RULES AND REGULATIONS

Title 12—COMMERCE, TRADE AND LOCAL GOVERNMENT

PENNSYLVANIA MINORITY BUSINESS DEVELOPMENT AUTHORITY

[12 PA. CODE CH. 81]

General Provisions

The Pennsylvania Minority Business Development Authority (Authority), under the authority of section 9 of the Pennsylvania Minority Business Development Authority Act (act) (73 P.S. § 390.9), amends §§ 81.111, 81.112, 81.122, 81.124, 81.131, 81.143 and 81.144.

Introduction

The act was promulgated for the express purposes of: (1) alleviating and overcoming the many barriers to business opportunity that have too long handicapped socially and economically disadvantaged persons; and (2) providing assistance, financial and otherwise, which will contribute to well-balanced National and State economies by facilitating the acquisition or maintenance of ownership of business enterprises by persons whose participation in the free enterprise system is hampered because of social or economic disadvantages. See section 2 of the act (73 P.S. § 390.2). The act created the Authority, a body corporate and politic with a 16-member board of directors composed of 4 cabinet officers, 8 persons appointed by the Governor and 4 persons appointed by the General Assembly. In 1975 the Authority promulgated regulations which describe in detail the Authority's lending and financial assistance programs, covering topics such as purpose of the program, eligible applicants and projects, application procedures, amount and terms of loans and other financial assistance, loan closing procedures, default procedures, late charges and the procedures to be used for examinations and investigations conducted by the Authority.

Analysis

This final-form rulemaking amends the regulations that impede the Authority's ability to be responsive and flexible to its target market.

Section 81.111(a)(6) (relating to eligible applicants) is amended to delete the requirement that the applicant shall commit to full time management of the company. Instead, the applicant is required to maintain complete control of the enterprise. This will allow the Authority to fund start-up businesses when the applicant will have another job until the new enterprise can financially support a full-time manager.

To delete the requirement that to be eligible, the applicant shall commit to work full-time in the enterprise for which he is seeking a loan, and if he is otherwise employed shall terminate employment prior to or at the time of closing is deleted from former § 81.111(a)(7). This will also allow the Authority to fund start-up businesses when the applicant will have another job until the new enterprise can financially support a full-time manager.

Section 81.112(a)(3) (relating to eligible projects) is amended to delete the requirement of an escrow account for project funds provided by other sources.

Section 81.122 (relating to applications, review and requirements) is amended to delete the requirement that applications be submitted through the regional offices, which no longer exist.

Section 81.124 (relating to additional conditions) is amended to delete the requirement of credit life insurance and assignments of life insurance policies as loan collateral. Life insurance can be difficult or very expensive to obtain, or both.

Section 81.131 (relating to amount and terms of loans) is amended to delete detailed requirements as to loan amounts, interest rates and job creation criteria. The amendments allow the Authority to establish these parameters through policies to be published from time to time in the *Pennsylvania Bulletin*.

Section 81.143 (relating to late charges) is amended to delete the requirement of a 6.0% monthly late charge.

Section 81.144 (relating to loan closing) is amended to delete the requirement of the use of an escrow fund for loan closings.

The amendments allow the Authority to quickly adapt to changing markets by modifying interest rates, loan terms, minimum and maximum loan amounts, job creation requirements and making changes to program delivery options. By embedding these fundamental elements of financing in regulations, and making them inflexible rules with the force of law, the Authority's program is frozen in its efforts to flex to changing economic conditions and thus unable to be responsive to its target market (businesses owned by socially and economically disadvantaged persons). Viable nonregulatory alternatives exist to deal with these matters, namely guidelines and descriptive application materials.

Comments and Response

Notice of proposed rulemaking was published at 46 Pa.B. 3069 (June 18, 2016), with a 30-day public comment period. No comments were received from the public, the Independent Regulatory Review Commission (IRRC), the House Commerce Committee or the Senate Community, Economic and Recreational Development Committee.

