

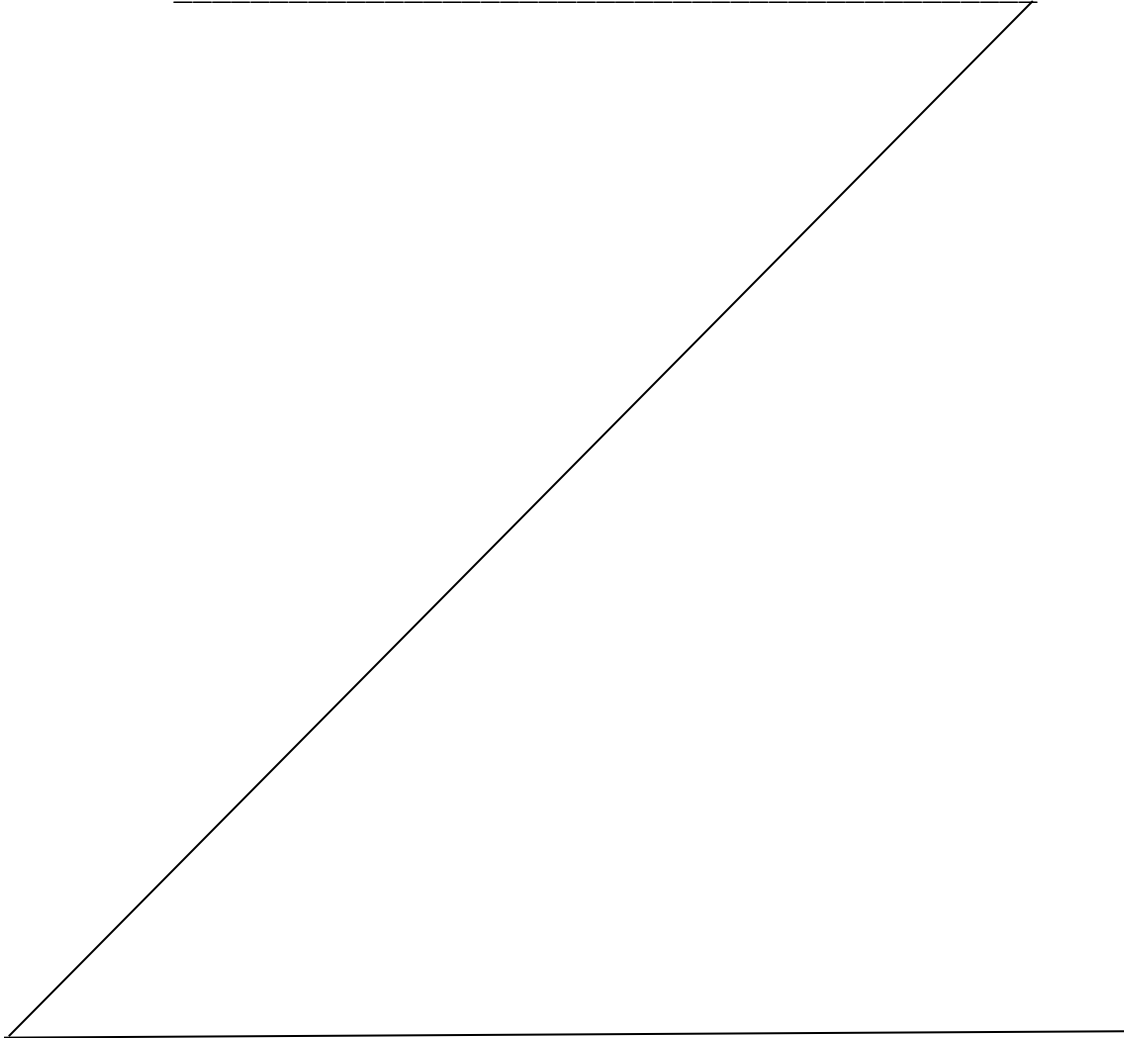
DEPARTMENT OF HEALTH

Repeal of Chapter 11-164 and Adoption of
Chapter 11-164.2
Hawaii Administrative Rules

(date adopted)

