[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.

NOTE: **Unchanged Code text and uncodified text** are in plain Arial font.
Additions to Codes are in *single-underline italics Times New Roman font*.
Deletions to Codes are in ~~*strikethrough italics Times New Roman font*~~.
Board amendment additions are in double-underlined Arial font.
Board amendment deletions are in ~~strikethrough Arial font~~.
Asterisks (* * * *) indicate the omission of unchanged Code subsections or parts of tables.

Be it ordained by the People of the City and County of San Francisco:

Section 1. The Health Code is hereby amended by adding Article 49, consisting of Sections 4901 through 4906, to read as follows:

ARTICLE 49:

SPECIMEN TEST COLLECTION SITES

SEC. 4901. FINDINGS AND PURPOSE.

(a) Since the onset of the COVID-19 emergency, it has become increasingly common for City residents to see organizations and businesses operate clinical testing sites on City sidewalks and in other public locations. 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 and the California Department of Public Health 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 ("Specimen Collection Sites") are not subject to CMS or CDPH regulation or oversight.

(b) Generally, under the Health Insurance Portability and Accountability Act and its implementing regulations (collectively, "HIPAA"), Specimen Collection Sites that collect specimens on behalf of covered entities, such as clinical laboratories, are business associates of those covered entities as those terms are defined under HIPAA. Business associates are obligated to follow HIPAA's privacy and safety requirements.

(c) It is critically important that Specimen Collection Sites in San Francisco protect the privacy of individuals' health information and comply with health and safety protocols for handling and testing infectious disease specimens. Accordingly, the purpose of this Article 49 is to set forth the minimum privacy and health and safety requirements for Specimen Collection Sites to ensure that such sites are operating in a safe and lawful manner.

SEC. 4902. DEFINITIONS.

For purposes of this Article 49, the following terms have the following meanings:

"CDC" means the federal Centers for Disease Control and Prevention.

"CDPH" means the California Department of Public Health.

"City" means the City and County of San Francisco.

"CLIA" means the Clinical Laboratory Improvement Amendments, codified at 42 U.S.C. § 263a, as it may be amended from time to time, and including any implementing regulations or guidance promulgated by CMS, the CDC, or the federal Food and Drug Administration.

"CMS" means the federal Centers for Medicare and Medicaid Services.

"Covered Operator" means a private, for-profit or non-profit person, company, or other organization operating one or more Specimen Collection Sites anywhere in the City. Covered Operator includes a person, company, or organization that collects specimens without charge to the Examinee, regardless of whether reimbursement or payment is sought from insurance companies or federal, state, or local governmental agencies. Covered Operator does not include government entities or any facility (such as a general acute care hospital, skilled nursing facility, or ambulatory clinic) that directly collects specimens and is subject to regulation by CDPH.

"Department" means the San Francisco Department of Public Health.

"Director" means the Director of Health, or the Director's designee.

"Examinee" means an individual providing a specimen to the Specimen Collection Site.

"Personnel" means employees, contractors and sub-contractors, including but not limited to those who sell goods or perform services onsite or who deliver goods for the Covered Operator, vendors who are permitted to sell goods onsite, volunteers, and other individuals who regularly provide services to a Covered Operator.

"PPE" means Personal Protective Equipment.

"Specimen Collection Site" means a site where a Covered Operator or its Personnel obtain specimens for testing for medical or health conditions, including by way of example but not limitation, COVID-19 and flu, from an Examinee and for delivery to an off-site CLIA-certified laboratory for clinical processing. Specimen Collection Sites do not include sites regulated by CMS or CDPH where clinical laboratory tests are performed on the premises.

"Well-Fitted Mask" means a face covering that is well-fitted to an individual and covers the nose and mouth while talking. A Well-Fitted Mask does not include a scarf, ski mask, balaclava, bandana, turtleneck, collar, or single layer of fabric, or any mask that has an unfiltered one-way exhaust valve.

SEC. 4903. REQUIREMENTS FOR SPECIMEN COLLECTION SITES.

(a) Each Covered Operator must provide its Personnel with guidelines for wearing appropriate PPE based on the type of specimen to be collected by Personnel. Covered Operators must provide Personnel with information and training on the proper procedures for putting on and taking off PPE based on the type of specimen collected by the Personnel. Each Covered Operator's guidelines for wearing appropriate PPE must include the following minimum standards:

(1) If collecting specimens or working within six feet of Examinees, Personnel must wear a Well-Fitted Mask, eye protection, gloves, and a gown.

(2) Personnel who handle specimens, but are not directly involved in collection (e.g., handling self-collected specimens) and not working within six feet of the Examinee, must wear a Well-Fitted Mask and gloves.

(3) Personnel must change gloves after handling a specimen or whenever their gloves become soiled or torn.

(b) Personnel at Specimen Collection Sites must designate a surface area for specimen collection and handling and disinfect that area using a disinfectant product registered with the federal Environmental Protection Agency for use against contagious, infectious, or communicable diseases. Personnel must disinfect the surface areas at the following times: (1) before specimen collection begins each day; (2) after Personnel collect a specimen; (3) when visibly soiled; (4) in the event of a specimen spill; and (5) at the end of every day. Each Covered Operator must at all times during hours of operation make hand sanitizer available for use by Personnel and Examinees.