Fiscal Impact

There will be no fiscal impact on the Commonwealth, political subdivisions or the public.

Paperwork

This final-form rulemaking will allow the Authority to set forth procedures and loan parameters in written guidelines and application materials, which can be modified as market forces dictate. The Authority does not foresee new or different paperwork requirements emerging because of this final-form rulemaking.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on June 2, 2016, the Authority submitted a copy of the notice of proposed rulemaking, published at 46 Pa.B. 3069, to IRRC and the Chairpersons of the House Commerce Committee and the Senate Community, Economic and Recreational Development Committee for review and comment.

Under section 5(c) of the Regulatory Review Act, the Authority shall submit to IRRC and the House and Senate Committees copies of comments received during the public comment period, as well as other documents when requested.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on November 16, 2016, the final-form rulemaking was deemed approved by the House and Senate Committees. Under section 5(g) of the Regulatory Review Act, the final-form rulemaking was deemed approved by IRRC effective November 16, 2016.

Effective Date

This final-form rulemaking will be effective March 24, 2017.

Sunset Date

The regulations will be monitored on a regular basis and updated as needed.

Contact Person

For an explanation of this final-form rulemaking, contact Timothy M. Anstine, Deputy Chief Counsel, Department of Community and Economic Development, 400 North Street, 4th Floor, Harrisburg, PA 17120, (717) 720-7312.

Findings

The Authority finds that:

(1) Public notice of intention to adopt the regulation has been given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202) and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) This final-form rulemaking is necessary and appropriate for the Authority's lending program.

Order

The Authority, acting under the authorizing statute, orders that:

(a) The regulations of the Authority, 12 Pa. Code Chapter 81, are amended by amending §§ 81.111, 81.112, 81.122, 81.124, 81.131, 81.143 and 81.144 to read as set forth at 46 Pa.B. 3069.

(b) The Authority shall submit this order and 46 Pa.B. 3069 to IRRC, the House and Senate Committees, the Office of Attorney General and the Office of General Counsel for approval as to legality as required by law.

(c) This order shall take effect March 24, 2017.

CATHY ONYEAKA,
Executive Director

(*Editor's Note*: See 46 Pa.B. 7603 (December 3, 2016) for IRRC's approval.)

Fiscal Note: Fiscal Note 4-99 remains valid for the final adoption of the subject regulations.

[Pa.B. Doc. No. 16-2255. Filed for public inspection December 23, 2016, 9:00 a.m.]

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 1171]

Medical Marijuana; Laboratories; Temporary Regulations

The Department of Health (Department) is publishing temporary regulations in Chapter 1171 (relating to laboratories) to read as set forth in Annex A. The temporary regulations are published under the Medical Marijuana Act (act) (35 P.S. §§ 10231.101—10231.2110). Section 1107 of the act (35 P.S. § 10231.1107) specifically provides that, to facilitate the prompt implementation of the act, the Department may promulgate temporary regulations that are not subject to sections 201—205 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201—1205), known as the Commonwealth Documents Law, the Regulatory Review Act (71 P.S. §§ 745.1—745.14) and sections 204(b) and 301(10) of the Commonwealth Attorneys Act (71 P.S. §§ 732-204(b) and 732-301(10)).

To implement the Medical Marijuana Program, the Department will be periodically publishing temporary regulations regarding various sections of the act. The temporary regulations for laboratories will expire on December 24, 2018.

Chapter 1171 pertains to laboratories that will test medical marijuana in accordance with the act. The next set of temporary regulations that the Department anticipates publishing relate to practitioners, followed by temporary regulations relating to patients and caregivers, and academic clinical research centers.

Interested persons are invited to submit written comments, suggestions or objections regarding the temporary regulations to John J. Collins, Office of Medical Marijuana, Department of Health, Room 628, Health and Welfare Building, 625 Forester Street, Harrisburg, PA 17120, (717) 787-4366, RA-DHMedMarijuana@pa.gov. Persons with a disability who wish to submit comments, suggestions or objections regarding the temporary regulations may do so by using the previous contact information. Speech and/or hearing impaired persons may use V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Service at (800) 654-5984 (TT). Persons who require an alternative format of this document may contact John J. Collins so that necessary arrangements may be made.

