

Article - Health - General

17-201.

(a) In this subtitle the following words have the meanings indicated.

(b) (1) "Medical laboratory" means any [laboratory] FACILITY, ENTITY, OR SITE that OFFERS OR PERFORMS TESTS OR [makes] examinations in connection with the diagnosis and control of human diseases or the assessment of human health, nutritional, or medical conditions OR IN CONNECTION WITH JOB-RELATED DRUG AND ALCOHOL TESTING.

(2) "MEDICAL LABORATORY" INCLUDES ANY LABORATORY OWNED OR OPERATED BY THE STATE OR OWNED OR OPERATED BY A COUNTY OR MUNICIPAL CORPORATION IN THE STATE.

[(2) "Medical laboratory" does not include tests or examinations that:

(i) Are performed by a health care practitioner who is licensed under the Health Occupations Article, with the exception of a physician, if the tests or examinations:

1. Are performed on the patients of the practitioner; and
2. Are within the practitioner's lawful scope of practice; or

(ii) Concern pregnancy screening.]

(c) ["Permit"] "LICENSE" means a permit, LETTER OF EXCEPTION, CERTIFICATE, OR OTHER DOCUMENT issued by the Secretary GRANTING APPROVAL OR AUTHORITY TO:

(1) [To operate a] OFFER OR PERFORM medical laboratory TESTS OR EXAMINATIONS in this State;

[(2) To represent or service in this State a medical laboratory that is outside this State; or

(3) To perform tests or examinations pertaining to individuals in this State at a medical laboratory located outside this State.]

(2) OFFER OR PERFORM MEDICAL LABORATORY TESTS OR EXAMINATIONS ON SPECIMENS ACQUIRED FROM HEALTH CARE PROVIDERS IN THIS STATE AT A MEDICAL LABORATORY LOCATED OUTSIDE THIS STATE; OR

(3) REPRESENT OR SERVICE IN THIS STATE A MEDICAL LABORATORY REGARDLESS OF THE LABORATORY'S LOCATION.

17-202.

(a) (1) The Secretary shall adopt [rules and] regulations that set standards AND REQUIREMENTS for medical laboratories.