Frequently Asked Questions (FAQs) of the Medical Marijuana Final-Form Regulations

The Department of Health (Department) provides the below FAQs to address the programmatic changes resulting from the promulgation of the medical marijuana final-form regulations. The FAQs are sorted by chapter.

Chapter 1141a. GENERAL PROVISIONS

Can an Academic Clinical Research Center (ACRC) receive patient data for research purposes?

ACRCs can now receive de-identified data released by the Department for research purposes. This de-identified data is subject to approval and oversight by the Department and an Institutional Review Board (IRB) to ensure that the use of the data is limited to the specified research purposes. *See* § 1141a.22(f).

When are tax clearance certificates verifying the absence of outstanding tax obligations to the Commonwealth required for an applicant and its principals and other persons affiliated with the applicant?

Tax clearance certificates issued by the Department of Revenue (DOR) and the Department of Labor and Industry (L&I) are required for both initial permit applications and renewal permit applications. Neither initial permit nor renewal permit applications are considered complete without the required tax clearance certificates and will result in a rejection by the Department. *See* § 1141a.27(c).

What if my renewal application was already submitted without tax clearance certificates or principals and affiliates cannot get tax clearance certificates before the renewal period?

Permit renewal applications for 2023 that have already been submitted without the tax clearance certificates will not be rejected solely for that reason. Any permittee who anticipates that it will have difficulty securing the tax clearance certificates within the renewal application period should submit the necessary tax clearance certificate applications to DOR and L&I and provide evidence of those submissions to the Department. Upon receipt, these permittees should provide the Department with the tax clearance certificates as they are returned from DOR and L&I.

This allowance will only apply to 2023 renewal permit applications that cannot receive the tax clearance certificates within the 2023 renewal period prior to the current 2022 permit expiration. Moving forward, permittees should be prepared to provide the required tax clearance certificates as part of the renewal permit application submission.

Is a medical marijuana organization required to report to the Department any change in its diversity plan or community impact plan provided as part of its initial permit application or renewal permit application?

A medical marijuana organization is required to report to the Department any change in its diversity plan or community impact plan. As part of the initial permit applications, applicants provided a diversity plan demonstrating the ability to meet the diversity goals outlined in Section 615 of the Medical Marijuana Act (Act) and a statement summarizing how the applicant intends to positively impact the community where operations are proposed to be located. *See* § 1141a.29. Medical marijuana organizations have an ongoing duty to notify the Department in writing of any change in facts or circumstances reflected in the initial permit application or any permit renewal application submitted to the Department, or any newly discovered or occurring fact or circumstance which would have been included in the application if known at the time the application was submitted. *See* §§ 1141a.36 and 1141a.38.

What if a medical marijuana organization has not implemented aspects of its originally reported community impact commitments?

Medical marijuana organizations that fail to follow through on community impact commitments and likewise fail to report that change to the Department now face suspension or revocation of a permit. Falsification of information on any application submitted to the Department including, but not limited to, failure to follow through on commitments made in the Community impact section of the permit application may result in a suspension or revocation of a permit as well as any other penalty imposed by law for violations of the Act or regulations. *See* § 1141a.47(v).

What diversity information needs to be included as part of the medical marijuana organization's renewal permit application?

As part of the renewal permit application, the medical marijuana organization must report its efforts to meet the diversity goals of the Act and the effectiveness of its

diversity plan provided as part of its initial permit application and subsequent renewal permit applications. *See* 35 P.S. § 10231.615 and §§ 1141a.29(b)(16) and 1141a.32(c). Each annual diversity report from each medical marijuana organization must include information regarding the following, as applicable:

1. Representation of diverse participants in the medical marijuana organization's workforce.
2. Efforts to reach out to and recruit diverse participants for employment, including for executive and managerial positions.
3. Employee retention efforts.
4. A list of all contracts entered into or transactions conducted by the medical marijuana organization for goods or services with diverse groups.

See § 1141a.32(f).

Will the Department provide any feedback on the diversity plan submitted?

Yes. As part of its review, the Department will provide information regarding activities that may be undertaken by the medical marijuana organization to improve its efforts to encourage and promote participation by diverse participants and diverse groups to comply with the diversity goals of the Act. *See* § 1141a.32(h).

