

# STATEMENTS OF POLICY

## Title 4—ADMINISTRATION

### PART II. EXECUTIVE BOARD

#### [ 4 PA. CODE CH. 9 ]

#### Reorganization of the Department of Community and Economic Development

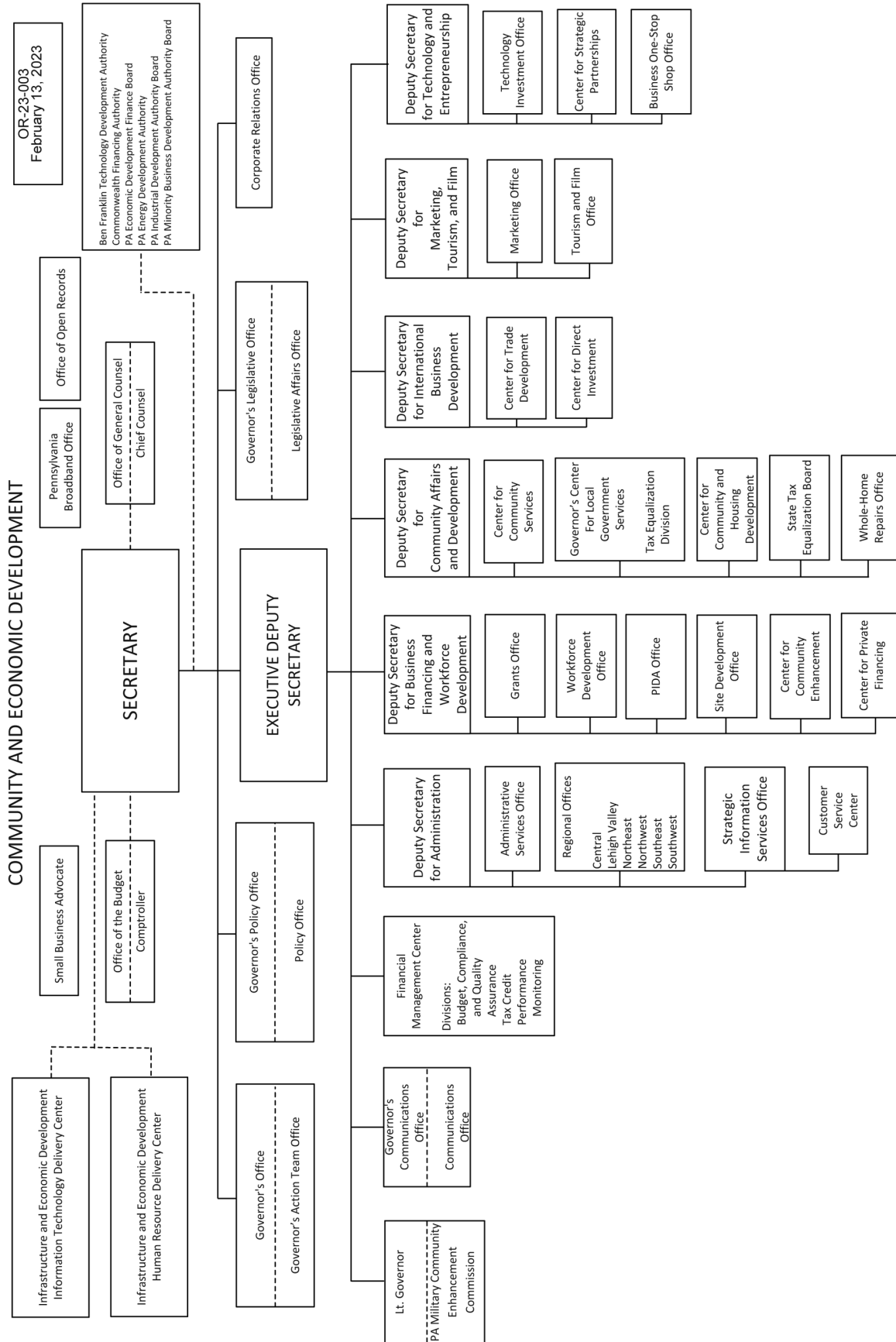
The Executive Board approved a reorganization of the Department of Community and Economic Development effective February 13, 2023.

The organization chart at 53 Pa.B. 1178 (March 4, 2023) is published at the request of the Joint Committee on Documents under 1 Pa. Code § 3.1(a)(9) (relating to contents of *Code*).

*(Editor's Note: The Joint Committee on Documents has found organization charts to be general and permanent in nature. This document meets the criteria of 45 Pa.C.S. § 702(7) (relating to contents of Pennsylvania Code) as a document general and permanent in nature which shall be codified in the Pennsylvania Code.)*

[Pa.B. Doc. No. 23-289. Filed for public inspection March 3, 2023, 9:00 a.m.]

---



## DEPARTMENT OF HEALTH

### [ 28 PA. CODE CH. 1171a ]

#### Medical Marijuana

The Department of Health (Department) provides notice of this statement of policy to provide guidance to all growers/processors and laboratories approved to test medical marijuana under the Medical Marijuana Program.

