

BEFORE THE BOARD OF SUPERVISORS
OF THE COUNTY OF FRESNO
STATE OF CALIFORNIA
ORDINANCE NO. _____

AN ORDINANCE ADOPTING CHAPTER 8.52 OF THE ORDINANCE CODE OF FRESNO
COUNTY, "Fresno County Infectious Materials Ordinance."

The Board of Supervisors of the County of Fresno ordains as follows:

Section 1: Chapter 8.52 of the Ordinance Code of Fresno County, entitled "FRESNO COUNTY
INFECTIOUS MATERIALS ORDINANCE," is adopted, as follows:

8.52.010 - Declaration of findings.

8.52.020 - Purpose.

The purpose of this chapter is to establish a monitoring and inspection system to oversee
privately funded laboratories that handle infectious agents without oversight from an existing
permitting public agency. This ordinance is to address an existing absence of federal and
state legislative oversight over these businesses and activities specified herein.

8.52.030 - Area of application.

- A. This ordinance shall apply to all non-Clinical Laboratory Improvement Amendments (CLIA)
regulated laboratories and research and development businesses (as that term is defined in
42 USC §263a) located or operating within the geographic area in which the health
department enforces state and local statutes, orders, quarantines, rules, regulations and
ordinances relating to public health in the unincorporated area of Fresno County or within the
incorporated area of any city within the county, to which cities have signed a memorandum of
understanding that authorizes the County to conduct oversight of the laboratories.
- B. In order to authorize the County of Fresno to enforce the provisions of this public safety
ordinance in Incorporated cities within the County of Fresno, said cities must adopt the
provisions of this ordinance delegating enforcement authority to the County of Fresno and
must enter into a memorandum of understanding with the County of Fresno. Said

memorandum of understanding shall include terms providing for the reimbursement of all costs incurred by the County of Fresno and not recouped by the fees developed by the County or other recovery actions, the assistance by city law enforcement, fire and emergency personnel when necessary, the prosecution when appropriate of violations of this Chapter by city attorneys in the relevant jurisdictions, and other matters as may be deemed necessary or appropriate by the parties.

8.52.040 - Definitions.

As used in this chapter:

- A. "Clinical Laboratory Improvement Amendments (CLIA)" means language found in 42 USC 263a.
- B. "CLIA Regulations" means language found at 42 CFR 493.
- C. "Laboratory" means a facility for the biological, microbiological, serological, chemical, immunopharmacological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body or other type of materials from research and development processes for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include a procedure to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.
- D. "Research Laboratories" means facilities performing research testing on human specimens that do not report patient-specific results, as described at 42 C.F.R. § 493.3(b)(2).
- E. "Infectious Agents" means a microorganism (including, but not limited to, bacteria (including rickettsiae), viruses, fungi, or protozoa) or prion, whether naturally occurring, bioengineered, or artificial, or a component of such microorganism or prion that is capable of causing communicable disease in a human. 42 CFR 71.54.
- F. "Hazardous Materials Certified Unified Program Agency (CUPA)" means a local agency certified by CalEPA to implement and enforce six state hazardous waste and hazardous materials regulatory management programs. See California Health and Safety Code Division

20, Chapter 6.11, Sections 25404-25404.9; California Code of Regulations Title 27, Division 1, Subdivision 4, Chapter 1, Sections 15100-15620; and California Code of Regulations Title 27, Division 3, Subdivision 1.

G. "Medical Waste Permit" means a permit issued by the California Department of Public Health; Medical Waste Program under the Medical Waste Management Program as found in California Health & Safety Code 117915-117946.

H. "California Animal Use Permit Program" means the language found in The California Health and Safety Code Division 2, Chapter 5, commencing with Section 1650 and the California Code of Regulations Title 17, Chapter 2, Subchapter I, Group 5.

I. Cal/OSHA Guidelines means the language found in Title 8 of the California Code of Regulations section 5199, Aerosol Transmissible Diseases.

J. "Person" means any individual, association, partnership, firm or corporation.

8.52.050 - Permit for Operation Required.

A. All facilities meeting the definition of a laboratory or research laboratory not subject to CLIA law and regulations, shall be required to obtain a permit in the County of Fresno and any incorporated cities within the County having a memorandum of understanding with the County that authorizes the County to conduct oversight of the unregulated laboratories or research laboratories. The permit will allow the operation of the laboratory or research laboratory not subject to CLIA law and regulations and the handling, storage, testing or use of Infectious Agents as defined in this Ordinance. The County shall determine a reasonable fee to be charged to applicants and permittees to cover the cost of the issuance of the permit and the administrative costs of overseeing the monitoring and enforcement of this Chapter.

