

LEGISLATIVE DIGEST

[Health Code - Regulating Medical Specimen Test Collection Sites]

Ordinance amending the Health Code to require that sites that collect medical specimens on behalf of clinical laboratories partner with either a governmental entity, a licensed health care provider located in the City, or an educational or academic institution, establish hygiene, sanitation, and privacy standards, and adhere to the Health Insurance Portability and Accountability Act; and providing that a violation of the specimen collection standards is a public health nuisance subject to an administrative penalty that may be imposed by the Department of Public Health.

Existing Law

Existing law does not address medical specimen test collection sites.

Amendments to Current Law

The proposed ordinance would allow medical specimen test collection sites that partner with (1) a governmental entity; (2) a licensed health care provider in the City; or (3) an educational or academic institution to operate in the City. Specimen collection sites already regulated by CLIA or the California Department of Public Health (CDPH) would not be subject to the proposed ordinance. The proposed ordinance would require collection sites to provide its employees with personal protective equipment, provide sanitation, and have written policies and procedures covering: (1) specimen collection, storage, and transport; (2) training of employees; (3) test result notification; and (4) a privacy policy. The proposed ordinance would require the specimen collection site to produce documentation of an ordering prescriber and current and valid CLIA and CDPH licenses. Finally, the proposed ordinance would require specimen collection sites to comply with applicable privacy laws and in the event that HIPAA does not apply to the site, the site must adhere to the same standards as HIPAA.

Background Information

Medical testing sites that both collect specimens and then perform clinical tests on those specimens are called “laboratories” or “clinical laboratories,” and are licensed and regulated by federal Centers for Medicare and Medicaid Services (CMS) and CDPH or the applicable state agency for laboratories outside California. By contrast, sites that collect specimens but do not actually perform clinical tests, and merely send the specimens to a laboratory for testing are not subject to CMS or CDPH regulation or oversight.