(c) Each Covered Operator must provide all Examinees a written informed consent form consenting to the collection of the specimen and the testing of that specimen. Before the specimen is collected, the Examinee must sign the informed consent form. Personnel must provide a copy of the signed form, either in hard copy or electronically, to the Examinee.

(d) Each Covered Operator must have written policies covering the following topics:

(1) Specimen collection, storage, and transport, that addresses the specific types of specimens the Specimen Collection Site will collect or are consistent with the test manufacturers' instructions.

(2) Training of Personnel in PPE requirements; specimen collection, storage, and transport; and protection of personal information of Examinees seeking or considering seeking medical testing at the Specimen Collection Site.

(3) Test Result Notification, including how results are provided to Examinees either by the Covered Operator, its Personnel, or by the CLIA-certified laboratory where the specimens are tested.

(4) A privacy policy regarding Examinees' medical and health information, biological samples, and test results.

The written policies and procedures specified in subsection (d)(1) through (d)(4) must be provided to: all Personnel; any member of the public, upon request, including, but not limited to, Examinees seeking or considering seeking medical testing at a Specimen Collection Site; City, state, or federal employees conducting inspections or investigations; and any CLIA-certified laboratory where the specimens will be tested to enable the lab to verify the integrity of the specimens being collected.

(e) Covered Operators may use human biological/viral specimens only for (1) clinical testing and (2) laboratory validation and quality control, to the extent such uses are allowed by applicable laws, rules, regulations, and licensure requirements.

(f) Upon request by any member of the public, including, but not limited to, Examinees seeking or considering seeking testing at a Specimen Collection Site, and City, state, or federal employees conducting inspections or investigations, Personnel at Specimen Collection Sites must produce the name of the Specimen Collection Site's ordering/prescribing provider, where a prescription is required for collection of samples and processing by CDPH-approved laboratories.

(g) Upon request by any member of the public, including, but not limited to, Examinees seeking or considering seeking testing at a Specimen Collection Site, and City, state, or federal employees conducting inspections or investigations, Personnel at Specimen Collection Sites must produce the following documentation from the laboratory that will be processing/performing tests on the specimens collected at the Specimen Collection Site: (1) a current and valid CLIA license; and (2) a current and valid Clinical and Public Health Laboratory License from CDPH.

(h) A Specimen Collection Site operated by a Covered Operator must comply with all applicable privacy laws, including but not limited to HIPAA. In the event HIPAA does not apply to the Covered Operator, then the Covered Operator must adhere to the same standards as provided by HIPAA to safeguard Examinee confidentiality and medical information.

(i) Each Covered Operator must partner with one of the following entities: (a) a governmental entity; (b) a licensed health care provider located in the City; or (c) an educational or academic institution (including but not limited to licensed child care providers, preschools, public and private schools, colleges, universities, and similar institutions of higher learning).

SEC. 4904. ADMINISTRATION AND ENFORCEMENT.

(a) This Article 49 shall be administered and enforced by the Department. The Director may adopt regulations, guidelines, and forms to carry out the provisions and purposes of this Article 49.

(b) For purposes of assessing penalties for violation of Section 4903, each instance that a Specimen Collection Site violates any provision of Section 4903 shall constitute a separate violation.

(c) The Director may issue a notice of violation for violations of Section 4903. The Director may impose an administrative penalty of not less than $250 and not more than $1,000 per violation. Administrative Code Chapter 100, "Procedures Governing the Imposition of Administrative Fines," is hereby incorporated in its entirety, except: (1) as it relates to the definition of a violation and the

calculation of penalty amounts, addressed in Sections 4904(b) and (c); and (2) that the Director shall appoint the hearing officer to conduct hearings for appeals.

(d) A violation of Section 4903 shall be considered a nuisance under Health Code Section 581, or any successor provision.

(e) The Department shall have authority to enforce Section 4903 under Health Code Sections 594, 595, 596, 596.5, 599, 600, and 610.

SEC. 4905. UNDERTAKING FOR THE GENERAL WELFARE.

In enacting and implementing this Article 49, the City is assuming an undertaking only to promote the general welfare. It is not assuming, nor is it imposing on its officers and employees, an obligation for breach of which it is liable in money damages to any person who claims that such breach proximately caused injury.

SEC. 4906. SEVERABILITY.

If any section, subsection, sentence, clause, phrase, or word of this Article 49, or any application thereof to any person or circumstance, is held to be invalid or unconstitutional by a decision of a court of competent jurisdiction, such decision shall not affect the validity of the remaining portions or applications of this Article. The Board of Supervisors hereby declares that it would have passed this Article and each and every section, subsection, sentence, clause, phrase, and word not declared invalid or unconstitutional without regard to whether any other portion of this Article or application thereof would be subsequently declared invalid or unconstitutional.

Section 2. Effective Date. This ordinance shall become effective 30 days after enactment. Enactment occurs when the Mayor signs the ordinance, the Mayor returns the

ordinance unsigned or does not sign the ordinance within ten days of receiving it, or the Board of Supervisors overrides the Mayor's veto of the ordinance.

APPROVED AS TO FORM:
DAVID CHIU, City Attorney

By: /s/ Henry L. Lifton
HENRY L. LIFTON
Deputy City Attorney

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