B. It is unlawful for any person, without first having obtained a permit from the health department, to engage in the businesses and activities of a laboratory or research laboratory not subject to CLIA law and regulations, in the County or any city that has signed a memorandum of understanding with the County.

C. It is unlawful for any person, currently engaging in the businesses and activities of a laboratory or research laboratory not subject to CLIA law and regulations on the effective date of this

1 Ordinance in the County or any city that has signed a memorandum of understanding with the
2 County to continue to engage in said business and activities without obtaining a permit from the
3 health department, to engage in the businesses and activities of a laboratory or research
4 laboratory not subject to CLIA law and regulations within ninety (90) days of the effective date of
5 this Ordinance.

- 6 D. It is unlawful for any person, to engage in the businesses and activities of a laboratory or
7 research laboratory not subject to CLIA law and regulations, in the County or any city that has
8 signed a memorandum of understanding with the County under an expired, revoked or
9 suspended permit issued by the County Department of Public Health pursuant to this Chapter,
10 except that no person shall be guilty of a misdemeanor for violation of this Chapter for engaging
11 in the businesses and activities of a laboratory or research laboratory not subject to CLIA law
12 and regulations, in the County or any city that has signed a memorandum of understanding with
13 the County under a revoked or suspended permit so long as the person is actively engaged in
14 the appeal process set out in Section 8.52.065 of this Ordinance Code and has complied with all
15 provisions of that section, including but not limited to ceasing operations in the case of a
16 revoked permit, and compliance with any directions or order of the public health director or
17 designee to immediately abate or correct any immediate danger to the public health or safety.

18 **8.52.060 – Certificate of Inspection required.**

- 19 A. All facilities meeting the definition of a laboratory or research laboratory not subject to
20 CLIA law and regulations, shall be required to have an annual site visit by the County. The
21 County shall determine a reasonable fee to be paid by permittees to cover the costs of the
22 annual inspection, which must be paid within ten days of the date of the annual inspection.
- 23 B. It is unlawful for any person, without first having obtained a written certificate of
24 inspection from the health department, to engage in the businesses and activities of a laboratory
25 or research laboratory in the County or any city that has signed a memorandum of
26 understanding with the County or to continue to engage in said business and activities without
27 allowing a reasonable opportunity for the County Health Department to conduct the required
28 inspections on an annual basis.

- 1 C. The County shall evaluate applicability to Hazardous Materials CUPA, participation in
2 the State's Medical Waste Management Program, participation in the State's Animal Use Permit
3 Program, receive an inventory of chemicals and biological agents onsite, receive an inventory
4 of safety protocols in management of biological agents including but not limited to testing
5 methodologies, environmental controls, and safety equipment applicable annual certification.
6 Safety protocols in management of biological agents shall be consistent with Cal/OSHA
7 Guidelines.
- 8 D. All facilities meeting the definition of a laboratory or research laboratory not subject to
9 CLIA law and regulations must report to the County their operational plan and compliance with
10 applicable federal, state, and local regulations.
- 11 E. County staff will assess and coordinate with and refer appropriate matters to any
12 federal, state, or local agency to ensure compliance with existing federal, state, and local
13 regulations.

14 **8.52.065 - Permit suspension or revocation.**

- 15 A. A permit or interim permit (90 days) may be suspended or revoked for a violation of the
16 Fresno County Ordinance Code or state statutes, orders, quarantines, rules, and regulations.
17 Any business or activity for which a permit has been suspended shall cease operation and
18 remain out of operation until the permit has been reinstated. Any business or activity for which
19 a permit has been revoked shall cease operation and remain out of operation until a new
20 permit has been issued.
- 21 B. 1. Whenever an enforcement officer finds that an applicant or a permitted business or activity
22 is not in compliance, a written notice to comply shall be issued to the permittee or applicant.
23 2. If the permittee or applicant fails to comply, the enforcement officer shall issue to the
24 permittee or applicant a notice setting forth the acts or omissions with which the permittee or
25 applicant is charged and informing him or her of a right to a hearing, if requested, to show
26 cause why the permit should not be denied, suspended, or revoked. A written request for a
27 hearing shall be made by the permittee or applicant within fifteen calendar days after receipt
28 of the notice. Failure to request a hearing within fifteen calendar days after receipt of the

notice shall be deemed a waiver of the right to a hearing. When circumstances warrant, the public health director or designee may order a hearing at any reasonable time within this fifteen-day period to expedite the permit denial, suspension or revocation process.

3. The hearing shall be held before the public health director or designee within fifteen calendar days of the receipt of a request for a hearing. Upon written request of the permittee or applicant, the public health director or designee may postpone any hearing date, if warranted.