KAREN M. MURPHY, PhD, RN,
Secretary

Fiscal Note: 10-202. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

PART IX. MEDICAL MARIJUANA

CHAPTER 1171. LABORATORIES

Sec.

§ 1171.21. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Accreditation body—An organization which:

(i) Certifies the competency, expertise and integrity of a laboratory and operates in conformance with the current version of International Organization Standard ISO/IEC 17011.

(ii) Determines a laboratory's compliance with and conformance to the relevant standards established by the International Organization for Standardization, including ISO/IEC 17025.

(iii) Is a signatory to the International Accreditation Cooperation Mutual Recognition Arrangement for Testing.

(iv) Is not affiliated with a laboratory applicant for which it has or will issue a certificate of accreditation.

Approved laboratory—A laboratory that has applied for, and received, the approval of the Department to identify, collect, handle and conduct tests on samples from a grower/processor and test samples from the Department used in the growing, processing or dispensing of medical marijuana as required by the act and this part.

Certificate of accreditation—A document issued by an accreditation body evidencing that a laboratory is in compliance with International Organization for Standardization Standard ISO/IEC 17025 or other standards relevant to the operation of laboratories conducting tests on medical marijuana and other items used in the growing, processing or dispensing of medical marijuana.

Certificate of analysis—A document that confirms that the test performed by an approved laboratory on a harvest batch, harvest lot or process lot meets the testing requirements set forth by the Department.

Certified registered nurse practitioner—The term as defined in section 2 of The Professional Nursing Law (63 P.S. § 212).

Chain of custody—The written procedures used by employees of an approved laboratory to record the possession and transfer of samples and test samples from the time the samples and test samples are collected until the test of the sample or test sample is completed.

Harvest batch—A specifically identified quantity of medical marijuana plant that is uniform in strain, cultivated utilizing the same growing practices, harvested at the same time and at the same location, and cured under uniform conditions.

Harvest lot—A specifically identified quantity of medical marijuana plant taken from a harvest batch.

Laboratory applicant—A laboratory that submits an application to the Department for approval to identify, collect, handle and test medical marijuana and other items used by a medical marijuana organization in the growing, processing or dispensing of medical marijuana as required under the act and this part for the Department or a grower/processor.

Medical marijuana extract—A substance obtained by separating cannabinoids from medical marijuana plants by a mechanical, chemical or other process.

Medical marijuana product—The final form and dosage of medical marijuana that is grown, processed, produced, sealed, labeled and tested by a grower/processor and sold to a dispensary.

Pharmacist—The term as defined in section 2 of the Pharmacy Act (63 P.S. § 390-2).

Physician—The term as defined in section 2 of the Medical Practice Act of 1985 (63 P.S. § 422.2) and section 2 of the Osteopathic Medical Practice Act (63 P.S. § 271.2).

Physician assistant—The term as defined in section 2 of the Medical Practice Act of 1985 and section 2 of the Osteopathic Medical Practice Act.

Process lot—Any amount of a medical marijuana product of the same type and processed using the same medical marijuana extract, standard operating procedures and the same or combination of different harvest lots.

Processing—The compounding or conversion of medical marijuana extract by a grower/processor into a medical marijuana product.

Sample—Medical marijuana collected by an employee of an approved laboratory from a grower/processor for testing by the laboratory.

Test sample—An amount of medical marijuana or an amount of soil, growing medium, water or solvents used to grow or process medical marijuana, dust or other particles obtained from the swab of a counter or equipment used in the growing or processing of medical marijuana, or other item used in the growing or processing of medical marijuana in a facility taken by an employee of an approved laboratory or an agent of the Department at the request of the Department from a grower/processor and provided to an approved laboratory for testing.

§ 1171.22. Laboratories generally.

