators holding a permit issued by the Department of Agriculture.

The definition of "immediate family" is deleted in this final-form rulemaking since it is unnecessary.

The definition of "laboratory applicant" was deleted from the proposed rulemaking because the definition of "applicant" is revised to include persons who apply to become an approved laboratory.

The definition of "marijuana" was amended in the proposed rulemaking to exclude synthetic marijuana. Additionally, in response to multiple commentors requesting the inclusion of hemp-derived CBD products, and per Act 44 of 2021, the definition of "marijuana" is amended in this final-form rulemaking to remove the industrial hemp exclusion in subsection (ii), and the now unnecessary definition of "industrial hemp" is deleted. 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. Chapter 15. See 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 these 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 35 P.S. § 10231.304(c). Additionally, Act 44 of 2021 gave the Medical Marijuana Advisory Board (Board), with the Secretary's concurrence, authority to change the forms of medical marijuana permitted under the act. See 35 P.S. § 10231.1201.

The definition of "medical marijuana organization" was amended in the proposed rulemaking to delete the exclusion of a clinical registrant, to comport with section 2002(b)(5) of the act (35 P.S. § 10231.2002(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 sectored off solely for research markets. The Department, however, is unable to adopt the requested change. The definition mirrors the act. 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 growers/processors. The commentator articulated the benefits that trim's inclusion would provide by increasing patient access to products, as other growers/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. See 35 P.S. § 10231.702(a)(2.1). Additionally, this 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 in this final-form rulemaking, which corresponds to the 90-day supply set at 192 medical marijuana units in § 1161a.24(b) (relating to limitations on dispensing). A 90-day supply, rather than a 30-day supply, is used under statutory change implemented in Act 44 of 2021.

In response to public comments, reiterated by IRRC, the definition of "medical marijuana waste" is amended in this final-form rulemaking to address a specific scenario that resulted in financial loss to the grower/processor. Historically, products erroneously delivered to the wrong dispensary were required to be returned to the grower/processor and destroyed since products returned to a 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 amendment of the definition of "medical marijuana waste" to delete medical marijuana roots from the definition. This commentator stated that destroying the roots requires extensive effort, and this effort provides 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, growers/processors can ably destroy medical marijuana waste as currently required.

The definition of "municipality" was amended in the proposed rulemaking 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 amended in this final-form rulemaking to reflect changes made, by Act 44 of 2021, to the definition of "continuing care" in section 103 of the act (35 P.S. § 10231.103), deleting the requirement of "in-person" consultations and allowing for telemedicine. The definition of "permit" was amended in the proposed rulemaking by changing "applicant" to "medical marijuana organization" to reflect the definition of "permit" in the act.

Per request for amendment 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 in this final-form rulemaking to mirror the definition added to section 702(a)(2.1) of the act by Act 44 of 2021.

The definition of "research initiative" is added in this final-form rulemaking to mirror the definition added to section 103 of the act by Act 44 of 2021.

IRRC questioned whether the references to a "research program" or "study" within the definition of "research protocol" should be amended 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 amended. Section 2003 of the act (35 P.S. § 10231.2003), which does not become effective until marijuana is rescheduled at the Federal level, pertains only to a "research project" or a "research study." To advance other medical marijuana research, the Department added the definition of "research program," consistent with the language used in section 2000 (35 P.S. § 10231.2000) and section 2002 of the act. However, to add clarity, the definition of "research protocol" is amended to include research projects.

The definition of "serious medical condition" was amended in the proposed rulemaking. Act 44 of 2021 amended the statutory definition of "serious medical condition" to include "other conditions that are recommended by the 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 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 (35 P.S. § 10231.1201(j)(6)), 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. Consequently, the definition of "serious medical condition" is deleted in this final-form rulemaking 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 web site.

IRRC commented that the process for amending the definition of "serious medical condition" should be included in this final-form rulemaking, 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 (relating to 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 previously described, these amendments 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 the 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. See 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 deletion 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 previously explained and 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 Board, with concurrence of the Secretary, as previously explained. 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" in this final-form rulemaking in response to public comments. Several public commentors, including IRRC, questioned the need for "species" on the product label and suggested that, if it is required, a definition should be provided. While section 303(b)(8) of the act (35 P.S. § 10231.303(b)(8)) requires medical marijuana products to identify the species, 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 or cannabis indica, or both. Accordingly, "species" is 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. See 35 P.S. § 10231.103. The definition of "THC" is amended to clarify that the term refers to "delta-9" tetrahydrocannabinol.

Some commentators sought to amend 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 temporary § 1141.22 (relating to records subject to disclosure; confidentiality) to permanent § 1141a.22. Subsection (b) was amended in the proposed rulemaking and subsections (f) and (g) were added, as detailed as follows. In addition, subsections (d) and (e) were modified in this final-form rulemaking, as detailed as follows.

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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

Subsection (b).

This subsection lists what information is considered confidential and not subject to the RTKL. Paragraph (11) of this subsection was amended from the temporary rulemaking to the proposed rulemaking 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 this act 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 this protection remains necessary to carry out the provisions of the act.

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

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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

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 the temporary rulemaking to the proposed rulemaking. 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)" to clarify when redactions are required.

Subsection (e).

This subsection, as proposed, matched 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 amended in this final-form rulemaking 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 to the proposed rulemaking 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 institutional review board (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. In response, section 302 of the act 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 nonpublic disclosure of de-identified data for research purposes. Moreover, in section 2000(a) 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. To facilitate this research and achieve the greatest benefit offered by this 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 previously explained, no confidential data of a grower/processor will be released.

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

Subsection (g).

This subsection was added to the proposed rulemaking 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(a)(11) of the act. No comments were received on this subsection, and no changes were made to this subsection from the proposed rulemaking to the final-form rulemaking.

§ 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).

Proposed § 1141a.23 mirrored 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 amending incorrect citations in subsection (3).

In response to IRRC's request to delete 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" in this final-form rulemaking. Subsection (3) is deleted from this final-form rulemaking to comport with deletion 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 temporary § 1141.24 (relating to medical marijuana regions). No comments were received on this section and no changes were made to this section from the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 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 temporary § 1141.25 (relating to general requirements for permits). No changes were made to this section from the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

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 as follows under § 1141a.40.1 (relating to 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. This section mirrors temporary § 1141.26 (relating to privilege and nontransferability). No comments were received on this section and no changes were made to this section from the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 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 as follows. Subsections (a), (c) and (d) were revised in the proposed rulemaking, as detailed as follows. No changes to subsections (a) and (b) were made from the proposed rulemaking to this final-form rulemaking.

Subsection (a).

This subsection lists the types of applications to be submitted to the Department. Subsections (a)(3)—(5) were amended in the proposed rulemaking by deleting 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. Temporary subsection (a)(4), which currently provides for "[a]n application for approval of a change of location of a facility," was amended in the proposed rulemaking to add that an application to change location may be submitted only for an "operational" facility. This amendment clarifies that the application is not intended to pertain to non-operational facilities. A commentator requested that the Department delete "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 amended in this final-form rulemaking to add "or renewal of" a laboratory to capture the laboratory renewal application that must be filed every 2 years. Beyond these amendments, this subsection mirrors temporary subsection (a).

Subsection (b).

As proposed, this subsection mirrored 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. In response to IRRC's request to remove non-regulatory language, the phrase "to the extent deemed appropriate by the Department" is deleted 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 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 from the proposed rulemaking to this final-form rulemaking.

Subsection (d).

This subsection provides that an incomplete application will be rejected. As proposed, this subsection amended the language in 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 the proposed rulemaking stage, this subsection deleted the requirement that the Department return an incomplete application, making for a more efficient and cost-effective operation. Additionally, the language regarding refunding the initial permit fee is moved to § 1141a.28(a)(2) and (b)(2) (relating to fees), and "for an initial permit" is added after "application" to clarify that this provision applies only to initial permit applications. No comments were received on this section and no changes are made to this section from the proposed rulemaking to this final-form rulemaking.

§ 1141a.28. Fees

This section tracks section 607 of the act (35 P.S. § 10231.607). Subsections (a)—(c) were amended, as detailed as follows.

Subsection (a).

This subsection provides the fee amounts for initial and renewal grower/processor permits, and to whom initial permit fees will be refunded. Temporary subsection (a) provides that the fee for these permits must be paid by "certified check or money order." This subsection was revised in the proposed rulemaking to expand the acceptable forms of payment to include cashier's checks. This amendment provides applicants greater flexibility in their choice of payment. Subsection (a)(2) was also amended 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 amendments are made to this subsection from the proposed rulemaking to this final-form rulemaking.

Subsection (b).

This subsection provides the fee amounts for initial and renewal dispensary permits, and to whom initial permit fees will be refunded. Temporary subsection (b) provides that the fee for these permits must be paid by "certified check or money order." This subsection was amended on proposed to expand the acceptable forms of payment to include cashier's checks. This amendment provides applicants greater flexibility in their choice of payment. Subsection (b)(1) was also amended to match the language in subsection (a)(1) and subsection (b)(2) was amended 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 the proposed rulemaking to this final-form rulemaking.

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 amended in the proposed rulemaking to add "cashier's check" as an acceptable form of payment, consistent with the amendment to subsections (a) and (b). Additionally, the unnecessary phrase "authorized by permit" in temporary subsection (a)(2) and (3) was deleted. Finally, subsection (c)(2) was amended to add the word "operational" before "facility," consistent with the amendment to § 1141a.27(a)(4) (relating to general requirements for application) 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 the proposed rulemaking to this final-form rulemaking.

§ 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 as follows.