Can an individual with a felony conviction hold a volunteer or employment position with a medical marijuana organization or clinical registrant under any circumstances?

A financial backer, principal or employee may not hold a volunteer position, position for renumeration or otherwise be affiliated with a medical marijuana organization or a clinical registrant if the individual has been convicted of a **felony** criminal offense relating to the manufacture, delivery or possession with intent to manufacture or deliver a controlled substance in violation of the Act of April 14, 1972 (P.L. 233, No. 64), known as the Controlled Substance, Drug, Device and Cosmetic Act, or similar law in any other jurisdiction **unless**: 10 or more years have passed since the entry of a final disposition of the felony conviction, or one year has passed since the individual's release from imprisonment for the felony conviction, whichever is later. *See* § 1141a.31(d).

When can an employee begin working at a medical marijuana organization?

An individual may begin employment at a medical marijuana organization **in a supervised capacity** once the medical marijuana organization submits proof to the Department that the individual's fingerprints have been obtained for background check purposes. Upon receipt of the individual's background check, the Department will notify the medical marijuana organization on the individual's affiliation approval status. If the individual does not meet the affiliation requirements, they must be immediately terminated from the medical marijuana organization. *See* § 1141a.31(b.1).

Can a medical marijuana organization request a change of the location of a grower/processor or dispensary facility identified in an initial permit application before it becomes operational?

A medical marijuana organization may submit a request to change the location of a non-operational facility to the Department. However, because the initial permit applications are scored based upon the location(s) provided within the application itself, any successful applicant's attempt to relocate before operationalizing the location undercuts the application and scoring process, so the Department will review a request to change the location of a non-operational facility based upon individual circumstances and the following factors:

1. Inability to operationalize the location due to circumstances beyond the permittee's control unless the permittee knew, or should have known, of the circumstances prior to selecting the site location.
2. Viability of the permittee, the ability to sustain the permitted location, or both, is at risk.
3. Whether impact on patient access to medical marijuana, resulting acquisition costs of medical marijuana in this market, or both may be excessive.

See § 1141a.40.1(a)

Can a medical marijuana organization relocate its non-operational facility to any medical marijuana region as provided in § 1141a.24?

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. *See* § 1141a.40.1(b).

Are medical marijuana organizations required to submit reports to the Department?

Yes. At the end of the first 12-month period following the issuance of a permit, and as of the end of each 3-month period thereafter, the following quarterly reports must be submitted:

1. In the case of a grower/processor:
   (i) The number of medical marijuana products sold by the grower processor to dispensaries during the period for which the report is being submitted.
   (ii) The average price per unit of medical marijuana products sold by the grower/ processor to a medical marijuana organization.
   (iii) The number or amount of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products sold by the grower/processor to other grower/processors during the period for which the report is being submitted.
2. In the case of a dispensary:
   (i) The number of medical marijuana products purchased by the dispensary during the period for which the report is being submitted.
   (ii) The average price per unit of medical marijuana products purchased by the dispensary.
   (iii) The average price per unit of an amount of medical marijuana products dispensed to a patient or caregiver by the dispensary.

See § 1141a.46(a).

The Department may also require ongoing reporting of operational and financial information and any reports necessary to carry out its responsibilities under the Act and regulations. *See* §§ 1141a.46(c) and (d).

Will the reported information be publicly accessible?

The Department will aggregate the information in the quarterly reports submitted by medical marijuana organizations under § 1141a.46(a) and post the information on the Department 's website. *See* § 1141a.46(b).

Can a medical marijuana organization be sanctioned for failure to comply with an executed labor peace agreement submitted with the permit application?

Yes. In addition to any other penalty imposed by law for violations of the Act or regulations, the Department may suspend or revoke a permit if the medical marijuana organization submitted falsified information on any application submitted to the Department. Failure to comply with an executed labor peace agreement submitted with the permit application is one non-exclusive example of a falsification that may result in a suspension or revocation of the permit. *See* 1141a.47(a)(1)(v).

Chapter 1151a. GROWERS/PROCESSORS

When can a grower/processor obtain and transport seeds or immature medical marijuana plants from outside of this Commonwealth?