#### *Statutory Authority*

The Department established final-form regulations (Regulation # 10-219: Medical Marijuana) as a final-form rulemaking published at 53 Pa.B. 1275 (March 4, 2023) to carry out the provisions of the Medical Marijuana Act (act) (35 P.S. §§ 10231.101—10231.2110). The act of June 30, 2021 (P.L. 210, No. 44) specifically amended section 704(a) of the act (35 P.S. § 10231.704(a)) to require a grower/processor to contract with “one or more independent laboratories” to test medical marijuana. As a result of this amendment and to promote patient safety, § 1171a.29(c) (relating to testing requirements) of the final-form rulemaking requires the growers/processors to contract with two independent laboratories approved to test medical marijuana: one approved laboratory to conduct the harvest batch/lot test and a separate approved laboratory to conduct the process lot test. In addition, § 1171a.31(c) (relating to test results and reporting) requires a confirming test for re-testing of previously failed samples to be conducted by an approved laboratory other than the one that conducted the previous test.

#### *Background and Purpose*

Under sections 102(3)(ii) and 301(a)(4) of the act (35 P.S. §§ 10231.102(3)(ii) and 10231.301(a)(4)), the Department is tasked with ensuring patient safety and access to medical marijuana, which includes monitoring the testing of medical marijuana in this Commonwealth. As stated in the preamble of the final-form rulemaking published at 53 Pa.B. 1275, the Department is concerned with the Nationwide issues regarding passing tests that failed for contaminants, as well as artificially elevated tetrahydrocannabinol (THC) percentages.

In this statement of policy, the Department clarifies its interpretation of the language of § 1171a.29(c), “an approved laboratory other than the one that tested the harvest batch or harvest lot,” to provide guidance to growers/processors and approved laboratories. This statement of policy clarifies how the Department intends to evaluate whether the two approved laboratories are considered as separate and distinct approved laboratories, each capable of meeting all financial and professional suitability requirements. This statement of policy also applies to approved laboratories conducting confirming tests for re-testing of previously failed samples under § 1171a.31(c).

#### *Fiscal Impact and Paperwork Requirements*

This statement of policy has no adverse fiscal impact on the Commonwealth or its political subdivisions and imposes no additional paperwork requirements upon the Commonwealth, political subdivisions and the public.

This statement of policy imposes no additional costs to this regulated community other than minimal cost increases grower/processor permittees may experience in complying with §§ 1171a.29(c) and 1171a.31(c). This statement of policy will not impose additional paperwork requirements upon the regulated community.

#### *Effective Date and Sunset Dates*

This statement of policy will be effective upon publication in the *Pennsylvania Bulletin*. A sunset date will not be established. The Department will continually review and monitor the effectiveness of this statement of policy.

#### *Contact Person*

The contact person for technical questions related to this statement of policy is 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 RA-DHMMregulations@pa.gov. Persons with a disability may contact the Director 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).

DR. DEBRA L. BOGEN,  
*Acting Secretary*

**Fiscal Note:** 10-238. No fiscal impact; recommends adoption.

#### Annex A

#### TITLE 28. HEALTH AND SAFETY

#### PART IXa. MEDICAL MARIJUANA

#### CHAPTER 1171a. LABORATORIES

#### § 1171a.39. Clarification of the requirements of §§ 1171a.29(c) and 1171a.31(c)—statement of policy.

(a) This section clarifies §§ 1171a.29(c) (relating to testing requirements) and 1171a.31(c) (relating to test results and reporting). The Department interprets “an approved laboratory other than the one that tested the harvest batch or lot” in § 1171a.29(c)(2) to be a separate and distinct approved laboratory that meets all financial and professional suitability requirements under this chapter independently from the approved laboratory that conducted the harvest batch or harvest lot test. The Department will consider the following factors to determine whether an approved laboratory is a separate and distinct laboratory:

(1) Separate, independent location from the other approved laboratory, such as no interest in the land or the building in which the other approved laboratory is located or part interest in any mortgage, deed, trust, note or the long-term liability secured in whole or in part by the land or building in which the other approved laboratory conducts testing. For clarification, this statement of policy does not impact the Department’s ability to approve laboratories with multiple locations, including those with shared finances, staffing or operations.

(2) Separate legal entity from the other approved laboratory.

(3) No shared financial ownership with the other approved laboratory, such as filing joint tax returns, shared Federal or Tax Identification Numbers, having direct or indirect ownership interest in another laboratory, commingling of funds or shared bank accounts.

(4) Separate ownership and management in terms of members of a board of directors, shareholders or partners

that represent a controlling interest, or management, compliance staff or employees in common with the other approved laboratory.

(5) Separate accreditation from the other approved laboratory.

(6) Separate operations from the other approved laboratory, such as no shared policies or standard operating procedures, reliance on input or oversight of the other approved laboratory or reliance on the other approved laboratory to financially support the approved laboratory's operations.

(7) No shared equipment or interest in any mortgage, deed, trust, note or other long-term liability secured in whole or in part by equipment used by the other approved laboratory.

(b) The Department will consider the factors in subsection (a)(1)—(7) with respect to determining approved laboratories to conduct confirming tests for re-testing of previously failed samples in § 1171a.31(c).

[Pa.B. Doc. No. 23-290. Filed for public inspection March 3, 2023, 9:00 a.m.]