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 temporary subsection (a), except that the citation in subsection (a)(2) was changed in the proposed rulemaking to refer to this new chapter. No comments were received on this subsection and no additional amendments were made to this subsection from the proposed rulemaking to this final-form rulemaking.

Subsection (b).

This subsection requires certain information from an applicant in addition to that required by § 1141a.27.

Per comments from IRRC directing deletion of non-regulatory language, the phrase "at a minimum" is deleted in this final-form rulemaking from subsection (b)(3)(ii) and (iii) and (12).

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

Former subsection (b)(6)(iii), now subsection (b)(6)(ii), is amended in this final-form rulemaking 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 amended in the proposed rulemaking 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 amended at the proposed rulemaking 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), is further amended to reflect changes made by Act 44 of 2021, which now requires reporting of only felony drug convictions less than 10 years old. See 35 P.S. § 10231.614. Subsection (b)(6)(iv) also added subsections (C) and (D) to the proposed rulemaking. These subsections were reworded and relocated from temporary subsection (b)(9)(vi) and (vii), because those subdivisions were more appropriately located in the section of the application requiring disclosures by means of 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 rulemaking stage, subsection (b)(9)(v) was deleted as duplicative of background check requirements in subsection (b)(6). Subsection (b)(9)(vi) and (vii) was reworded and moved to § 1141a.29(b)(6)(iii) because this text is more appropriately located in the section of the application requiring disclosures by means of affidavit.

In response to IRRC's request to delete the non-regulatory language, subsection (b)(12) is amended in this final-form rulemaking 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) is deleted from this final-form rulemaking to comport with deletion of this requirement from Act 44 of 2021. See 35 P.S. § 10231.602(a)(7)(i).

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

Subsection (c).

This subsection 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 werereceived on this subsection and no changes were made to this subsection from the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 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. No comments were received on this section and no changes were made to this section from the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 1141a.31. Background checks

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

Subsection (a).

This subsection provides the way the Department will conduct criminal background checks on applicants and their affiliates. This subsection was amended at the proposed rulemaking stage 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 the proposed rulemaking to this final-form rulemaking.

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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

Subsection (b.1).

This subsection is added to comport with new language in Act 44 of 2021. See 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 amended at the proposed rulemaking 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 this final-form rulemaking, this section is further amended, under 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 2-week period. The Department understands these commentators' frustration. Recent changes implemented by Act 44 of 2021 will streamline this process. Act 44 of 2021 enables the Department to receive background checks electronically from the Federal Bureau of Investigation and the Pennsylvania State Police instead of by paper, which often took 6—12 weeks. See 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. See 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 the proposed rulemaking stage. This subsection is amended 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 Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101—780-144), 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 previously indicated, Act 44 of 2021 eliminated the lifetime ban and narrowed the disqualifying convictions.

One commentator proposed to extend 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 amendments made by Act 44 of 2021 and provisional employment is now permitted as reflected in subsection (b.1) of this final-form rulemaking.

§ 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 regarding their efforts to meet their diversity goals and the effectiveness of their diversity plans. The only change made to this section from the temporary rulemaking to the proposed rulemaking was amending the citation in subsection (g) to refer to this new chapter.

The phrase "are reasonable and represent a good faith effort to" in subsection (c) is deleted from this final-form rulemaking, 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 the temporary rulemaking to the proposed rulemaking was amendment 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 the proposed rulemaking to this final-form rulemaking.

§ 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. The only changes to this section from the temporary rulemaking to the proposed rulemaking were amendment of the citations in paragraphs (3) and (8) to refer to this new chapter. In this final-form rulemaking amendments are made to paragraph (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 the proposed rulemaking to this final-form rulemaking.

§ 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 the temporary rulemaking to the proposed rulemaking was amendment of a citation to refer to Chapter 1230a (relating to practice and procedure). No comments were received on this section and no additional changes were made to this section from the proposed rulemaking to this final-form rulemaking.

§ 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 the temporary rulemaking to the proposed rulemaking was the amendment 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, this subsection is amended in this final-form rulemaking 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 are made to this section from the proposed rulemaking to this final-form rulemaking.

One commentator objected to the requirement under this provision that a medical marijuana organization submit a permit renewal application no less than 4 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 30 days of the expiration of the current permit because having to submit a permit renewal application 8 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 4-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 time frame of the active permit. Instead, the renewal application seeks information based on time frames 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 § 1141a.36(c)(2) regarding seeking information from the 12-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, 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 the temporary rulemaking to the proposed rulemaking were amendment 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 the proposed rulemaking to this final-form rulemaking.

§ 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.

At the proposed rulemaking stage, consistent with the amendments to § 1141a.39 (relating to 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 amendment 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, in the proposed rulemaking, the citations in subsections (b) and (c) were amended to refer to this new chapter.

In this final-form rulemaking, references to submitting an application for change in ownership are deleted, 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 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 as follows.

Title.

This section omits the words "approval of a" from the title of temporary § 1141.39, consistent with the amendments to § 1141a.38 discussed previously. 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 deleted from the title of this section in this final-form rulemaking and additional clarifying amendments are made as detailed as follows.

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 the proposed rulemaking stage, the words "approval of a" were omitted when discussing the application for a change in ownership, for the same reasons as discussed previously. Also in the proposed rulemaking, the citation was amended to refer to this new chapter. In this final-form rulemaking, 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 deleted 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 from the proposed rulemaking, as it did not reflect the internal process used to evaluate affiliation of individuals with a medical marijuana organization. Pro-posed subsection (b) tracked the substantive requirements of temporary subsection (c), but omitted the words "approval of a" when discussing the application for a change in ownership, for the same reasons discussed previously; amended the citation to refer to this new chapter; and deleted "the Department may reject an incomplete application" as this language did not reflect actual practice. In this final-form rulemaking, consistent with changes to the title and subsection (a), this subsection is further amended to delete 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 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 the proposed rulemaking to this final-form rulemaking.

Subsection (d).

This subsection, as proposed, was modeled after 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 deleted from this subsection in this final-form rulemaking. 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 explain the need for written approval of all individuals affiliating with the medical marijuana organization, or to delete the requirement. As indicated previously, the Department has deleted the requirement.

Subsection (e).

Temporary subsection (e) was deleted in its entirety at the proposed rulemaking 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. See 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 the proposed rulemaking stage, the following amendments were made to the temporary provisions: the word "operational" was added to the title and to subsections (a) and (b), consistent with the amendments to §§ 1141a.27 and 1141a.28; the phrase "authorized under a permit" was deleted from subsections (a) and (b), as the language was unnecessary; and subsection (a) was amended to refer to this new chapter.

IRRC requested the Department 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 (relating to request to change location of a non-operational facility).

§ 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 this type of alteration must submit an application to do so if the proposed alteration involves one or more of the scenarios delineated in subsection (b)(1)—(3). The only change to this section from the temporary rulemaking to the proposed rulemaking was amendment 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 the proposed rulemaking to this final-form rulemaking.

§ 1141a.42. Failure to be operational

This section requires a medical marijuana organization to notify the Department that it is operational within 6 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 the temporary rulemaking to the proposed rulemaking was amendment 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, 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 6 months as permitted by the Department. After consideration, the Department will not adopt the requested amendment. The regulations as written allow for extensions of the 6-month operational timeline, which multiple permittees have utilized in operationalizing their respective facilities. As the regulations currently allow for the requested amendment, 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 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 recieved on this section and no changes were made to this section from the proposed rulemaking to this final-form rulemaking.

§ 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 temporary § 1141.44 (relating to insurance requirements). No comments were received on this section and no changes were made to this section from the proposed rulemaking to this final-form rulemaking.

§ 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 temporary § 1141.45 (relating to inspection and investigation). No comments were received on this section and no changes were made to this section from the proposed rulemaking to this final-form rulemaking.

§ 1141a.46. Reports

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

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, amendments were made to subsection (a)(1) and (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 amendments 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 amended to delete "and in a unit of measurement as determined by the Department."

Subsection (b).

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

Subsection (c).

As proposed, this subsection mirrored 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 deleted from this subsection in this final-form rulemaking.

Subsection (d).

As proposed, this subsection mirrored 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 the proposed rulemaking to this final-form rulemaking.

§ 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 the proposed rulemaking 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, 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 deleted as they constitute non-regulatory language. Additionally, the remainder of the subsection is amended 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 2-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 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" in section 103 of the act and § 1141a.21 (relating to definitions).

§ 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 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 the proposed rulemaking to this final-form rulemaking.

§ 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 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 amendment is warranted.

Another commentator sought deletion 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 amendment. 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 amendment requires legislative change, the Department is unable to implement this comment. No changes were made to this section from the proposed rulemaking to this final-form rulemaking.

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 previously indicated, the act requires the Department to restrict the advertising and marketing of medical marijuana, which includes 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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

Chapter 1151a. Growers/processors

This chapter pertains to growers/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—10231.705). This chapter replaces temporary Chapter 1151 (relating to growers/processors—temporary regulations). New sections and amendments to sections of the temporary regulations are discussed more fully as follows.

§ 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 18 years of age to work at its facility. The only change to this section from the temporary rulemaking to the proposed rulemaking was amendment of 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 subsection (a)(2)(ii) was amended as proposed by replacing the word "visitors" with the phrase "individuals requiring access to the facility." This amendment emphasizes that grower/processor facilities are not open to the public and are not permitted to have nonessential visitors. Finally, the citation in subsection (a)(12) was amended as proposed to refer to this new chapter. No comments were received on this section and no changes were made from the proposed rulemaking to this final-form rulemaking.

§ 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 the 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 nonessential visitors.

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

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 growers/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 amendment 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—that is, paper versus 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.

Commentators 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, and replaces temporary § 1151.24 (relating to start-up inventory). This section contains multiple changes from the temporary rulemaking, as detailed as follows.