Grower/processors may obtain seeds or immature medical marijuana plants from outside of this Commonwealth within 30 days from the date that the grower/processor is deemed operational by the Department; between December 1 and December 30 annually; or within an additional 30-day window requested in writing by a grower/processor and approved by the Department. *See* § 1151a.24(a).

What is the process for requesting an additional 30-day window?

A grower/processor may make a written request to the Department to open an additional 30-day window for the importation of seeds or immature medical marijuana plants at least 60 days before the proposed start date. The **written** request must provide a justification for the importation of additional seeds or immature medical marijuana plants including, but not limited to, the need to refresh or improve genetics, patient demand, and the need to ensure ample supply of product. The written request must state the starting and ending date of the 30-day window being requested. *See* § 1151a.24(a)(1)-(4).

How will the grower/processor know if the additional 30-day window request is approved?

The Department will provide written notice to the requesting grower/processor no later than 30 days prior to the proposed start date. *See* § 1151a.24(a)(5).

When does the grower/processor need to record the seeds or immature medical marijuana plants into the electronic tracking system obtained during a 30-day window?

The grower/processor is required to record each seed or immature medical marijuana plant that enters the site during any 30-day period into the electronic tracking system within 24 hours of receipt. *See* § 1151a.24(c).

Is a grower/processor permitted to obtain and transport bulk postharvest medical marijuana plant material?

Yes. A grower/processor may obtain and transport bulk postharvest medical marijuana plant material from another grower/processor within this Commonwealth to process medical marijuana. *See* § 1151a.24(e). Postharvest plant material is defined in § 1141a.21 as "all unfinished plant and plant-derived material, whether fresh, dried, partially dried, frozen or partially frozen, oil, concentrate or similar byproducts derived or processed from medical marijuana or medical marijuana plants."

Can a grower/processor obtain finished but unpackaged medical marijuana products from another grower/processor to package it for sale?

No. Grower/processors may not obtain finished medical marijuana products from another grower/processor to solely package it for sale. This is not *processing* medical marijuana and does not meet the definition of postharvest plant material.

Is a grower/processor permitted to obtain harvested hemp to process into medical marijuana products?

Yes. A grower/processor may obtain harvested hemp from a person holding a permit issued by the Pennsylvania Department of Agriculture (Dept. of Agriculture) to grow hemp if the hemp received by the grower/processor is subject to the medical marijuana program's laboratory testing requirements. *See* § 1151a.24(f); *See also* 35 P.S. § 10231.704 and Chapter 1171a (relating to laboratory testing requirements); *See also* § 1151a.24(g) (relating to the addition of hemp or hemp-derived additives in medical marijuana products).

Does "harvested hemp" mean a grower/processor can only obtain hemp flower?

No, harvested hemp also includes concentrates, extracts, and other derivatives. Harvested hemp is defined in § 1141a.21 as "**plant material**, certified as hemp by

a [Dept. of Agriculture] approved laboratory, obtained directly from a person holding a permit issued by the [Dept. of Agriculture] to grow or cultivate hemp under the 3 Pa.C.S. Ch. 15 (relating to controlled plants and noxious weeds) by a grower/processor holding a permit under the Act."

As provided by the Dept. of Agriculture, persons holding a permit issued by the Dept. of Agriculture to grow hemp may process their own hemp under their grow permit. You can find further information on what is permitted under a Dept. of Agriculture permit to grow hemp at Hemp (pa.gov).

Does the Dept. of Agriculture's required hemp testing count as the harvest test required under Section 704 of the Act?

No. The Dept. of Agriculture testing certifies the plant as hemp (*Cannabis sativa* L. and any part of the plant with a THC concentration of not more than 0.3% on a dry weight basis). The Act and regulations require harvested hemp obtained by a grower/processor to be subject to harvest testing and process testing by laboratories approved to test medical marijuana in this program. *See* § 1151a.24(f); *See also* 35 P.S. § 10231.704 and Chapter 1171a (relating to laboratory testing requirements).

Who is permitted access to a grower/processor facility?