(a) A laboratory may not identify, collect, handle or conduct tests on samples from a grower/processor or conduct tests on test samples for the Department unless the laboratory has been approved by the Department under § 1171.23 (relating to approval of laboratories) and has entered into a written contract with the grower/processor under § 1171.29 (relating to testing requirements).

(b) The Department will post on its web site a current list of approved laboratories.

(c) An approved laboratory shall employ at least one director to oversee and be responsible for the identification, collection, handling and testing operations of the approved laboratory. A director shall have earned, from a college or university accredited by a National or regional accrediting authority, at least one of the following:

(1) A doctorate of science or an equivalent degree in chemistry, biology, or a subdiscipline of chemistry or biology.

(2) A master's level degree in a chemical or biological science and a minimum of 2 years postdegree laboratory experience related to testing of medicinal or pharmaceutical products or other experience as approved by the Department.

(3) A bachelor's degree in a biological science and a minimum of 4 years postdegree laboratory experience

related to testing of medicinal or pharmaceutical products or other experience as approved by the Department.

(d) A principal or employee of a medical marijuana organization may not also own, be employed by or affiliated with an approved laboratory that has a contract with that medical marijuana organization.

(e) An approval issued by the Department to a laboratory under this part is valid for 2 years from the date of issuance and is valid only for the laboratory named and the location specified in the approval.

(f) An approval issued by the Department to a laboratory under this part is not transferable to any other person or any other location unless the laboratory obtains the prior written consent of the Department.

§ 1171.23. Approval of laboratories.

(a) A laboratory wishing to identify, collect, handle and conduct tests on samples and test samples and other items used by a grower/processor in the growing and processing of medical marijuana as required under the act and this part shall submit an application for approval to the Department on a form and in a manner prescribed by the Department.

(b) An application submitted under this section must include the following information:

(1) The name and address of the laboratory applicant or its authorized agent.

(2) The name and address of the owner of the laboratory applicant, and, if applicable, the medical or pharmacy licensure information regarding the owner.

(3) The name of the laboratory applicant's proposed director and technical personnel who are or will be employed by the laboratory at the location to be approved.

(4) A copy of the laboratory applicant's most recent certificate of accreditation.

(5) Copies of the standard operating procedures and sampling procedures adopted by the laboratory applicant and approved by the accreditation body that issued the certificate of accreditation to the laboratory applicant.

(6) A list of the specialized laboratory equipment utilized or to be utilized by the laboratory applicant in its testing operations, including the manufacturer's name and the serial and model number of the equipment, and other specifications as may be required by the Department.

(7) A description of the tests which are capable of being conducted by the laboratory applicant at the location to be approved.

(8) A description of the laboratory applicant's quality assurance program, which must be in compliance with § 1171.32 (relating to quality assurance program).

(9) The procedures to be followed to establish chain of custody when collecting samples or test samples.

(10) A copy of the evaluation process that the laboratory applicant uses or will use to monitor, evaluate and document the competency of employees when testing samples and test samples and overseeing quality assurance controls.

(11) Other information required by the Department.

(c) By submitting an application for approval to the Department, a laboratory applicant consents to an investigation, to the extent deemed appropriate by the Department, of the laboratory applicant's ability to meet the requirements under the act and this part.

(d) An application for approval submitted under this chapter must include a statement that a false statement made in the application is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).

(e) The Department may issue an approval under this chapter if the Department determines that the laboratory applicant is financially and professionally suitable to conduct the testing required under the act and this part.

§ 1171.24. Suspension or revocation of an approval issued to a laboratory.

(a) An approval issued by the Department under this chapter may be suspended or revoked if the Department determines that the approved laboratory has engaged in unethical practices or has failed to do any of the following:

(1) Maintain proper standards of accuracy.

(2) Comply with the requirements of the act or this part applicable to the approved laboratory.

(b) An approval issued by the Department under this chapter may be revoked if the Department determines that the approved laboratory has engaged in any of the following conduct:

(1) Dishonest reporting.

(2) Repeated errors in conducting the required testing.