Title.

The title of the subsection is changed to replace "start-up" with "growing and processing" as amendments 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 deleted references to "immature medical marijuana plants" as section 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 deleting "immature medical marijuana plants" from this provision if the provision remained unchanged in this final-form rulemaking. Since Act 44 of 2021 amended the act to include this language, no explanation is necessary, 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." Subsection (a) is amended under statutory changes made in Act 44 of 2021. 35 P.S. § 10231.702. In accordance with amended section 702 of the act, growers/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 amended 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 amendments previously explained. In response to IRRC's questioning how the process would be implemented, subsection (a)(1)—(5) are added. This subsection outlines 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—that is, 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. 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 temporary subsection (b).

One commentator objected to subsection (b) of this provision and requested that growers/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 previously, 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, deleted "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. This subsection is further amended to allow for the importation of immature medical marijuana plants during multiple importation windows pursuant to statutory change made in Act 44 of 2021. See 35 P.S. § 10231.702(a)(1).

One commentator objected to the deletion 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 previously explained, this initial amendment has been reversed due to Act 44 of 2021.

Subsection (d).

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 amended at the proposed stage to incorporate an additional 30-day window that may be provided for the importation of seeds or immature medical marijuana plants. No additional changes were made from the proposed rulemaking to this final-form rulemaking.

Subsection (e).

This subsection is added to this final-form rulemaking under 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. See 35 P.S. § 10231.702(a)(2.1).

Subsection (f).

This subsection is added to this final-form rulemaking under 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 3 Pa.C.S. Chapter 15 if the hemp received by a grower/processor is subject to the laboratory testing requirements of section 704 of the act. See 35 P.S. § 10231.702(a)(4).

Subsection (g).

This subsection is added in this final-form rulemaking under 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). See 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 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 the proposed rulemaking 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 amended at the 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 onsite and in the facility. This subsection clarifies who may have access to a facility and for what purpose. No changes were made from the proposed rulemaking to this final-form rulemaking.

One commentator objected to the proposed changes in this provision, though not specifically referencing this regulatory subsection, and requested that growers/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 amended 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. Temporary subsection (b) provides that "visitors" must present proper identification; this subsection, as proposed, replaced "visitors" with "individuals," consistent with the Department's deletion of the term "visitor" from this final-form rulemaking. No changes were made from the proposed rulemaking to this final-form rulemaking.

Subsections (c) and (d).

Subsection (c) provides that individuals under 18 years of age 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 are made from the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

Subsection (e).

This subsection provides the requirements for a grower/processor to admit an individual into its facility. The changes from the temporary rulemaking to the proposed rulemaking 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 delete 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 the proposed rulemaking to this final-form rulemaking.

The Department received comments objecting to the requirement under subsection (e)(5) that, when admitting an individual to a site or facility, growers/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) (relating to access to grower/processor facilities). 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 (relating to selection protocol for samples).

One commentator objected to this subsection's requirements that an individual's name and company name be listed on a temporary identification badge. 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. Facility safety and security could be threatened by not obtaining this information; accordingly, the Department will not adopt the requested amendment.

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 amended at the proposed rulemaking stage to replace the word "visitor" with words or phrases corresponding to amendments made in other subsections within this section. Additionally, the date is added in this final-form rulemaking as a required entry on the log.

The Department received a comment from IRRC regarding the need to require maintenance of logs for 4 years and questioned whether the log could be maintained electronically. In response, the Department reduces the storage requirement in paragraph (1) to 180 days, unless otherwise required for investigative or litigation purposes, which aligns with the time frame required by Act 44 of 2021 for growers/processors to retain security surveillance records. This time frame 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 the proposed rulemaking 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 temporary subsection (h) was replacement of the word "visitor" with "individual" at the proposed rulemaking stage, consistent with the rationale previously explained. No changes were made from the proposed rulemaking to this final-form rulemaking.

§ 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. This section further provides requirements for accessing rooms containing security and surveillance monitoring equipment. This section largely mirrors temporary § 1151.26 (relating to security and surveillance), except for the changes detailed as follows.

The following changes are made in this final-form rulemaking per comments from IRRC regarding the use of non-regulatory language, the phrase "at least" in subsection (a)(1)(viii) and (2)(i)(E)(ii) is replaced with "no less than." Subsection (a)(2) is amended to require "continuous" surveillance per the statutory change made in Act 44 of 2021. See 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 2 years. The storage requirement is reduced to 180 days, unless otherwise required for investigative or litigation purposes, per Act 44 of 2021. See 35 P.S. § 10231.702(b)(2). Due to the statutory amendment, the Department is unable to reduce the storage requirement to 90 days as suggested by multiple commentors. The phrase "at least" in subsection (b)(3) is deleted, per comment from IRRC, as it constitutes non-regulatory language and is unnecessary. Subsection (b)(3) is further amended in this final-form rulemaking, 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 4 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. See 35 P.S. § 10231.702(b)(2).

Subsection (b)(5) was amended at the proposed rulemaking 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 amended 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 delete 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—that is, 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 amending 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 by deleting 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 this final-form rulemaking 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 the proposed rulemaking 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)—(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. See 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 amended 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 amended 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 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, the 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. See 35 P.S. § 10231.702(a)(3).

This section is amended 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 Pennsylvania Pesticide Control Act of 1973 (Pesticide Control Act) (3 P.S. §§ 111.21—112), and designated by the Secretary of Agriculture in consultation with the Secretary for use by a grower/processor. See 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 to delete "that is greater than an acceptable level as determined by the Department."

One commentator requested that the "Comments" section be deleted from Appendix A regarding 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 deleted per the changes made in § 1151a.27(a) (relating to requirements for growing and processing medical marijuana), 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 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 this final-form rulemaking. Substantial changes have been made, as previously explained, 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 delete subsection (h)(1) to allow growers/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, 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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

The Department received comments seeking to add edibles to subsection (a), as to allow growers/processors to process medical marijuana into edible or drink form. For several reasons, the Department is unable to make this amendment. 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 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 35 P.S. § 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. See 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 6 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 6 months. This section mirrors temporary § 1151.29 (relating to limit on medical marijuana processing), excepting the following amendments.

Subsection (a) was amended at the proposed rulemaking 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 amendments 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 time frame. 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 deleted from 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%, subsection (a)(2), (3), and (5)—(7) is amended in this final-form rulemaking 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. See 35 P.S. §§ 10231.303(b)(8) and 10231.801(i)(5). In addition to the previously stated reasoning, the Department will not act on one commentator's suggestion that paragraphs (1)—(5) only be listed if the cannabinoid profiles are greater than 0.1% and paragraphs (6)—(10) should be provided by means of 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 the proposed rulemaking 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 growers/processors still growing accustomed to the market, and from IRRC requesting clarification on the notification time frame, this requirement is further amended 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, 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 temporary § 1151.30 (relating to inventory data) at the proposed stage. Only one amendment is made in this final-form rulemaking to subsection (b)(2), per comment from IRRC, to delete the non-regulatory phrase "at least."

§ 1151a.31. Storage requirements

This section, consistent with section 703 of the act, 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 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 the proposed rulemaking to this final-form rulemaking.

§ 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 temporary § 1151.32 (relating to equipment, operation and maintenance) at the proposed rulemaking stage. Per comment from IRRC, regarding the use of vague non-regulatory language, the word "routinely" in 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 § 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 temporary § 1151.33 (relating to sanitation and safety in a facility) at the proposed rulemaking stage. No comments were received on this section and no changes were made from the proposed rulemaking to this final-form rulemaking.

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

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

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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

Subsection (b).

This subsection lists the general requirements for medical marijuana product packaging. Temporary subsection (b)(3) provides that packaging must be "[l]ight resistant or opaque, or both." This subsection was amended at the proposed rulemaking stage to delete the "light resistant" packaging option. This amendment effectuates the Department's intent for nontransparent 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 amendments are 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 adds subsection (b)(5) to this final-form rulemaking, 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, adds subsection (b)(6) to this final-form rulemaking 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 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 subsection (d)(9) and (10), the Department takes 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 temporary subsection (d) were expanded, in the proposed rulemaking, 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 amendment at the proposed rulemaking stage to correct syntax.

IRRC asked the Department to clarify how a grower/processor obtains packaging and labeling approval, including how a request is made, the time frame 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 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 amended in this final-form rulemaking 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 amended in this final-form rulemaking to accommodate a clinical registrant selling medical marijuana products to another grower/processor and the dispensary destination is unknown. In these 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 amended 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 these 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 previously indicated, 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 previously indicated, a clarifying definition of "species" is added. As it relates to including the cannabinoid and terpene profile on the label, this is already a requirement found under § 1161a.28(b)(6) (relating to labels and safety inserts). 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 deleted from outer packaging. Additionally, patients relayed inability to distinguish products once deleted 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 delete 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 this requested amendment. 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 by means of 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 temporary subsection (e). No comments were received on this subsection and no changes were made from the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 1151a.35. Transportation of medical marijuana

This section details transportation requirements, consistent with section 703 of the act. Deviations from temporary § 1151.35 (relating to transportation of medical marijuana) are noted as follows.

Some commentators sought an addition to this provision to allow for the transportation of medical marijuana trim between growers/processors. The commentators asserted that trim would classify as "plant material," which may be transferred between growers/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 growers/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. See 35 P.S. § 10231.702(a)(2.1). References to transporting "medical marijuana" in subsections (a)—(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 is amended in this final-form rulemaking to reconcile Act 44 of 2021's addition of "postharvest plant material," as previously explained. Subsection (a)(1) replaces "medical marijuana" with "postharvest plant material" as well as replaces "medical marijuana organization" with "grower/processor, dispensary, . . ." to clarify that postharvest plant material may not be delivered to a dispensary. Subsection (a)(5) is added to clarify that postharvest plant material can only be obtained and transported from one grower/processor to another grower/processor within this Commonwealth for the purpose of processing medical marijuana.