1. Chapter 11-164, Hawaii Administrative Rules, entitled "Tuberculosis", is repealed.

2. Chapter 11-164.2, Hawaii Administrative Rules, entitled "Tuberculosis", is adopted to read as follows: _____



"HAWAII ADMINISTRATIVE RULES

TITLE 11

DEPARTMENT OF HEALTH

CHAPTER 164.2

TUBERCULOSIS

- §11-164.2-1 Purpose
- §11-164.2-2 Definitions
- §11-164.2-3 Penalties
- §11-164.2-4 Severability
- §11-164.2-5 Suspension of rules

- §§11-164.2-6 to 11-164.2-9 (Reserved)

- §11-164.2-10 Reports to the department by practitioners, individuals in charge of an inpatient or outpatient health care facility, laboratory directors, and infection control officers
- §11-164.2-11 Release of information by practitioners, individuals in charge of an inpatient or outpatient health care facility, laboratory directors, and infection control officers
- §11-164.2-12 Evaluation of persons with TB disease, persons suspected of having TB disease, or persons exposed to communicable TB
- §11-164.2-13 TB clearance evaluation procedures for practitioners and the department

- §§11-164.2-14 to 11-164.2-19 (Reserved)

- §11-164.2-20 TB clearance requirements for school personnel
- §11-164.2-21 TB clearance requirements for school attendance

§11-164.2-1

- §11-164.2-22 TB clearance requirements for post-secondary school personnel
- §11-164.2-23 TB clearance requirements for post-secondary school attendance
- §11-164.2-24 TB clearance requirements for child care facility personnel
- §11-164.2-25 TB clearance requirements for child care facility attendance
- §11-164.2-26 TB clearance requirements for persons living or working in health care facilities or residential care settings licensed or otherwise regulated by the department
- §11-164.2-27 TB clearance requirements for food handlers

Historical note: Chapter 11-164.2 is based substantially on chapter 11-164. [Eff 11/05/81; am and comp 10/23/97; comp 08/27/01; R]. Chapter 11-164 was based substantially on Public Health Regulations Chapter 23, Tuberculosis, Department of Health, State of Hawaii. [Eff 06/11/60; am 04/16/64; 07/30/72, 07/31/73, 04/16/74; R 11/5/81]

§11-164.2-1 Purpose. The purpose of this chapter is to establish minimum requirements for the control of tuberculosis in the State. [Eff] (Auth: HRS §§321-1, 321-9, 325-13) (Imp: HRS §§302A-1162, 321-1, 321-9, 325-13)

§11-164.2-2 Definitions. As used in this chapter:

"Annually" means within the range of three hundred thirty-five to three hundred ninety-six days.

"Child care facility" has the same meaning as defined in section 346-151, Hawaii Revised Statutes (HRS).

"Child care facility operator" means the person with responsibility for the overall direct operation

of a child care facility, including but not limited to the owner, operator, manager, or director of the facility.

"Child care facility personnel" means adults who work or live in a child care facility, including but not limited to operators, caregivers, providers, household members, volunteers, and staff members such as child care and maintenance workers.

"Communicable TB disease" means TB disease caused by *Mycobacterium tuberculosis* which may spread from person to person through airborne contact. It generally includes pulmonary or laryngeal TB disease. It may also include other specific conditions determined by the department to represent a risk of transmission to other persons.

"Congregate setting" means any place where a number of persons meet, gather, reside, or share the same enclosed area.

"Course of study" means a sequence of classes leading to a certificate, diploma, degree, or other recognition of educational accomplishment.

"Department" means the department of health of the State of Hawaii, or an authorized officer or agent of the department.

"Director" means the director of health of the State of Hawaii or the director's duly authorized agent.

"Food establishment" means a place where food or beverages are prepared, packaged, served, sold, or otherwise provided for human consumption, but excludes establishments that offer only prepackaged foods, produce stands that only offer unprocessed fresh fruits and vegetables, or kitchens in private homes.

"Food handler" means any person who prepares, packages, serves, sells, or otherwise provides food or beverages for human consumption.

"Food handling" means engaging in the activities of a food handler in a food establishment.

"Hawaii TB Control Branch" means the department's Tuberculosis Control Branch.

"Health care facility" means a place licensed or certified by the department, including but not limited to hospitals, at which health care is provided.