(3) Allowing unauthorized individuals to perform testing or to sign reports.

(4) Including false statements in the application for approval or renewal.

(5) Advertising medical marijuana testing services to the general public.

(6) Knowingly accepting a sample from an individual other than a grower/processor or a test sample from an individual other than the Department or an authorized agent of the Department.

(7) Failing to maintain standard operating procedures approved by the accrediting body that issued the certificate of accreditation to the approved laboratory.

(8) Failing to properly enter test results into the electronic tracking system.

(9) Loss by the approved laboratory of its certificate of accreditation.

(c) A laboratory applicant may appeal a determination made by the Department under this section in accordance with 2 Pa.C.S. Chapter 5 (relating to practice and procedure).

§ 1171.25. Renewal of an approval issued to a laboratory.

An approved laboratory wishing to renew the approval issued to the laboratory under this chapter shall, not more than 6 months nor less than 4 months prior to the expiration of the approval, submit an application under § 1171.23 (relating to approval of laboratories) and update all of the information required to be submitted with the application.

§ 1171.26. Stability testing and retention of samples.

(a) A grower/processor shall request that a sample be identified and collected by an approved laboratory from

each harvest batch sufficient to perform stability testing at 6-month intervals for a 1-year period.

(b) The stability test shall be performed to ensure product potency and purity and provide support for expiration dating.

(c) An approved laboratory shall retain a sample from each harvest batch sufficient to provide for stability testing and properly store the sample for 1 year.

§ 1171.27. Sampling procedures for testing.

(a) An approved laboratory shall ensure that its employees prepare all samples in accordance with policies and procedures that include appropriate information necessary for identifying, collecting and transporting samples in a manner that does not endanger the integrity of the samples for any testing required by this part.

(b) The sampling policies must at a minimum be:

(1) Appropriate to the matrix being sampled.

(2) In accordance with guidance provided by the Department.

(c) The sampling procedures must include the following:

(1) Surveying the conditions in which the sample is being stored.

(2) Using appropriate sampling equipment and consistent procedures.

(3) Selecting and removing equal portions for each sample.

(4) Random or systematic taking of samples throughout the harvest batch or harvest lot.

(5) Obtaining a minimum number of samples based on harvest batch or harvest lot size.

(6) Checking all parts of the harvest batch when harvest lots are created from that harvest batch.

(7) Recording on a form prescribed by the Department all observations and procedures used when collecting the sample.

(8) Creating a unique sample identification number that will be linked to the harvest batch or harvest lot number assigned by the grower/processor in the electronic tracking system.

(9) Entering all required information into the electronic tracking system.

§ 1171.28. Selection protocols for samples.

(a) An employee of an approved laboratory may only enter a facility operated by a grower/processor for the purpose of identifying and collecting samples and shall have access to limited access areas in the facility for these purposes.

(b) An employee identifying and collecting samples under subsection (a) shall follow the chain of custody procedures included in the approved laboratory's application and approved by the Department.

(c) While at a facility operated by a grower/processor, an employee of an approved laboratory shall identify and collect the following for testing:

(1) Samples at the time of harvest.

(2) Samples of medical marijuana product before being sold or provided to a dispensary.

(3) Test samples at other times when requested by the Department.

§ 1171.29. Testing requirements.

(a) Prior to conducting any testing of a sample at the request of a grower/processor, an approved laboratory shall enter into a written contract with the grower/processor for testing services. The approved laboratory shall provide a copy of the contract to the Department within 2 days following the Department's request.

(b) A grower/processor shall submit through the electronic tracking system a request to the approved laboratory with which it has a written contract under subsection (a) for each test to be conducted.

(c) At a minimum, an approved laboratory shall perform tests as prescribed by the Department on the following:

(1) Samples from a harvest batch or harvest lot prior to being used to produce a medical marijuana product.

(2) Samples from each process lot before the medical marijuana is sold or offered for sale to another medical marijuana organization.