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 amendment to § 1161.35(b)(1) (relating to transportation of medical marijuana products) 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 temporary § 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.

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 at the proposed rulemaking stage to read that transportation vehicles must "[m]aintain current State inspection and vehicle registrations." This amendment 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 previously explained.

One commentator requested that the Department increase the permissible size of 1`×1`×1` to accommodate more medical marijuana products when transporting products between grower/processor facilities. As this requirement is not present in this provision or any other provision in this final-form rulemaking, 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 this final-form rulemaking. For the same reason, the phrase "at least" is deleted from subsection (c)(1) in this final-form rulemaking.

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

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 5 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 5 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 amended in this final-form rulemaking, 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 deleted from subsections (f) and (g).

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

One commentator requested that the Department amend subsection (d) to allow for both delivery and pickup within the same trip. This practice, however, is not prohibited by this final-form rulemaking. 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 amended, as previously indicated, 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, 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 temporary § 1151.36 (relating to transport manifest) except for revising the citation in subsection (c) to refer to this new chapter. In this final-form rulemaking, all references to transporting "medical marijuana" are replaced with "postharvest plant material" consistent with Act 44 of 2021 and § 1151a.35 (relating to transportation of medical marijuana).

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 amendment. To allow for medical marijuana organizations to manually tamper with the information in the transport manifest allows for possible diversion or unaccounted for medical marijuana products, or both. Accordingly, the Department will take no action in response to this comment.

One commentator requested that the Department amend 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, 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 temporary § 1151.37 (relating to transportation of seeds, immature medical marijuana plants and medical marijuana plants), except for amending three cross-references in subsection (c) to refer to this new chapter. In this final-form

rulemaking, subsection (b) and references to transporting "postharvest plant material" are added to be consistent with Act 44 of 2021 and § 1151a.35.

The Department received a public comment, reiterated by IRRC, objecting to the Department not permitting growers/processors to transport final-form medical marijuana products or biomass to another grower/processor. This comment has been partially adopted by the addition of § 1151a.24(e), allowing growers/processors to obtain and transport "postharvest plant material" from another grower/processor, which was added under Act 44 of 2021. See 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 temporary § 1151.38 (relating to evidence of adverse loss during transport) except for adding "unresolved" to subsection (a). This change is made to eliminate required refusal of a delivery if the discrepancy is resolved. This amendment eliminates unnecessary delay in growers/processors obtaining inventory, which will ultimately affect delivery of products to dispensaries and patients.

In this final-form rulemaking, all references to transporting "medical marijuana" are replaced with "postharvest plant material" consistent with Act 44 of 2021 and § 1151a.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 deleted from subsections (a) and (b).

§ 1151a.39. Electronic tracking system

This section, consistent with section 701 of the act, provides that a grower/processor must use an electronic tracking system prescribed by the Department. As proposed, this section mirrored 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 amended in this final-form rulemaking 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. See 35 P.S. § 10231.701(c.1) (effective December 31, 2021).

One commentator, referencing an e-mail 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 by means of e-mail. This commentator, however, is mistaken. While the Department did send an e-mail to that effect, it did so after publishing the same at 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 application programming interface (API) of its choosing to connect to the database; and to consider the suggestions of commentators as their concerns relate to the use of an API and the potential benefits of safety and efficiency that commentators contend can be realized. As previously indicated, 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 amended, as previously described, to allow the use of API integration under 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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

One commentator suggested amending 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 this final-form rulemaking. As indicated previously, the definition of "medical marijuana waste" is amended 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—that is, products dispensed and later returned to a grower/processor are considered waste and must be destroyed.

One commentator requested that the Department amend 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, growers/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 rulemaking 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 this final-form rulemaking, 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 deleted from subsection (g)(10) as unnecessary, as all required reporting elements are listed in subsection (g)(1)—(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—that is, 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—that is, seeds, fungus, other problems with products—to the Department. This procedure is already in place. Patients may report information to the Department by means of e-mail 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 § 1141a.21.

One commentator requested that the Department amend 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, 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 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. At the proposed rulemaking stage, this section mirrored temporary § 1151.43 (relating to pesticides), 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 this final-form rulemaking, references to "postharvest plant material" are added to be consistent with Act 44 of 2021. In this final-form rulemaking, per comments from IRRC regarding the use of non-regulatory language, the phrase "at least" is deleted from subsection (c)(2).

One commentator requested that the Department expand the list of pesticides acceptable for use on medical marijuana. This change is implemented per Act 44 of 2021 and will be continually reviewed as detailed in § 1151a.27(a)

One commentator requested that the Department, in conjunction with the 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 this final-form rulemaking. Substantial changes have been made, as previously explained, 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 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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

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 temporary Chapter 1161 (relating to dispensaries—temporary regulations). New sections and amendments to sections of the temporary regulations are discussed more fully as follows.

§ 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 18 years of age, 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 temporary § 1161.22 (relating to dispensaries generally), except for amending a citation in subsection (b)(1) to refer to Chapter 1141a. No comments were received on this section and no changes were made from the proposed rulemaking to this final-form rulemaking.

§ 1161a.23. Dispensing medical marijuana products

This section details dispensing requirements, consistent with section 801 of the act. As proposed, this section mirrored temporary § 1161.23 (relating to dispensing medical marijuana products). Subsection (a) is amended, to comport with Act 44 of 2021, which allows for curbside delivery. See 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 amended in this final-form rulemaking 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 deletion 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 delete. See 35 P.S. § 10231.801(f).

One commentator requested that the Department amend 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 amend subsection (c)(4) to delete 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 amend 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, 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. At the proposed rulemaking state, this section mirrored temporary § 1161.24 (relating to limitations on dispensing). Subsection (a)(3) is amended in this final-form rulemaking to incorporate changes made to section 1201 and section 1202 (35 P.S. § 10231.1202) 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*. See 35 P.S. §§ 10231.1201 and 10231.1202.

Subsection (b) is amended in this final-form rulemaking to reflect statutory amendment in Act 44 of 2021 to a 90-day supply. See 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 amended 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. See 35 P.S. § 10231.801(d)(1).

One commentator sought to delete (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, 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 amended in this final-form rulemaking to reflect amendments 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. See 35 P.S. § 10231.801(b).

Subsection (b) was amended at the proposed rulemaking 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 instead 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 amended in this final-form rulemaking 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 rulemaking 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 2 years that includes relevant yearly updates of any amendments, announcements and the like. 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. It also provides that individuals under 18 years of age 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 the temporary rulemaking to the proposed rulemaking. A comment from IRRC indicated that the phrase "as approved" by the Department in subsection (a) constituted non-regulatory language. Therefore, in this final-form rulemaking, the phrase is replaced with "that has been inspected and deemed operational" by the Department. Subsection (a) is further amended to comport with Act 44 of 2021, which allows for curbside delivery. See 35 P.S. § 10231.802(a)(1).

At the proposed rulemaking stage, subsection (b)(1) was amended 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 18 years of age, 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. See 35 P.S. § 10231.802(b).

The Department received a comment of general opposition to the regulatory packet, raising a myriad of questions regarding safety. One 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 daycare 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) and 10231.2104. As protections are already provided in the act and this final-form rulemaking, the Department takes no action in response to this request.

Subsection (e)(1) was amended at the proposed rulemaking stage to replace the word "visitors" with "individuals." This amendment deletes references to "visitors," as discussed elsewhere in this preamble.

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

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—that is, paper versus 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 amend 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 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 amends temporary § 1161.27, as detailed as follows.

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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

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 this 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 the proposed rulemaking 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 delete the industrial hemp exclusion from the definition of marijuana, this subsection is amended in this final-form rulemaking to delete 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 growers/processors to offer hemp-based CBD products to be sold in dispensaries. In accordance with the statutory changes implemented by Act 44 of 2021, growers/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 deleted the prohibition on advertising activities, as that provision caused confusion. The deletion 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 amended, at the proposed rulemaking stage, 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 rulemaking stage. These amendments 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 the proposed rulemaking to this final-form rulemaking.

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—that is, 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 amendment 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 deleted. 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 (relating to items and services provided at a dispensary) 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(i) of the act. This section mirrors temporary § 1161.28 (relating to labels and safety inserts) with two exceptions, as detailed as follows.

Subsection (c)(6) and (15) were amended at the proposed rulemaking 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 amendments 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 in this final-form rulemaking 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 deleted from subsection (c)(14) and is replaced with "a process lot identification number." This additional information is the only other labeling requirement under § 1151a.34 (relating to packaging and labeling of medical marijuana products) that does not currently appear in subsection (c). Subsection (e)(6) is deleted from this final-form rulemaking 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 delete 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 amendment. 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 is incorporated in § 1151a.34(b).

Some commentators, including IRRC, sought deletion 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 delete. See 35 P.S. § 10231.303(b)(8). As previously indicated, a clarifying definition of "species" is 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 commentors, 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 time frame. 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 temporary § 1161.29 (relating to plans of operation) with two exceptions, as detailed as follows.

At the proposed rulemaking stage, subsection (a)(2)(ii) replaced the word "visitors" with "individuals requiring access to the facility." This amendment is to delete references to "visitors" wherever possible, as discussed elsewhere in this preamble. Additionally, subsection (c) was added at the proposed rulemaking 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 the proposed rulemaking to this final-form rulemaking.

§ 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 as follows.

Title.