C. The public health director or designee shall issue a written notice of decision to the permittee or applicant within five working days following the hearing. In the event of a denial, suspension or revocation, the notice shall specify the acts or omissions with which the permittee or applicant is charged, and shall state the terms of the denial or suspension or that the permit has been revoked.

D. 1. If any immediate danger to the public health or safety is found, unless the danger is immediately corrected, the public health director or designee may temporarily suspend the permit and order the business closed or activity to cease. Immediate danger to the public health and safety means any condition, based upon inspection findings or other evidence, that can cause infection, poisoning, disease transmission, or hazardous condition.

2. Whenever a permit is suspended as the result of an immediate danger to the public health or safety, the public health director or designee shall issue to the permittee a notice setting forth the acts or omissions with which the permittee is charged, specifying the pertinent code section, and informing the permittee of the right to a hearing.

3. At any time within fifteen calendar days after service of a notice pursuant to subdivision (2) of this subsection, the permittee may request in writing a hearing before the public health director or designee to show cause why the permit suspension is not warranted. The hearing shall be held within fifteen calendar days of the receipt of a request for a hearing. A failure to request a hearing within fifteen calendar days shall be deemed a waiver of the right to such hearing.

E. The public health director or designee may, after providing opportunity for a hearing,

1 modify, suspend or revoke a permit for serious or repeated violations of any state and local
2 requirements or for interference in the performance of the duty of the enforcement officer.

3 F. A permit may be reinstated or a new permit issued if the public health director determines that
4 conditions which prompted the suspension or revocation no longer exist. Applicable fees must
5 be paid upon issuance of a new permit.

6 G. Permit modification, denial, suspension, or revocation may be appealed to the County
7 Hearing Officer. A written request for an appeal hearing shall be made by the permittee or
8 applicant within fifteen days of receipt of the notice of decision from the public health director.

9 H. Failure to request a hearing before the County Hearing Officer pursuant to subsection G of this
10 section shall be deemed a waiver of the right to such hearing. If a hearing is timely requested,
11 the County Hearing Officer may sustain, modify or reverse the decision of the public health
12 director.

13 I. Any interested party, including the health officer, may appeal the decision of the County Hearing
14 Officer to the board of supervisors by filing an appeal in writing with the clerk of the board of
15 supervisors within fifteen days of the decision. Failure to request a hearing within fifteen
16 calendar days shall be deemed a waiver of the right to such hearing. The board of supervisors
17 may sustain, modify or reverse the decision of the County Hearing Officer. The board of
18 supervisors' decision shall be final.

19 **8.52.070 - Enforcement.**

20 A. Any person authorized by the public health department to conduct inspections or to collect
21 fees for any business or activity subject to this chapter shall have the authority and immunities
22 of a public officer and employee as provided in Section 836.5 of the California Penal Code, to
23 make arrests without a warrant whenever the officer or employee has reasonable cause to
24 believe that the person to be arrested has committed an act in the officer's or employee's
25 presence which is a violation of this chapter.

26 B. Violation of this Chapter is a misdemeanor, subject to a penalty of up to six months in jail and
27 a fine of up to \$1,000.00.

28 C. Violation of this Chapter is declared to be a public nuisance.

- 1 D. Notwithstanding any other provision of this Ordinance Code, this Chapter may be enforced by
2 levying a civil penalty of up to \$1,000.00 per violation, each day that such violation exists
3 constituting a separate violation.
- 4 E. Notwithstanding any other provision of this Ordinance Code this Chapter may be enforced by a
5 civil action seeking injunctive relief, civil penalties, costs of abatement of non-compliant facilities,
6 and/or costs of enforcement.
- 7 F. Notwithstanding any other provision of this Ordinance Code any costs of abatement of
8 dangerous or non-compliant conditions that violate this Chapter may be recovered by the
9 County through any procedure provided under this Ordinance Code or state law.
- 10 G. The remedies provided in this Section are not exclusive to other remedies or procedures
11 that the County have authority under its ordinances or state law to pursue.

12 **Section 2:** This Ordinance shall take effect thirty (30) days after final passage.

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1 THE FOREGOING was passed and adopted by the following vote for the Board of Supervisors
2 of the County of Fresno this ____ day of _____, 2023, to-wit:

3 AYES:

4 NOES:

5 ABSENT:

6 ABSTAINED:

7 _____
8 Sal Quintero, Chairman of the Board of Supervisors of the
County of Fresno

9 **ATTEST:**

10 Bernice E. Seidel
11 Clerk of the Board of Supervisors
County of Fresno, State of California

12 By: _____
13 Deputy

14 FILE # _____

15 AGENDA # _____

16 ORDINANCE # _____

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