"Hospital" means any institution currently licensed as such by the department, pursuant to section 321-14.5, HRS.

"Infection control officer" means an individual designated by a health care facility to provide surveillance, detection, prevention, or control of infectious agents.

"Initial TB evaluation" means the first evaluation for TB disease required for persons subject to TB clearance evaluation procedures as set forth in this chapter.

"Laryngeal TB" means TB disease involving the larynx.

"Latent TB infection" means Mycobacterium tuberculosis is present inside the body of a person and is not actively replicating or causing TB symptoms and is not communicable.

"Mycobacterium tuberculosis" means the bacterial species that causes latent TB infection or TB disease in humans.

"Notifiable Disease Report for Tuberculosis" means a department-approved form for reporting a person who is diagnosed with TB disease or suspected of having TB disease to the department. The "Notifiable Disease Report for Tuberculosis" form is included in the DOH TB Clearance Manual, referenced in section 11-164.2-13.

"Person suspected of having TB disease" means a person with laboratory, radiological, epidemiological, or clinical findings indicative of TB disease until a diagnostic evaluation is completed to rule out or confirm TB disease.

"Physician" means a person licensed to practice allopathic, osteopathic, or naturopathic medicine in any of the states or territories of the United States. A person who has a license or is accredited in chiropractic, homeopathy, acupuncture, or herbal healing does not qualify as a physician under this chapter.

"Post-secondary school" means an adult education school, business school, trade school, community college, college, or university enrolling students above the age of compulsory school attendance.

"Practitioner", for the purposes of this chapter, means an allopathic, osteopathic, or naturopathic physician, a physician assistant, or an advanced practice registered nurse authorized by the State of Hawaii to practice within the State.

"Pulmonary TB" means TB disease involving the lungs.

"Residential care setting" means a place licensed or certified by the department where people live, and medical care, therapeutic care, or other services are provided.

"Risk factor" means a variable associated with an increased risk of or susceptibility to latent TB infection or TB disease.

"School" means a congregate setting for care giving or educational purposes, for example, a child care center, day care center, day nursery, group child care home, Head Start, preschool, kindergarten, elementary, intermediate, middle, or secondary school, but excludes after school programs, drop-in child care centers, family child care, parent cooperatives, play groups, respite programs, and summer recreation programs.

"School personnel" means personnel employed by a school, including bus drivers and volunteers, or other persons anticipated to have contact with students for more than thirty days cumulatively within a twelve-month period.

"TB" or "tuberculosis" means infection or disease caused by *Mycobacterium tuberculosis*. The spectrum of illness is divided into two forms, "Latent TB infection" and "TB disease".

"TB clearance" means a department-approved form that provides documentation that a person has been evaluated by a practitioner and found to be free of communicable TB. The TB clearance provides a reasonable assurance that the individual is free from communicable TB at the time of the evaluation. The TB

clearance form does not imply any guarantee of protection from future tuberculosis risk for the individual listed. The department may require additional evaluation or testing of any person known, reported, or suspected to have TB disease, pursuant to section 11-164.2-11. The TB clearance form is included in the DOH TB Clearance Manual, referenced in section 11-164.2-13.

"TB disease" or "active TB" means Mycobacterium tuberculosis is active and multiplying in any part of the body of a person. TB disease can be either communicable or non-communicable.

"TB infection" means Mycobacterium tuberculosis is present inside the body of a person and may be latent TB infection or TB disease.

"TB risk assessment" means a department-approved evaluation tool to assess and document whether a person has TB symptoms or a risk factor for latent TB infection or TB disease. TB risk assessment tools for adults and children are available in the DOH TB Clearance Manual, referenced in section 11-164.2-13.

"TB symptoms" means findings, including cough, fever, weight loss, or night sweats, which suggest the possible existence of TB disease.

"Test for TB infection" means a department-approved test that is approved by the U.S. Food and Drug Administration and recommended by the Centers for Disease Control and Prevention for determining the presence of Mycobacterium tuberculosis in the body of a person. The results of the test may detect latent TB infection or TB disease. A list of department-approved tests for TB infection and guidelines for the interpretation of test results is included in the DOH TB Clearance Manual, referenced in section 11-164.2-13.