Temporary § 1161.30 is entitled: "Visitor access to dispensary facilities." At the proposed rulemaking stage, the title was changed to: "Access to dispensary facilities." This change deletes the term "visitor" to emphasize that dispensaries are not open for general visitation.

Subsection (a).

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 18 years of age 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 18 years of age 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 amendment and to continue allowing minor children to accompany parents or guardians in the dispensary. Accordingly, subsection (a) is amended in this final-form rulemaking to revert to the language contained in the temporary provision.

Subsection (b).

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

Subsection (c).

Temporary subsection (c) provides that "visitors" must present a government-issued photo identification to enter a dispensary. At the proposed rulemaking stage, this subsection eliminated the word "visitor" consistent with the Department's deletion of the term "visitor" from this final-form rulemaking. The new language clarifies that the subsection applies to an 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 in this final-form rulemaking 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 § 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 amended in this final-form rulemaking 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 onsite, 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, proposed subsection (d) amended temporary subsection (d) to replace the term "visitor" with "individual." No additional changes were made from the proposed rulemaking to this final-form rulemaking.

One commentator objected to this subsection's requirement that an individual's name and company name be listed on a temporary identification badge. After consideration, the Department declines to adopt the requested amendment. 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 amendment 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 4 years and questioned whether the log could be maintained electronically. In response, the Department reduces the storage requirement in this final-form rulemaking to 1 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 (relating to access to dispensary facilities) 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 the proposed rulemaking 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 the proposed rulemaking stage to this final-form rulemaking.

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. At the proposed rulemaking stage, the only change to the language of temporary subsection (d) was the replacement of the word "visitor" with "individual," consistent with the rationale previously explained. No comments were received on this subsection and no changes were made from the proposed rulemaking to this final-form rulemaking.

§ 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 as follows.

In this final-form rulemaking, per comments from IRRC regarding the use of non-regulatory language, the phrase "at least" in subsection (a)(1)(viii) and (2)(ii) is replaced with "no less than." For the same reason, the phrase "at least" is deleted from subsections (b)(3) and (c). Subsection (b)(3) is further amended in this final-form rulemaking, 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 4 years, will be minimal.

Subsection (a)(2) is amended in this final-form rulemaking to require "continuous" surveillance per the statutory change made in Act 44 of 2021. See 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 2 years. The storage requirement is reduced to 180 days, unless otherwise required for investigative or litigation purposes, per Act 44 of 2021. See 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 delete 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—that is, 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 amended at the proposed rulemaking 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 amendment 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 amended at the proposed rulemaking 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 amended at the 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 delete the § 1161a.31(d) (relating to security and surveillance) requirement in 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 amending 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 this final-form rulemaking 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 temporary § 1161.32 (relating to inventory data). No comments were received on this subsection and no changes were made from the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 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 temporary § 1161.33 (relating to storage requirements), except for amending a citation in subsection (a) to refer to Chapter 1151a (relating to growers/processors). No comments were received on this subsection and no changes were made from the proposed rulemaking to this final-form rulemaking.

§ 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. At the proposed rulemaking stage, this section mirrored temporary § 1161.34 (relating to sanitation and safety in a facility), 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 the proposed rulemaking to this final-form rulemaking.

§ 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.

At the proposed rulemaking stage, 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 these 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 rulemaking. Accordingly, subsection (b)(1) is amended in this final-form rulemaking to mirror the temporary provision. However, subsection (d) is amended in this final-form rulemaking 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 amended at the proposed rulemaking stage to require transport vehicles to maintain current State inspection and vehicle registrations, whereas the temporary rulemaking required current vehicle registration and the display of a State inspection sticker. This amendment 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 5 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 5 years.

Per comments from IRRC regarding the use of non-regulatory language, the phrase "at least two" in subsection (c) is replaced with "two or more." For the same reason, the phrase "at least" is deleted from subsection (c)(1) and the phrase "in a form and manner prescribed by the Department" is deleted from subsections (f) and (g) in this final-form rulemaking.

§ 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. At the proposed rulemaking stage, subsection (c) requires all medical marijuana products be transported in a secure lockbox located within a locked cargo area, whereas the temporary rulemaking required that the product be packaged in a shipping container. As previously indicated, multiple public comments were received regarding the unnecessary cost associated with this new requirement. Upon careful consideration, the Department agrees to further amend the language in this final-form rulemaking to mirror temporary § 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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

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 amendment. To allow for medical marijuana organizations to manually tamper with the information in the transport manifest allows for possible diversion or unaccounted for medical marijuana products, or both. 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.

Temporary subsection (a) provides that a dispensary must refuse acceptance of a delivery in the event of any discrepancy in the transport manifest. In the proposed rulemaking, subsection (a) requires a dispensary to refuse delivery only when the discrepancy has not been resolved. This amendment 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 deleted from subsections (a) and (b) in this final-form rulemaking. No other changes were made from the proposed rulemaking to this final-form rulemaking.

§ 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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

Some commentators, reiterated by IRRC, requested that the Department add a procedure to allow patients to report problematic products—that is, seeds, fungus, other problems with products—to the Department. This procedure is already in place. Patients may report information to the Department by means of e-mail 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. 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, provides that a dispensary must use an electronic tracking system prescribed by the Department. At the proposed rulemaking stage, this section mirrored 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 amended in this final-form rulemaking 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. See 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 (35 P.S. § 10231.403(c.1)) allows for practitioners to access the PDMP to review a patient's controlled substance history during a consultation. Adding medical marijuana to the PDMP, however, is prohibited, as cardholder information is deemed confidential under the act. See 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 amendment. 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 amendment 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 commentators as their concerns relate to the use of an API and the potential benefits of safety and efficiency that commentators contend can be realized. As previously indicated, 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 amended, as previously described, to allow the use of API integration under 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 of 2021 allows medical marijuana organization permittees, not laboratories, to establish that gateway. As the requested amendment 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 § 1141a.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 the temporary rulemaking to the proposed rulemaking. In this final-form rulemaking, subsection (f), allowing a dispensary to interchange the designation of a primary, secondary or tertiary location, is added and the title of this section is amended, to effectuate changes made to section 609 of the act by Act 44 of 2021. See 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, and replaces temporary Chapter 1171 (relating to laboratories—temporary regulations). New sections and amendments to sections of the temporary regulations are discussed more fully as follows.

§ 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 web site 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. At the proposed rulemaking stage, this section mirrored temporary § 1171.22 (relating to laboratories generally), except for revising citations in subsection (a) to refer to this new chapter. Subsection (g) is added to this final-form rulemaking to reflect that laboratory testing requirements also apply to harvested hemp under Act 44 of 2021. See 35 P.S. §§ 10231.702(a)(4) and 10231.704.

In this final-form rulemaking, 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, growers/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 growers/processors and laboratories enter into a contract. See 35 P.S. § 10231.704. While the commentator suggests that a noncontractual relationship may allow for better business relationships, legislative change would be required to delete 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 web site. 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.

At the proposed rulemaking stage, this section mirrored temporary § 1171.23 (relating to approval of laboratories), except for amending 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 deleted from 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 the proposed rulemaking to this final-form rulemaking.

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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 1171a.25. Renewal of an approval issued to a laboratory.

This section provides the time frame in which an approved laboratory must submit an application for renewal. At the proposed rulemaking stage, this section mirrored temporary § 1171.25 (relating to renewal of an approval issued to a laboratory), except for revising a citation to refer to this new chapter. Changes were not made in this final-form rulemaking.

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 2 years. See 28 Pa. Code § 1171a.22. As to the second question, growers/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

At the proposed rulemaking stage, this section mirrored 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 1 year.

Revisions are made in this final-form rulemaking to reflect changes made to section 704(b) of the act by Act 44 of 2021. See 35 P.S. § 10231.704(b). Subsection (a) is amended to provide that a grower/processor shall retain a sample from each process lot in an amount sufficient to perform stability testing to ensure product potency and purity and maintain documentation to support the expiration date. Subsection (b) is amended to reflect that stability testing will be done at 6-month intervals if the product remains in inventory at a dispensary. Subsection (c) is amended 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 1 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 6-month and 12-month intervals and the need to perform stability testing under subsection (c) if a product is no longer in inventory. As previously explained, the act has been amended to require stability testing at 6-month intervals as long as unexpired product remains in inventory. See 35 P.S. § 10231.704(b).

With the previously stated reasoning provided, the Department is unable to delete 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 growers/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, growers/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. At the proposed rulemaking stage, this section mirrored temporary § 1171.27 (relating to sampling procedures for testing).

In this final-form rulemaking, per comments from IRRC regarding the use of non-regulatory language, the phrase "at a minimum" is deleted 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 incorporated testing methods and standards into this final-form rulemaking. Subsection (b)(2) is amended in this final-form rulemaking to reflect that samples must be representative of the harvest batch, harvest lot or process lot. Subsection (b)(3) is added to this final-form rulemaking to address that the amount being deleted 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 amends 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 amended § 1171a.29 in this final-form rulemaking.

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 Pharmacopeia'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. At the proposed rulemaking stage, this section mirrored temporary § 1171.28 (relating to selection protocol for samples). Subsection (c)(4) is added in this final-form rulemaking under Act 44 of 2021. See 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 amended in this final-form rulemaking 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. This final-form rulemaking also permits 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 Annex A 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. See 35 P.S. § 10231.704(a).

§ 1171a.29. Testing requirements

This section details testing requirements. Several changes are made to temporary § 1171.29 (relating to testing requirements), as detailed as follows.

Subsections (a) and (b).