(d) The samples identified in subsection (c) shall be tested, at a minimum, for the following:

(1) Pesticides.

(2) Solvents.

(3) Water activity and moisture content.

(4) THC and CBD concentration.

(5) Microbiological contaminants.

(e) Sampling and testing under this chapter shall be conducted with a statistically significant number and size of samples and with methodologies acceptable to the Department to ensure that all harvest batches, harvest lots and medical marijuana products are adequately tested for contaminants and that the cannabinoid profile is consistent throughout.

(f) An approved laboratory may not test any samples when there is evidence of improper collection, improper preservation, apparent spoilage, excessive time lapse between collection of the sample and testing, or any other factor sufficient to render the findings of questionable validity.

(g) An approved laboratory shall enter into the electronic tracking system and, under § 1151.40 (relating to disposal of medical marijuana), properly dispose of all tested and untested samples and test samples.

§ 1171.30. Standards for testing.

An approved laboratory shall follow the methodologies, ranges and parameters acceptable to the Department which are contained in the scope of the certificate of accreditation issued to the laboratory.

§ 1171.31. Test results and reporting.

(a) Only the results of the following tests are in compliance with the testing requirements of this chapter:

(1) Tests conducted on harvest batch samples or harvest lot samples requested by a grower/processor under § 1171.29 (relating to testing requirements) and identified and collected by an employee of an approved laboratory.

(2) Tests conducted on process lot samples requested by a grower/processor under § 1171.29 and identified and collected by either an employee of a grower/processor or an employee of an approved laboratory.

(b) The test results for each sample shall be entered into the electronic tracking system and shall only be accessible to the grower/processor submitting the sample and to the Department.

(c) If a sample fails any test required under § 1171.29, the following apply to the sample:

(1) The approved laboratory that performed the initial test may re-test the sample upon a request from the grower/processor in accordance with subsection (d).

(2) If the sample passes the re-test, another approved laboratory shall sample the same harvest batch, harvest lot or process lot to confirm the passing test result.

(3) If the Department does not agree to accept the results from the approved laboratory, the sample shall be disposed of by the approved laboratory under § 1151.40 (relating to disposal of medical marijuana).

(d) A grower/processor shall notify the Department and the approved laboratory through the electronic tracking system of its intent to re-test the sample or test another sample from the same harvest batch, harvest lot or process lot that failed a test.

(e) An approved laboratory shall issue to a grower/processor a certificate of analysis, including the supporting data, for each harvest batch, harvest lot or process lot sample that was tested at the request of the grower/processor. The certificate of analysis must include:

(1) Whether the chemical profile of the harvest batch, harvest lot or process lot conforms to the chemical profile of the strain as determined by the Department for the following compounds:

(i) THC.

(ii) Tetrahydrocannabinolic acid.

(iii) CBD.

(iv) Cannabidiolic acid.

(v) Cannabigerol.

(vi) Cannabinol.

(2) That the presence of the following contaminants within the harvest batch, harvest lot or process lot does not exceed the levels as determined by the Department for the following:

(i) Heavy metals, mercury, lead, cadmium or arsenic.

(ii) Foreign material such as hair, insects, or any similar or related adulterant.

(iii) Any microbiological impurity, including:

(A) Total aerobic microbial count.

(B) Total yeast mold count.

(C) *P. aeruginosa.*

(D) *Aspergillus* spp.

(E) *S. aureus.*

(F) Aflatoxin B1, B2, G1 and G2.

(G) Ochratoxin A.

(H) Pesticide residue.

(iv) Whether the harvest batch, harvest lot or process lot is within the specification for the strain for the characteristics of:

(A) Odor.

(B) Appearance.

(C) Fineness.

(D) Moisture content.

§ 1171.32. Quality assurance program.

(a) An approved laboratory shall establish and implement a quality assurance program to ensure that measurements are accurate, errors are controlled, and devices used for testing are routinely and properly calibrated.

(b) The quality assurance program required under subsection (a) must include the following components:

(1) An organizational chart that includes the testing responsibilities of each employee of the approved laboratory named in the chart.