Grower/processor facilities are not open to the general public. However, individuals who require access to a grower/processor facility for purposes regarding the growing, processing, or testing of seeds, immature medical marijuana plants, medical marijuana plans, medical marijuana or medical marijuana plants or for potential investment or prospective employment may be granted access to a grower/processor facility if subject to the requirements in § 1151a.25(a)-(e). This access should be limited to only those instances when on-site facility access is necessary and cannot be accomplished remotely.

The access requirements do not limit the right of the Department or its authorized agents, State or local law enforcement or other Federal, State or local government officials, from entering any area of a grower/processor site or facility if necessary to perform the governmental officials' functions and duties that pertain to the Act or the regulations. *See* § 1151a.25(g).

Are employees of an approved laboratory required to follow the access requirements under § 1151a.25?

Employees of an approved laboratory entering a grower/processor facility for purposes of identifying and collecting samples for compliance testing under § 1171a.28(a) have access to the limited access areas in a grower/process facility.

However, employees of an approved laboratory may be granted access to grower/process facilities, without collecting compliance samples, for purposes regarding "testing" under § 1151a.25(a), which may include the collection of research and development samples, ongoing account management, and/or aspects of the contractual relationship with the approved laboratory.

Can a grower/processor use motion-activated security and surveillance systems?

No. The security and surveillance system must be operational 24 hours per day, 7 days per week and record **continuously** in images capable of clearly revealing facial detail. *See* § 1151a.26(a)(2) and 35 P.S. § 10231.702(b)(2).

What are the expectations for monitoring the security and surveillance system at the facility?

The grower/processor must designate employees to **continuously** monitor the security and surveillance systems at the facility. The employees should be capable of clearly monitoring all surveillance feeds simultaneously and should not be conducting other operational duties that may distract from continuously monitoring the surveillance system. *See* § 1151.26(b)(5) and 35 P.S. § 10231.702(b)(2).

Is the grower/processor permitted to add any excipients or added substances to medical marijuana?

A grower/processor must obtain written approval from the Department to use any added substances that alters the dosage level, color, appearance, smell, taste, affect or weight of the medical marijuana, and excipients must be pharmaceutical grade, unless otherwise approved by the Department. *See* § 1151a.27(f)

What does the Department consider when determining whether to approve an added substance?

The Department reviews all added substances in accordance with the Act's mandate to provide safe access to medical marijuana products to patients. In

determining whether to approve an added substance, the Department considers the following:

(i) Whether the added substance is permitted by the United States Food and Drug Administration for use in food or is Generally Recognized as Safe (GRAS) under Federal guidelines.
(ii) Whether the added substance constitutes a known hazard such as, but not limited to, diacetyl, CAS number 431-03-8, and pentanedione, CAS number 600-14-6.
(iii) Whether the added substance is permitted by the United States Food and Drug Administration for the applicable route of administration and dosage.
(iv) Whether the added substance has known drug interactions.

See § 1151a.27(f)(i)-(iv).

What are the labeling expectations for cannabinoids?

Product labels are required to list the percentage of THC and CBD even if the percentage is 0.0%. The other cannabinoids provided in § 1151a.29(a)(2), (3), and (5)-(10) are required to be on the label only if greater than 0.0%. Lastly, any other cannabinoid component must be listed on the label if at 0.1%. *See* § 1151a.29(a)(11).

Are grower/processors required to provide the Department with a forecast of the amount of medical marijuana products it projects it will produce?

Yes. The grower/processor must provide the Department with a forecast of the amount and form of medical marijuana products it projects it will produce within the first six months after being deemed operational. *See* § 1151a.29(b).

Are grower/processors required to notify the department of potential increases or decreases in that forecast?

Yes. Grower/processors are required to notify the Department in writing **within 48 hours** upon becoming aware of a potential increase or decrease in the forecasted amount occurring within any subsequent six-month period.

In addition to the cannabinoid labeling requirements, what other packaging and labeling requirements changed? *See* § 1151a.34.

Opaque packages are no longer required for packages containing dry leaf.

The packaging must clearly distinguish the contents of the package from the contents of any other package of similar appearance. Also, the packaging and labeling must list all product ingredients and include a warning for known allergens, such as tree nuts. Food Allergies | FDA.