These subsections provide that an approved laboratory must have a written contract with a grower/processor prior to conducting testing and submit a request for testing through the electronic tracking system. No changes were made to these subsections from the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

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 the proposed rulemaking 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 amended in this final-form rulemaking by deleting the phrases "at a minimum" and "as prescribed by the Department." Subsection (c)(3) is also added in this final-form rulemaking 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-form 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 amended section 704 to require a grower/processor to contract with "one or more independent laboratories" to test medical marijuana. See 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 the Commonwealth's Medical Marijuana Program has not seen wide-spread 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 these 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. In the proposed rulemaking, these subsections mirrored the temporary regulatory provisions.

In this final-form rulemaking, per comments from IRRC regarding the use of non-regulatory language, the phrase "at a minimum" is deleted from subsection (d) and "heavy metals" and "mycotoxins" are added in subsection (d)(7) and (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 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 specifies tracking and disposal requirements. Temporary subsection (g) required that all tests be entered into the electronic tracking system. At the proposed rulemaking stage, 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 is further amended in this final-form rulemaking 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 in the proposed rulemaking stage to refer to this new chapter and Chapter 1151a.

One commentator queried as to why growers/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 due to requests from the growers/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. See 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. At the proposed rulemaking stage, this section mirrored temporary § 1171.30 (relating to standards for testing). In this final-form rulemaking, 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 deleted.

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 temporary § 1171.31 (relating to test results and reporting), as detailed as follows, in addition to changing citations to reflect this new chapter and Chapter 1151a.

Subsection (a).

This subsection lists the tests to which the testing requirements of the chapter apply: testing on harvest lots and process lots. At the proposed rulemaking stage, 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) (relating to forms of medical marijuana), proper sanitary techniques and recording methods, subsection (a)(2) is amended in this final-form rulemaking to delete "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 the proposed rulemaking stage to clarify that only test samples collected under temporary § 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) is amended in this final-form rulemaking to account for the addition of non-mandatory testing under temporary § 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 growers/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 growers/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).

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, paragraph (2) requires a different laboratory to confirm that passing test. Paragraph (3) requires disposal of the sample if the Department declines to accept the confirming results. At the proposed rulemaking stage, this subsection mirrored the temporary provision, except for adding the term "confirming" to paragraph (3) as a grammatical clarification and amending citations to refer to this new chapter and new Chapter 1151a.

In this final-form rulemaking, subsection (c)(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. See 35 P.S. § 10231.702(a)(3). This language is added under 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 this final-form rulemaking 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. See 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 delete 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 growers/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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

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 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.

In this final-form rulemaking, per comments from IRRC regarding the use of non-regulatory language, the phrases "as determined by the Department" in subsection (e)(1) and (2) are deleted. Subsection (e)(1) is amended to include "approved" and paragraph (2) is amended 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 amended 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 delete the testing of those cannabinoids found in subsection (e)(1)(vii), (viii) and (x) reasoning that only the remaining cannabinoids should require listing. After consideration, the Department declines to add 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 added subsection addresses the approved laboratories' duty to immediately report to the Department as it relates to pesticides. Subsection (f)(1) provides the limit of quantification for pesticides. Subsection (f)(2) the sample size to analyze for residual pesticides.

Subsection (g).

This 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 (relating to laboratories). 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 temporary § 1171.32 (relating to quality assurance program). In this final-form rulemaking, per comments from IRRC regarding the use of non-regulatory language, subsection (a) is amended 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 temporary § 1171.33 (relating to transporting samples), except for amending citations in subsection (a) to refer to Chapter 1151a.

In this final-form rulemaking, in response to a public comment requesting clarification, "process lot" is deleted 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 5 hours should have additional staffing. After consideration, the Department declines to add 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 delete "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 7 days or sooner if requested by the Department. No comments were received on this section and no changes were made from the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 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 as follows.

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 amended to only pertain to samples collected under § 1171a.28(c). In this final-form rulemaking, this subsection is further amended to account for the addition of non-mandatory testing under temporary § 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 subsection (a)(3)—(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 4 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) is 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 growers/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 growers/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 growers/processors are not conducting numerous tests on the same lot until it achieves passing results. Moreover, section 301(a)(4)(iv) of 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." See 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 amendment 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 e-mail" is added to subsection (b)(1). A dedicated e-mail 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 subsection 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 onsite, 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 temporary § 1171.36 (relating to advertising). No changes were made from the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

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. In this final-form rulemaking, "postharvest plant material" is added to paragraph (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 2 Pa.C.S. §§ 501—508 (relating to practice and procedure of Commonwealth agencies) and its accompanying regulations, as modified by Chapter 1230a. As proposed, this section mirrored temporary § 1171.38 (relating to appeals), except for amending a citation to refer to new Chapter 1230a. No comments were received on this section and no changes were made from the proposed rulemaking to this final-form rulemaking.

Chapter 1181a. Physicians and Practitioners

This chapter, which tracks sections 401—405 of the act (35 P.S. §§ 10231.401—10231.405), pertains to practitioner registration, training requirements and prohibitions, issuance and revocation of patient certifications. This chapter replaces temporary Chapter 1181 (relating to physicians and practitioners—temporary regulations). New sections and amendments to sections of the temporary regulations are discussed more fully as follows.

IRRC reiterated a commentator who stated that terms "practitioner" and "physician" appear to be used interchangeably in the regulations and asked the Department to review the use of both terms throughout this final-form 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." See 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 this final-form rulemaking 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 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 temporary § 1181.22 (relating to practitioners generally), except for amending 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 Board has already created that process. No changes were made from the proposed rulemaking to this final-form rulemaking.

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, the Department agrees. Those requirements can be found in § 1181a.24 (relating to practitioner registration). 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 temporary § 1181.23 (relating to medical professionals generally), except for amending a citation in subsection (b) to refer to this new chapter. No changes were made from the proposed rulemaking to this final-form rulemaking.

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, the Department agrees. Those requirements can be found in § 1181a.25 (relating to practitioner registry). 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 amend subsection (c) to allow for e-mail 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—that is, 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 e-mail 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 temporary § 1181.24 (relating to physician registration), except for clarifying reorganization and amendment of a citation in subsection (c) to refer to this new chapter. This section as currently written in the temporary regulation implies 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 the proposed rulemaking stage to subsection (a). Additionally, temporary subsection (a)(2) was deleted, and subsection (c) was amended to clarify that the Department determines approval to issue patient certifications based on the information submitted in the application. Finally, temporary subsection (c) was amended 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.

In this final-form rulemaking, in response to a public comment, the Department amends the title of this section to mirror the title of practitioner registration, the title of section 401 of the act. See 35 P.S. § 10231.401. Further, per comments from IRRC regarding the use of non-regulatory language, the phrase "at a minimum" is deleted from subsection (b). No additional changes were made from the proposed rulemaking to this final-form rulemaking.

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 (35 P.S. § 10231.402). 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 this Commonwealth 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 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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 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. At the proposed rulemaking stage, this section mirrored temporary § 1181.26 (relating to denial, revocation or suspension of a practitioner registration), except for amending a citation in subsection (c) to refer to this new chapter. No changes were made from the proposed rulemaking to this final-form rulemaking.

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) (relating to rights of patients), 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, 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. At the proposed rulemaking stage, this section mirrored temporary § 1181.27 (relating to issuing patient certifications).

In this final-form rulemaking, per comments from IRRC regarding the use of non-regulatory language, the phrase "and any other factor deemed relevant by the practitioner" is deleted from subsection (a)(1). In its place, subsection (a)(1.1) is added to include the statutory requirement for the patient to be under the practitioner's continuing care for the serious medical condition. See 35 P.S. §§ 10231.403 and 10231.103. The Department additionally deletes the phrase "at a minimum" from subsection (c) as it constitutes non-regulatory language.

The Department received a comment seeking to delete 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 subsection (d)(1) and (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. See 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 e-mail address. A similar provision found in section 403(b)(1) of 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. See 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 section 302(a)(2) of 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 delete "if the records are available for review" from subsection (a)(2)(i). After consideration, the Department declines to adopt the requested amendment, 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 subsection (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 add 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. 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 this final-form rulemaking 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 by means of telemedicine, which would allow for this 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 by means of 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. At the proposed rulemaking stage, 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 IRRC, questioned the limitation in this subsection on a practitioner's modification of a patient certification within the first 30 days of issuance, which limits practitioners from correcting any mistakes. In response, subsection (a) is amended in this final-form rulemaking to delete the limitation and allows modification of a patient certification at any time after issuance and before expiration.

One commentator requested a 2-year duration for patient certifications as opposed to the current 1-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. See 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 amend this obligation as the act explicitly requires the practitioner to provide the certification to the patient. See 35 P.S. § 10231.403(d)(1).

§ 1181a.29. Revocation of a patient certification

Consistent with section 401 of the act, 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 this 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 temporary § 1181.29 (relating to revocation of a patient certification). No changes were made from the proposed rulemaking to this final-form rulemaking.

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 (35 P.S. § 10231.2103(a)(3)) 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.

§ 1181a.30. Prescription drug monitoring program

Consistent with section 403 of the act, 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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 1181a.31. Practitioner prohibitions

Consistent with section 402 of the act, 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 the proposed rulemaking stage, subsection (g) was added, prohibiting a practitioner from charging patients excessive fees. The Department added this amendment 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—422.53), 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 under § 1181a.26(a). As proposed, this section mirrored temporary § 1181.31 (relating to practitioner prohibitions), except for adding subsection (g).

The Department received a comment seeking to delete 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. See 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 this final-form rulemaking 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 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 or the Osteopathic Medical Practice Act 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 under § 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 costconcerns. This prohibition is found in section 403(e) of the act. See 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 this section specifies those individuals who must complete a 4-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 web site a list of approved training providers. As proposed, this section mirrored temporary § 1181.32 (relating to training), except for amending a citation in subsection (a) to refer to this new chapter.