(2) A description of sampling procedures to be utilized.

(3) Appropriate chain of custody protocols.

(4) Analytical procedures.

(5) Data reduction and validation procedures.

(6) A plan for implementing corrective action, when necessary.

(7) A requirement for the provision of quality assurance reports to management.

(8) A description of the internal and external quality control systems.

§ 1171.33. Transporting samples.

(a) An employee of an approved laboratory, grower/processor or third-party contractor shall follow the transportation requirements under §§ 1151.35 and 1151.36 (relating to transportation of medical marijuana; and transport manifest) when transporting a sample or test sample under this part.

(b) An employee of an approved laboratory, grower/processor or third-party contractor who transports process lot samples from a grower/processor to an approved laboratory shall:

(1) Protect the physical integrity of the sample.

(2) Keep the composition of the sample intact.

(3) Protect the sample against factors that will interfere with the validity of testing results, including the factors of time, temperature and other environmental factors that may work to jeopardize the integrity of the sample.

§ 1171.34. Department request for testing.

(a) The Department, in its sole discretion, may identify and collect a test sample from a grower/processor at any time and request an approved laboratory to conduct tests.

(b) The approved laboratory shall provide the Department with a written report of the test results from a test sample tested under subsection (a) within 7 days of the collection of the test sample, or sooner if requested by the Department.

§ 1171.35. Laboratory reporting.

(a) An approved laboratory shall enter into the electronic tracking system the following information for each sample collected and each test conducted:

(1) The unique sample identification number the approved laboratory assigns to the sample.

(2) The name of the grower/processor that supplied the sample.

(3) The employee identification number of the employee of the approved laboratory who identified and collected the sample at the request of the grower/processor.

(4) The date and time the sample was collected from the grower/processor.

(5) The date and time the sample was received by the approved laboratory.

(6) The date the test was completed.

(7) The condition of the sample when it was received by the approved laboratory.

(8) A description of each test performed.

(9) The results from the certificate of analysis issued under § 1171.31 (relating to test results and reporting).

(10) The date the testing results were provided to the grower/processor under § 1171.31 or the Department under § 1171.34 (relating to Department request for testing).

(b) An approved laboratory shall keep for 4 years a paper or electronic copy of the certificate of analysis performed on samples submitted by a grower/processor or test samples submitted by the Department. The laboratory shall provide a copy of a certificate of analysis within 2 days of a request made by the Department.

§ 1171.36. Advertising.

(a) An approved laboratory may not advertise, market or otherwise promote its medical marijuana testing services to the general public. An approved laboratory may advertise, market or otherwise promote its medical marijuana testing services to a grower/processor as provided in this section.

(b) Advertising, marketing and promotional materials proposed to be used by an approved laboratory under this section shall be reviewed and approved by the Department prior to circulation or other use.

(c) Personal solicitation by an employee, representative or agent of an approved laboratory to a grower/processor is considered advertising, marketing or otherwise promoting its medical marijuana testing services for the purposes of this section.

(d) An approved laboratory may only advertise, market or otherwise promote its medical marijuana testing services that are performed onsite at the location designated in the laboratory's application.

(e) A sign installed at the location of an approved laboratory that is designed to identify the laboratory or access to the laboratory is permissible as long as the sign meets local zoning requirements and does not violate the provisions of this section.

§ 1171.37. Ownership prohibition.

The following individuals may not have a management or a direct or indirect financial or other ownership interest in an approved laboratory:

(1) A principal, owner, financial backer or employee of a medical marijuana organization.

(2) A practitioner.

(3) A physician, pharmacist, physician assistant or certified registered nurse practitioner who is currently employed by a medical marijuana organization.

(4) Any other person, other than a patient, who may receive a direct or indirect financial benefit from the growing, processing, transporting, dispensing or selling of medical marijuana.

[Pa.B. Doc. No. 16-2256. Filed for public inspection December 23, 2016, 9:00 a.m.]