The label must contain the name and address of the dispensary to which the package is to be sold, except where a clinical registrant sells medical marijuana products to another grower/processor and the intended dispensary is not known. In such case, the grower/processor selling to a dispensary is required to affix a label displaying the dispensary name and address to the outer packaging, notwithstanding the exception for blinded research.

The label must be firmly affixed to the container directly holding medical marijuana product, except when the product is being used for a blinded research program, and be firmly affixed to outer packaging, if used. The label must be affixed to the container holding the medical marijuana product, not the product itself. For example, a vape cartridge is considered the product, not packaging, and therefore, the label should be on the container holding the vape cartridge. To illustrate further, if a grower/processor puts the vape cartridge inside a container, like a tube, and places that tube inside a boxed package, the label should be affixed to the tube that holds the vape cartridge and the outer package.

Have there been any software allowance changes pertaining to the electronic tracking system, such as application programming interface?

The grower/processors must use the electronic tracking system prescribed by the Department containing the requirements in Section 701 of the Act. *See* 35 P.S. § 10231.701. Changes enacted in Act 44 and reflected in the final form regulations, provide that this electronic tracking system is required to allow two-way communication, automation and secure application-programming interface with a medical marijuana organization's enterprise resource planning, inventory, accounting and point-of-sale software. This electronic tracking system is required to include a secure application program interface capable of accessing all data

required to be transmitted to the Department to ensure compliance with the operational reporting requirements. *See* § 1151a.39.

Chapter 1161a. DISPENSARIES

Are dispensaries permitted to allow curbside delivery?

Yes. *See* § 1161a.23(a) and 35 P.S. § 10231.802(a)(1).

The regulations state that medical professionals are responsible for verifying the validity of the patient or caregiver identification card. Does this mean that medical professionals must perform the in-take of the patient?

No. The Department is not asking medical professionals to be the in-take employees. This responsibility requires the medical professionals to verify the patient or caregiver identification card is valid, active and in-date **(not future dated)** PRIOR to any purchase being completed. If the medical professional is working via synchronous interaction, or otherwise not able to view the identification card, it is expected that medical professionals will communicate with dispensary staff to verify the card active date prior to any purchase being completed. No purchases should take place with an invalid or not-yet-active identification card. *See* § 1161a.23(b).

What are the dispensing requirements if a practitioner sets recommendations, requirements, or limitations on the patient certification?

If a practitioner sets forth recommendations, requirements, or limitations as to the form or dosage of a medical marijuana product on the patient certification, the medical marijuana product dispensed to a patient or a caregiver by a dispensary must conform to those recommendations, requirements or limitations. *See* § 1161a.23(b)(2)(i). In other words, dispensing should conform to the limitations and requirements and medical professionals should consider the recommendations.

What are the dispensing requirements if a practitioner does not set forth recommendations, requirements or limitations on the patient certification?

If a practitioner does not set forth recommendations, requirements or limitations as to the form or dosage of a medical marijuana product on the patient certification, the medical professional working at the facility is **required to consult with the patient or the caregiver** regarding the appropriate form and dosage of the medical

marijuana product to be dispensed. The Department believes that all patients, especially first-time patients, can benefit from consulting with a medical professional before engaging in the purchase of medical marijuana products. Patients should be encouraged to consult with the medical professional, not encouraged to waive this valuable resource. *See* § 1161a.23(b)(2)(ii).

Is the medical professional required to update the patient certification in the electronic tracking system?

The medical professionals are required to update the patient certification in the electronic tracking system by entering any recommendation as to the form or dosage of medical marijuana product that is dispensed to the patient. *See* § 1161a.23(b)(2)(iii).

How much medical marijuana product can be dispensed to a patient or caregiver?

The dispensary may not dispense an amount of medical marijuana product greater than a 90-day supply, 192 medical marijuana units, to a patient or caregiver until the patient has exhausted all but a 7-day supply of medical marijuana units provided pursuant to the patient certification currently on file with the Department. *See* § 1161a.24(b).

What is a medical marijuana unit?

A medical marijuana unit is an amount of medical marijuana equivalent to 3.5 grams of dry leaf, one gram of concentrate, or 100 milligrams of THC infused into a pill, capsule, oil, liquid, tincture, or topical form. *See* § 1141a.21.