In this final-form rulemaking, per comments from IRRC regarding the use of non-regulatory language, the phrase "at a minimum" is deleted 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 amended 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 web site 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 web site at https://www.health. pa.gov/topics/programs/Medical%20Marijuana/Pages/ Physicians.aspx. The application can be found at https://www.health.pa.gov/topics/Documents/Programs/Medical%20Marijuana/DOH%20-%20Application%20for%20 Approval%20to%20Provide%20a%204-hour%20Training %20Course%20in%20the%20Medical%20Marijuana%20 Program.pdf.

One commentator sought to require medical professionals to retake the 4-hour training every 2 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 2 Pa.C.S. §§ 501—508 and its accompanying regulations, as modified by Chapter 1230a of this final-form rulemaking. At the proposed rulemaking stage, this section mirrored temporary § 1181.33 (relating to appeals), except for amending a citation to reflect Chapter 1230a. No comments were received on this section and no changes were made from the proposed rulemaking to this final-form rulemaking.

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 temporary Chapter 1191 (relating to patients and caregivers—temporary regulations). New sections and amendments to sections of the temporary rulemaking are discussed more fully as follows.

§ 1191a.22. Patient and caregiver registry

Consistent with section 302 of the act 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 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 the proposed rulemaking to this final-form rulemaking.

§ 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 21 years of age 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 temporary § 1191.23 (relating to patients and caregivers generally), except for amending a citation in subsection (b) to refer to this new chapter. No changes were made from the proposed rulemaking to this final-form rulemaking.

The Department received a comment of general opposition to the regulatory packet, raising myriad questions regarding safety. One 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 this final-form rulemaking, 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—Federal and State—have determined that section 2103 of the act confers a private right of action for individuals alleging this 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. This 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 subsections (c) and (d)(3), the Department opted to delete both provisions entirely.

§ 1191a.24. Medical marijuana cardholder responsibilities

This section details cardholder responsibilities. Changes to temporary § 1191.24 (relating to medical marijuana cardholder responsibilities) are detailed as follows.

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 this capacity for the patient; and (5) a decision by patient to discontinue treatment from the practitioner who issued the patient certification. At the proposed rulemaking stage, subsection (a) was amended to correct a typographical error (changing "withdraw" to "withdrawal") and to change a citation in subsection (a)(2) to refer to new § 1181a.29 (relating to revocation of a patient certification). No changes were made from the proposed rulemaking to this final-form rulemaking.

Subsection (b).

At the proposed rulemaking stage, subsection (b) was replaced in its entirety and the temporary 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 was deleted. Returning the card is not necessary because the card will be deactivated and rendered unusable. Proposed subsection (b) provided that a medical marijuana cardholder must apply for a replacement identification card within 10 business days of discovering the loss or defacement of the identification card. This provision was relocated from 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 the proposed rulemaking to this final-form rulemaking.

§ 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. At the proposed rulemaking stage, 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 in this final-form rulemaking 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. At the proposed rulemaking stage, this section mirrored temporary § 1191.25 (relating to application for, and issuance or denial of, identification cards), except for amending citations throughout to refer to this new chapter and new Chapter 1181a (relating to practitioners).

In this final-form rulemaking, 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 deleted from subsections (a), (b) and (d); in subsection (d)(2) "or other documentation acceptable to the Department" is deleted; the word "promptly" is deleted from subsection (f); and subsections (b)(9) and (d)(10) are deleted as unnecessary. Further, subsection (d)(5) and (6) is amended to reflect removal of the background check requirement for caregiver renewal applications and of the five-patient caregiver cap implemented by Act 44 of 2021. See 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.

Subsections (a) and (b).

Subsections (a) and (b) provide that an applicant may pay no more than one $50 fee in a 12-month period for an identification card, unless the applicant is submitting a renewal application within the same 12-month period or the applicant requires a replacement card, in which case the cardholder will pay $25 for a replacement card. These subsections mirror temporary subsections (a) and (b) and no changes were made from the proposed rulemaking to this final-form rulemaking.

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*. At the proposed rulemaking stage, subsection (c) was amended to eliminate the requirement for the Department to publish these fees every January. No changes were made from the proposed rulemaking to this final-form rulemaking.

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 final-form 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 web site the qualification for financial hardship. At the proposed rulemaking stage, subsection (d) was amended 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 deleted as unnecessary in this final-form rulemaking.

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 this capacity. At the proposed rulemaking stage this section mirrored the temporary provision. In this final-form rulemaking, this section is amended to eliminate background check requirements for caregivers renewing identification cards, per statutory changes made by Act 44 of 2021. See 35 P.S. § 10231.502(b). No comments were received on this section and no changes were made from the proposed rulemaking to this final-form rulemaking.

§ 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. At the proposed rulemaking stage, this section omitted the requirement in temporary subsection (f) that cardholders apply for a replacement card within 10 business days of discovering the loss or defacement of the card, as this requirement was relocated to § 1191a.24(b) (relating to medical marijuana cardholder responsibilities).

In this final-form rulemaking, per comments from IRRC regarding the use of non-regulatory language, subsection (b)(8) is deleted 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. At the proposed rulemaking stage, subsection (a) was amended 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 amended to refer to Chapter 1181a (relating to physicians and practitioners).

Subsection (c) is added in this final-form rulemaking 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. See 35 P.S. § 10231.502(b). No comments were received on this section and no changes were made from the proposed rulemaking to this final-form rulemaking.

§ 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 these instances, 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 § 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. At the proposed rulemaking stage, subsection (c) was amended 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 previously explained. Additionally, citations were amended, at the proposed rulemaking stage, throughout this section to refer to Chapter 1181a.

In this final-form rulemaking, per comments from IRRC regarding the use of non-regulatory language, the phrase "as determined by the Department" is deleted from subsection (a)(3); subsection (a)(5) is amended 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 § 1161a.24, 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. At the proposed rulemaking stage, this section mirrored temporary § 1191.31 (relating to obtaining medical marijuana products from a dispensary), except for amending citations to refer to Chapters 1161a and 1181a.

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. See 35 P.S. § 10231.801(e). There are no changes made from the proposed rulemaking to this final-form rulemaking.

§ 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 years of age, 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. At the proposed rulemaking stage, 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 childcare 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. 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 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. There are no comments on this section and no changes are made from the proposed rulemaking to this final-form rulemaking.

§ 1191a.33. Appeals

This section provides that all actions of the Department under this chapter are governed by 2 Pa.C.S. §§ 501—508, as modified by Chapter 1230a. At the proposed rulemaking stage, this section mirrored temporary § 1191.33 (relating to appeals), except for amending a citation to reflect Chapter 1230a. No comments were received on this section and no changes were made from the proposed rulemaking to this final-form rulemaking.

Chapter 1211a. Clinical registrants and ACRCs

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 temporary Chapter 1211 (relating to clinical registrants and academic clinical research centers—temporary regulations). Consistent with deleting the definition of "certified ACRC" from Chapter 1141a, references to "certified" ACRC are deleted from §§ 1211a.25(b) and (d), 1211a.27(b)—(d), 1211a.27a, 1211a.30(c), 1211a.31(b), 1211a.32—1211a.35. Other amendments to sections of the temporary regulations are discussed more fully as follows.

§ 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 6 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. At the proposed rulemaking stage, this section mirrored the temporary provision.

Subsection (c) is amended in this final-form rulemaking to increase the permissible number of clinical registrants to ten in accordance with Act 44 of 2021. See 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 amended 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. At the proposed rulemaking stage, this section mirrored temporary § 1211.23 (relating to limitation on permits).

In response to IRRC's request to delete non-regulatory language, the phrase "approved by the Department" in subsection (b) is replaced in this final-form rulemaking with "as approved in its application or under § 1161a.40." No other changes were made from the proposed rulemaking to this final-form rulemaking.

§ 1211a.24. Capital requirements

This section outlines the capital requirements for a clinical registrant applicant, which must be affirmed by means of affidavit submitted with the application to become a clinical registrant, along with a release to allow the Department to verify this information. At the proposed rulemaking stage, this section mirrored temporary § 1211.24 (relating to capital requirements), except for amending citations to refer to new chapters. No comments were received on this section and no changes were made from the proposed rulemaking to this final-form rulemaking.

§ 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 web site and in the *Pennsylvania Bulletin*. As proposed, this section mirrored temporary § 1211.25 (relating to certifying ACRCs). Per comments from IRRC regarding the use of non-regulatory language, subsection (c)(8) is deleted in this final-form rulemaking as unnecessary. No other changes were made from the proposed rulemaking to this final-form rulemaking.

IRRC questioned whether the Department is still accepting applications and if this subsection is needed. Act 44 of 2021 increased the number of permissible clinical registrants who partner with ACRCs to ten. 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 nine. Act 44 of 2021 also provides that if the statutory maximum number of approved ACRCs or approved clinical registrants are not approved, the Department shall reopen the application process for the approval of ACRCs and clinical registrants. See 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 revocation of a certification 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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 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 by means of application. This section specifies the information that must be included in an application, some of which is confidential under the RTKL 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. At the proposed rulemaking stage, this section mirrored temporary § 1211.27 (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 ten. See 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 nine. Act 44 of 2021 also provides that if the statutory maximum number of approved ACRCs or approved clinical registrants are not approved, the Department shall reopen the application process for the approval of ACRCs and clinical registrants. See 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 amended 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 deleted 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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 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. At the proposed rulemaking stage, this section mirrored temporary § 1211.28 (relating to request for conversion of an existing permit), except for amending citations to refer to this, and other, new chapters. No comments were received on this section and no changes were made from the proposed rulemaking to this final-form rulemaking.