"Treatment for TB disease" means medication or medical therapy prescribed by a practitioner to cure a person of TB disease.

"Tuberculosis Case Follow-Up Report" means a department-approved form for reporting follow-up information on a person who is undergoing treatment for TB disease. The Tuberculosis Case Follow-Up

Report form is included in the DOH TB Clearance Manual, referenced in section 11-164.2-13.

[Eff] (Auth: HRS §§321-9, 325-13)
(Imp: HRS §§321-1, 321-9, 325-13)

§11-164.2-3 Penalties. (a) Any person who violates any provision of this chapter shall be guilty of a misdemeanor, and subject to the fines and penalties provided by law for a misdemeanor.

(b) Any person who fraudulently obtains a TB clearance shall be subject to the penalties in subsection (a) and shall also relinquish the fraudulently obtained TB clearance to the department.
[Eff] (Auth: HRS §§321-9, 321-18, 325-13, 325-14) (Imp: HRS §§321-1, 321-9, 321-18, 325-14)

§11-164.2-4 Severability. If any provision of this chapter or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this chapter which can be given effect without the invalid provision or application, and to this end the provisions of this chapter are severable.

[Eff] (Auth: HRS §§321-9, 325-13)
(Imp: HRS §§321-9, 325-13)

§11-164.2-5 Suspension of rules. The director may suspend any or all of these rules in the event of a shortage of diagnostic or treatment materials, or in the event of a public health emergency as declared by the director. [Eff] (Auth: HRS §§321-9, 325-13) (Imp: HRS §§321-9, 325-13)

§§11-164.2-6 to 11-164.2-9 (Reserved)

§11-164.2-10 Reports to the department by practitioners, individuals in charge of an inpatient or outpatient health care facility, laboratory directors, and infection control officers.

(a) Any practitioner, individual in charge of an inpatient or outpatient health care facility, laboratory director, or infection control officer who makes a diagnosis of TB disease or identifies a person suspected of having TB disease shall report this to the department using the Notifiable Disease Report for Tuberculosis (NDR-TB). The practitioner, individual in charge of an inpatient or outpatient health care facility, laboratory director, or infection control officer shall complete and submit the NDR-TB within seventy-two hours after the diagnosis or identification is made. Instructions for completing and submitting the NDR-TB to the department are included in the DOH TB Clearance Manual, referenced in section 11-164.2-13.

(b) Any practitioner, individual in charge of an inpatient or outpatient health care facility, laboratory director, or infection control officer providing treatment for TB disease shall provide the department a follow-up report using the department's Tuberculosis Case Follow-Up Report every sixty days until treatment is completed. The Tuberculosis Case Follow-Up Report form is included in the DOH TB Clearance Manual, referenced in section 11-164.2-13.

(c) If any of the information required by the Notifiable Disease Report for Tuberculosis or the Tuberculosis Case Follow-Up Report is unknown to the practitioner, individual in charge of an inpatient or outpatient health care facility, laboratory director, or infection control officer at the time of the report, the practitioner, individual in charge of an inpatient or outpatient health care facility, laboratory director, or infection control officer shall submit the required report with the information available at the time, and provide follow-up information as it becomes available.

(d) Any practitioner, individual in charge of an inpatient or outpatient health care facility, laboratory director, or infection control officer

providing treatment for TB disease shall provide the department information related to the diagnosis pursuant to section 325-71, HRS.

(e) Any laboratory identifying Mycobacterium tuberculosis shall submit a report to the department pursuant to section 325-71, HRS.
 [Eff] (Auth: HRS §§321-9, 325-13)
 (Imp: HRS §§321-1, 321-9, 325-2, 325-71)

§11-164.2-11 Release of information by practitioners, individuals in charge of an inpatient or outpatient health care facility, laboratory directors, and infection control officers. Upon request, any practitioner, individual in charge of an inpatient or outpatient health care facility, laboratory director, or infection control officer treating a person for TB disease shall provide the department any additional information relative to the person's case as is necessary, in the opinion of the department, for the protection and safety of the public and for case management and epidemiologic study of the case. [Eff] (Auth: HRS §§321-1, 321-9, 321-29, 325-13) (Imp: HRS §§321-1, 321-9, 321-29, 321-31, 325-71)