How will the medical marijuana units be calculated?

The electronic tracking system will automatically track purchases and calculate the medical marijuana patient's total number of medical marijuana units. It will be evident if a purchase would exceed the allowable 90-day supply at the point-of-sale when purchasing because the electronic tracking system will provide notice. Further communications on these calculations will be forthcoming.

Is a dispensary required to have a physician or a pharmacist available, either in person or by synchronous interaction, to verify patient certifications and provide consultations at all times during the hours of operation?

Yes, except when a dispensary is authorized to operate more than one facility under its permit. If there are other dispensary locations under its permit, a physician assistant or a certified registered nurse practitioner may conduct these services at each of the other locations instead of a physician or pharmacist. These medical professionals are permitted to rotate coverage of the facilities provided that a physician or pharmacist is always available, either in person or by synchronous interaction, at one of the facilities. *See* § 1161a.25(b).

Is a medical professional permitted to cover more than one dispensary at once? What about for brief periods of time during consults or lunch breaks?

No. Each distinct dispensary facility location is required to have no less than one dedicated medical professional present, either physically or by synchronous interaction, who is prohibited from covering more than one dispensary facility location regardless of whether in person coverage or synchronous interaction is used. *See* § 1161a.25(b).

The Department clearly defined this 1:1 ratio of medical professionals at each dispensary site after receiving numerous complaints from providers, patients, pharmacists, and other medical professionals concerned about the lack of ability of medical professionals to provide adequate care when multi-tasking to cover multiple locations.

Who is permitted to access dispensary facilities?

Dispensaries are limited access facilities generally accessible only by employees, patients, caregivers, or individuals under the age of 18 accompanied by a parent, guardian, or caregiver. However, an individual who is not approved to enter a dispensary facility may be granted access only to provide goods or services to the facility, to assist a patient with product selection as the certifying practitioner, or for potential investment or employment only when patients and caregivers are not at the dispensary. *See* § 1161a.30(a)-(c). This access should be limited to only those instances when on-site facility access is necessary and cannot be accomplished remotely.

The access requirements do not limit the right of the Department or its authorized agents, State or local law enforcement or other Federal, State or local government

officials, from entering any area of a dispensary if necessary to perform the governmental officials' functions and duties that pertain to the Act or the regulations. *See* § 1161a.30(f).

Why are potential investors or prospective employees only permitted access when patients and caregivers are not at the dispensary?

While the Department understands the business necessity to allow potential investors or potential employees to be on-site, 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.

Do certifying practitioners have any extra requirements to receive access to a dispensary when assisting their patients with product selection?

Yes. The identification of a certifying practitioner must match the name and medical credentials documented on the accompanied patient's certification. *See* § 1161a.30(c).

Can a dispensary use motion-activated security and surveillance systems?

No. The security and surveillance system must be operational 24 hours per day, 7 days per week and record **continuously** in images capable of clearly revealing facial detail. *See* § 1161a.30(a)(2).

What are the expectations for monitoring the security and surveillance system at the dispensary facility?

The dispensary must designate an employee or employees to **continuously** monitor the security and surveillance systems at the facility. The employees should be capable of clearly monitoring all surveillance feeds simultaneously and should not be conducting other operational duties that may distract from continuously monitoring the surveillance system. *See* § 1161a.30(b)(5) and 35 P.S. § 10231.802(a)(1.1).

Have there been any software allowance changes pertaining to the electronic tracking system, such as application programming interface?

A dispensary must use the electronic tracking system prescribed up by the Department containing the requirements in Section 701 of the Act. *See* 35 P.S. § 10231.701. This electronic tracking system is required to allow for two-way communication, automation and secure application-programming interface with a

medical marijuana organization's enterprise resource planning, inventory, accounting and point-of-sale software and allow for accessing all data required to be transmitted to the Department to ensure compliance with the operational reporting requirements of the Act and regulations. *See* § 1161a.39.

Is a dispensary permitted to interchange the designation of a primary, secondary or tertiary location at any time?

Yes. A dispensary may interchange the designation of a primary, secondary or tertiary location at any time, including the period before a location becomes operational, by providing written notice to the Department at least 14 days before the change in designation. A change in designation under this subsection may not be subject to approval of the Department. *See* § 1161a.40(f).