§ 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 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). At the proposed rulemaking stage, this section mirrored 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 deleted from 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).

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 § 1161a.27(e)(2). Additionally, research conducted under the act must be limited to forms of medical marijuana already approved for use. See definitions of "research program" and "medical marijuana" in § 1141a.21.

§ 1211a.29a. Research initiative

This section is added under Act 44 of 2021, which allows an ACRC, 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. See 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. At the proposed rulemaking stage, this section mirrored temporary § 1211.30 (relating to approval or denial of an application for approval of a clinical registrant), except for amending citations to refer to this and other new chapters and adding a subsection.

In this final-form rulemaking, subsection (c.1) is added under 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 ACRC. See 35 P.S. § 10231.2002(b)(4)(i). No other changes were made from the proposed rulemaking to this final-form rulemaking.

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 6 months of renewal. At the proposed rulemaking stage, this section mirrored temporary § 1211.31 (relating to renewal of approval of a clinical registrant), except for amending a citation to reflect new Chapter 1141a (relating to general provisions).

Per comments from IRRC regarding the use of non-regulatory language, subsection (b)(6) is deleted as unnecessary. There are no other changes made from the proposed rulemaking to this final-form rulemaking.

§ 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. At the proposed rulemaking stage, this section mirrored temporary § 1211.32 (relating to revocation of approval of a clinical registrant), except for amending a citation to refer to this new chapter. No comments were received on this section and no changes were made from the proposed rulemaking to this final-form rulemaking.

§ 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. At the proposed rulemaking stage, this section mirrored temporary § 1211.33 (relating to dispensing and tracking medical marijuana products), except for amending a citation to refer to Chapter 1161a (relating to dispensaries). No changes were made from the proposed rulemaking to this final-form rulemaking.

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 an ACRC established 1 year or more prior to the effective date of the act. No comments were received on this section and no changes were made from the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 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 web site 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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 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 amended in this final-form rulemaking 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. See 35 P.S. § 10231.2002(b)(8). Subsections (c) and (d) are deleted due to the statutory change.

One commentator requested that the Department delete subsections (c) and (d) from this provision. As indicated previously, this change is made due to the statutory change.

The Department received several comments concerned about growers/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 previously, 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 2 Pa.C.S. §§ 501—508 and its accompanying regulations, as modified by Chapter 1230a. At the proposed rulemaking stage, this section amended temporary § 1211.37 (relating to appeals) by adding the language that the accompanying regulations to 2 Pa.C.S. §§ 501—508, as modified by Chapter 1230a, apply to the appeal process. The citation was also amended to refer to Chapter 1230a. No comments were received on this section and no changes were made from the proposed rulemaking to this final-form rulemaking.

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 temporary Chapter 1230 (relating to practice and procedure—temporary regulations). Amendments to sections of the temporary rulemaking are discussed more fully as follows.

§ 1230a.21. Scope

This section provides that this chapter and 1 Pa. Code Part II (relating to 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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 1230a.22. Definitions

This section provides definitions not referenced in § 1141a.21 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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 1230a.23. Docket

This section provides the general duties and address of the docket clerk for the 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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 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 the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 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)—(d) supersede 1 Pa. Code §§ 31.21—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 in this final-form rulemaking.

§ 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 subsections (a)—(g) supersede 1 Pa. Code §§ 35.5—35.7 and 35.20. No comments were received on this section and no changes were made from the temporary rulemaking to the proposed rulemaking to this final-form rulemaking.

§ 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—35.7, 35.20 and 35.35. As proposed, subsection (a) was amended 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 amendment deletes ambiguity relating to timeliness of appeals and removes the possibility for differing time periods for appeal. Further, subsection (b) was amended 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 temporary § 1230.39 (relating to timeliness of Notice of Appeal) 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 the proposed rulemaking to this final-form rulemaking.

One commentator sought clarification on the time frame for an appeal and whether it has been extended due to mail delays. The time frame 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 amended 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 3 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 subsections (a)—(d) supersede 1 Pa. Code § 35.14 (relating to orders to show cause). No changes were made from the proposed rulemaking to this final-form rulemaking.

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. This change, however, is unnecessary. The Department—and, by extension, the courts—are aware of these issues and take these 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)—(e) supersede 1 Pa. Code § 35.37 (relating to answers to orders to show cause). At the proposed rulemaking stage, this section mirrored temporary § 1230.44 (relating to answers to orders to show cause, orders or other petitions filed by the Office), except for amending a citation to refer to this new chapter. No changes were made from the proposed rulemaking to this final-form rulemaking.

§ 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 the proposed rulemaking to this final-form rulemaking.

§ 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 the proposed rulemaking to this final-form rulemaking.

Uncategorized Comments/Responses

One commentator requested the deletion 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." See 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 nonpatients 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 § 1161a.31. As these areas are already monitored, the Department will take no action in response to this comment.

One commentator disagreed with prohibiting patients 18 years of age from entering 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—that is, no zero-cost products). Beyond that isolated area, pricing is solely controlled by the permittees. While the Department has the authority under section 705 of the act (35 P.S. § 10231.705) to implement a pricing cap, the Department hesitates to do so as the establishment of a pricing cap often becomes the pricing floor, that is, 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 this Commonwealth. The Department, however, is unable to add this amendment, as the number of available permits is set by the act itself. See 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—for example, an individual supporting a disabled person—violated discrimination laws against handicapped persons. 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. 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, section 801(i) of the act (35 P.S. § 10231.801(i)) requires dispensing of sealed packages. See 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 (35 P.S. § 10231.902) 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. See 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. See 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 PCC, who represents some, but not all, of the Medical Marijuana Program's permittees. The 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 this final-form rulemaking. The Department continues to have meetings with the PCC regularly. Additionally, all permittees have ongoing access to regional field supervisors and e-mail resource accounts to convey questions and concerns. The Department communicates regularly with permittees. The 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 section 302(a) of the act deems "[a]ll information obtained by the department relating to patients, caregivers and other applicants" confidential. See 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. See 35 P.S. § 10231.701(c). The 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 final-form 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 final-form 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 final-form 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

This final-form rulemaking will impose no additional costs and have no negative fiscal impact upon political subdivisions. Further, this final-form rulemaking does not impose any additional burden of enforcement or review on political subdivisions.

Regulated community

This final-form 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 amended policies regarding facility security and testing and reporting requirements imposed by this final-form rulemaking.

Practitioners will not experience any additional costs because of this final-form rulemaking.

General public

This final-form rulemaking will have no fiscal impact on the general public.

Paperwork Estimates

Commonwealth and the regulated community

This final-form rulemaking imposes no additional paperwork requirements on the Commonwealth or the regulated community.

Local government

This final-form rulemaking imposes no additional paperwork requirements on local government.

General public

This final-form 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 act. Section 301(b) of the act provides the Department with the authority to promulgate all regulations necessary to carry out the provisions set forth in the act. See 35 P.S. § 10231.301(b). Further, under section 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 this Commonwealth, and (2) authority to promulgate all regulations necessary to carry out the provisions of the act. (35 P.S. § 10231.301(a)(3) and (b)).

F. *Effectiveness and Sunset Dates*

This final-form rulemaking will become effective upon publication in the *Pennsylvania Bulletin*. A sunset date has not been 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, 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 October 19, 2022, the final-form rulemaking was deemed approved by the Senate Health and Human Services Committee and the House Heath Committee. Under section 5.1(e) of the Regulatory Review Act, IRRC met on October 20, 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 e-mailing RA-DHMMregulations@pa.gov. Persons with a disability who wish to submit comments, suggestions or objections regarding this final-form rulemaking may do so by using the previously listed number or address. Speech and/or hearing-impaired persons may use the Pennsylvania Hamilton 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), referred to as the Commonwealth Documents Law (CDL) and the regulations promulgated under those sections in 1 Pa. Code §§ 7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

(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 this final-form rulemaking do not enlarge the original purpose of the proposed rulemaking as published under section 201 of the CDL.

(4) The adoption of the regulations is necessary and appropriate for the administration of the act.

J. *Order*

(1) The regulations of the Department at 28 Pa. Code are amended by amending Part IX, Chapters 1131, 1141, 1151, 1161, 1171, 1181, 1191, 1211 and 1230 by deleting §§ 1131.1—1131.7, 1141.21—1141.52, 1151.21—1151.45, 1161.21—1161.41, 1171.21—1171.39, 1181.21—1181.34, 1191.21—1191.34, 1211.21—1211.37 and 1230.21—1230.46 and adding Part IXa, Chapters 1141a, 1151a, 1161a, 1171a, 1181a, 1191a, 1211a and 1230a specifically §§ 1141a.21—1141a.51, 1151a.21—1151a.40, 1151a.42—1151a.44, 1161a.22—1161a.40, 1171a.22—1171a.38, 1181a.22—1181a.33, 1191a.22—1191a.33, 1211a.22—1211a.37, 1230a.21—1230a.26, 1230a.38, 1230a.39 and 1230a.43—1230a.46 to read as set forth in Annex A.

(2) The Department shall submit this final-form rulemaking 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 rulemaking 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 rulemaking, as approved for legality and form, and shall deposit it with the Legislative Reference Bureau as required by law.

(5) This final-form rulemaking shall take effect upon publication in the *Pennsylvania Bulletin*.

DR. DEBRA L. BOGEN,
Acting Secretary

(*Editor's Note*: See 52 Pa.B. 6941 (November 5, 2022) for IRRC's approval order.)

(*Editor's Note*: See 53 Pa.B. 1179 (March 4, 2023) for a statement of policy that is related to this final-form rulemaking.)

Fiscal Note: Fiscal Note 10-219 remains valid for the final adoption of the subject regulations.

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