Chapter 1171a. LABORATORIES

Do the medical marijuana laboratory testing requirements apply to harvested hemp?

Yes. Notwithstanding the definitions of "harvest batch," "harvest lot," "medical marijuana extract," "process lot," "processing," "sample," and "test sample," Sections 1171a.22 - 1171a.28 applies to an approved laboratory's testing of harvested hemp. *See* § 1171a.22(g).

Are stability samples required, who retains them, and how are the samples retained?

Samples are required to be retained by the grower/processor in an amount sufficient to perform stability testing from each process lot to ensure product potency and purity. Grower/processors are required to maintain documentation to support the expiration date of the stability sample. *See* § 1171a.26(a).

A grower/processor is required to retain a sample from each process lot for subsequent stability testing, in an amount equivalent to the sample size initially identified and collected by an approved laboratory, for the duration of the expiration period as listed on the medical marijuana product. *See* § 1171a.26(c).

When are stability tests required to be performed?

At six-month intervals for the duration of the expiration date period as listed on the medical marijuana product and once within six months of the expiration date if the medical marijuana product is still in inventory at a dispensary in this Commonwealth as determined by the seed-to-sale system. *See* § 1171a.26(b).

What do the required compliance samples need to be representative of?

Employees of an approved laboratory are required to prepare compliance samples that are representative of the harvest batch, harvest lot or processed lot. *See* § 1171a.27(b)(2).

Is an approved laboratory authorized to test samples other than compliance samples at the request of a grower/processor or the Department?

Yes. An approved laboratory may test samples other than compliance samples at the request of a grower/processor or the Department. If a grower/processor is requesting testing on samples other than for compliance, the laboratory employees are subject to the access requirements of § 1151a.25. *See* §§ 1171a.29 and 1171a.28(a).

Do I currently have to follow the two-laboratory requirement in § 1171a.29(c)?

All grower/processors and approved laboratories were notified that on March 4, 2023, the Commonwealth Court issued an Order temporarily enjoining DOH from enforcing § 1171a.29(c)(1)-(2) of DOH's Regulations (relating to medical marijuana), in *Green Analytics North, LLC d/b/a Steep Hill PA*, et al. v. DOH. The Order grants a stay of the implementation of § 1171a.29(c)(1)-(2) of DOH's Regulations, 28 Pa. Code § 1171a.29(c)(1)-(2), effective immediately and until further order of the Court. Please note that the stay is only applicable to § 1171a.29(c)(1)-(2).

Will an updated laboratory guidance addressing the testing standards and methodologies found in §§ 1171a.29 through 1171a.31 be provided?

The Department is developing laboratory guidance to address what the samples must be tested for based on the American Herbal Pharmacopeia's "Cannabis Inflorescence Standards of Identity, Analysis and Quality Control", 2014 Revision

Edition and the corresponding resources testing standards and methodologies. Further communications on this guidance will be forthcoming.

What happens if a harvest sample or process sample fails testing?

If a sample fails any test required under § 1171a.29, the electronic tracking system quarantines the product. The grower/processor may request the approved laboratory that performed the initial test to retest the sample.

If the retested sample fails, the lot shall be disposed of under § 1151a.40 unless the lot failed only for yeast or mold and the grower/processor chooses to process the lot into a topical form under 702(a)(3) of the Act.

If the sample passes the re-test, then the grower/processor can continue to move forward to release the product from quarantine by having another approved laboratory sample the same harvest batch, harvest lot or process lot to confirm the passing test result.

Based on the considerations in § 1171a.31(c)(2.1) that the Department may require to determine whether to accept the confirming test results and to release the product from quarantine, the Department has created a form to aid the grower/processor in providing all requested materials.

See § 1171a.31(c).

Who maintains oversight of testing methods and sampling standards?

The Department will maintain oversight of testing methods and sampling standards under this chapter. The Department may conduct on-site visits; review certificates of analysis submitted by an approved laboratory; and identify and collect samples from a grower/processor at any time and request an approved laboratory conduct proficiency testing, conduct quality assurance measures, and perform tests under Chapter 1171a. *See* §§ 1171a.31(g) and 1171a.34.

Chapter 1181a. PHYSICIANS AND PRACTITIONERS

Is a practitioner required to report adverse reactions?

Yes. A practitioner must call the dispensary for a patient's adverse reaction to medical marijuana products dispensed by that dispensary immediately upon becoming aware of the reaction. *See* § 1181.22(c).

Is a practitioner permitted to request that a serious medical condition be changed, reduced, or added?

Yes. The Medical Marijuana Advisory Board (Board) allows practitioners to petition the Board to review whether a serious medical condition should be changed, reduced or added to those conditions for which medical marijuana is likely to provide therapeutic or palliative benefit to a patient. *See* § 1181a.22(d).

What are the criteria under which a practitioner may issue a patient certification?

A practitioner may issue a patient certification to the patient if the following conditions are met:

1. The practitioner has determined, based upon a patient consultation that the patient has a serious medical condition and has included that condition in the patient's healthcare record.
2. The patient is under the practitioner’s continuing care for the serious medical condition.
3. The practitioner has determined the patient is likely to receive therapeutic or palliative medical benefit from the use of medical marijuana based upon the practitioner’s professional opinion and review of the following:
    (i) the patient's prior medical history as documented in the patient's health care records if the records are available for review.
    (ii) The patient's controlled substance history if the records are available in the Pennsylvania Prescription Drug Monitoring Program.

See § 1181a.27(a).

Does a practitioner need to wait for 30 days from the date the receipt is entered into the electronic tracking system to modify a patient certification?

No. Practitioners are permitted to modify a patient certification at any time after issuance and before expiration. *See* § 1181a.28(a).

Is a practitioner permitted to advertise as a certifying practitioner?

No. The Act prohibits practitioners from advertising the practitioner's services as a practitioner who can certify a patient to receive medical marijuana products, which was adopted in the regulations. *See* § 1181a.31(c).

Is a practitioner permitted to certify themselves, or a family or household member?

No. Self-certification or certification of a family or household member is not only prohibited by the Act and cause for the Department to take disciplinary actions, but also is deemed unprofessional conduct under the Medical Practice Act, Osteopathic Medical Practice Act and will subject the practitioner to discipline by the State Board of Medicine or the State Board of Osteopathic Medicine, as appropriate. *See* § 1181a.31(d) and 35 P.S. §§ 10231.403(e) and 402(c).

Chapter 1191a. PATIENTS AND CAREGIVERS

If I was approved as a caregiver, do I have to submit fingerprints for a background check every year?

Fingerprints for background checks must be completed by applicants who have not previously been approved by the Department as a caregiver or persons re-applying to be a caregiver after being removed or electing to withdraw from participation in the medical marijuana program. *See* § 1191a.27(a).

Chapter 1211a. CLINICAL REGISTRANTS AND ACADEMIC CLINICAL RESEARCH CENTERS

What is a research initiative?

An ACRC, in coordination with its contracted clinical registrant, may conduct a research initiative on the antimicrobial effects of applying solvent-based extraction methods and processes to microbial contamination of immature medical marijuana

plants, medical marijuana plants, medical marijuana or medical marijuana products.

The ACRC must submit to the Department for approval a completed written research protocol of the planned research initiative. The Department has 15 days from the submission to grant approval or denial of the protocol. The following apply:

1. The research initiative commences no later than 30 days from the date the Department issues approval and is completed no later than six months from the start date of the research initiative.
2. The ACRC must provide the research initiative finding to the Department within 15 days of the research initiative's conclusion.
3. The ACRC and its contracted clinical registrant will present research initiative findings to the Board and the Board's research subcommittee for the Board's review and consideration. The Board shall issue a written report, with recommendations and findings regarding the use of solvent-based extraction methods and processes on microbial contamination by the clinical registrant or grower/processor. The Secretary may approve the Board's recommendation in accordance with Section 1202 of the Act.
4. Prior to implementing a recommendation of the Board, as approved by the Secretary, a clinical registrant or grower/processor must seek approval from the Department for a change in its grower/processor extraction process. The Department must inspect the site and facility equipment. Upon approval, the Department must issue a notice of final approval to implement the process.

See § 1211a.29a and 35 P.S. § 10231.2003.1.