§11-164.2-12 Evaluation of persons with TB disease, persons suspected of having TB disease, or persons exposed to communicable TB. Notwithstanding a person's possession of a TB clearance, any person who is:

- (1) Known to have TB disease;
- (2) Reported to the department as having TB disease;
- (3) Reasonably suspected by the department of having TB disease; or
- (4) Reasonably suspected by the department to have been exposed to communicable TB,

may be required by the department to be evaluated or tested at a department TB clinic, or at a hospital or by a practitioner approved by the department, for the

purpose of assessing the extent and progress of TB disease, if any, in the person.

[Eff _____] (Auth: HRS §§321-1, 321-9, 321-29, 325-13) (Imp: HRS §§321-1, 321-9, 321-29, 321-31, 325-76)

§11-164.2-13 TB clearance evaluation procedures for practitioners and the department. For purposes of evaluating persons required by this chapter to obtain a TB clearance, practitioners and the department shall follow the instructions and procedures in the document entitled "DOH TB Clearance Manual", dated 05/01/2017. This document is available from the department and can be found on the Hawaii TB Control Branch website.

[Eff _____] (Auth: HRS §§321-1, 321-9, 321-29, 325-13) (Imp: HRS §§321-1, 321-9, 321-29, 321-31, 325-71)

§11-164.2-14 to §11-164.2-19 (Reserved)

§11-164.2-20 TB clearance requirements for school personnel. (a) Prior to starting employment at a school, school personnel shall present to the administrator of the school:

- (1) A TB clearance obtained within twelve months prior to the start date; or
- (2) A TB clearance obtained after age sixteen.

(b) Every school shall maintain a copy of the TB clearance for all school personnel, and shall make the copy available for inspection by the department.

[Eff _____] (Auth: HRS §§302A-612, 302A-1162, 321-9, 321-11, 321-31, 325-13) (Imp: §§302A-612, 302A-1162, 321-1, 321-9, 321-31, 325-76)

§11-164.2-21 TB clearance requirements for school attendance. (a) Prior to attending school in the State a child shall present to the administrator of the school a TB clearance; provided that if a TB

clearance was obtained before the child was twelve months of age, the child shall obtain a new TB clearance after the child is twelve months of age and present it to the school before the child is sixteen months of age or the child shall be excluded from the school until a TB clearance is presented.

(b) Every school shall maintain a copy of each student's TB clearance while the student is enrolled, shall make that copy available for inspection by the department, and shall transmit a copy of the TB clearance and the student's health record to the school to which a student transfers.

(c) This section shall not apply to those persons who attend school through online or other off-campus training and who never physically attend school for instruction or training. [Eff]
 (Auth: HRS §§302A-1162, 321-9, 321-11, 321-31, 325-13) (Imp: HRS §§302A-1162, 321-1, 321-9, 321-31, 325-76)

§11-164.2-22 TB clearance requirements for post-secondary school personnel. (a) Prior to starting employment at a post-secondary school, post-secondary school personnel shall present to the administrator of the post-secondary school:

- (1) A TB clearance obtained within twelve months prior to the start date; or
- (2) A TB clearance obtained after age sixteen.

(b) Every post-secondary school shall maintain a copy of the TB clearance for all post-secondary school personnel, and shall make the copy available for inspection by the department. [Eff]
 (Auth: HRS §§302A-1162, 321-9, 321-11, 321-31, 325-13) (Imp: §§302A-612, 302A-1162, 321-1, 321-9, 321-31, 325-76)

§11-164.2-23 TB clearance requirements for post-secondary school attendance. (a) Prior to attending a post-secondary school in the State for a course of

study longer than one hundred twenty days, a person shall present to the administrator of the school:

- (1) A TB clearance obtained within twelve months prior to the start date; or
- (2) A TB clearance obtained after age sixteen.

(b) Every post-secondary school shall maintain a copy of each student's TB clearance while the student is enrolled, shall make that copy available for inspection by the department, and shall transmit a copy of the TB clearance and the student's health record to the post-secondary school to which a student transfers.

(c) This section shall not apply to those persons who attend school through online or other off-campus training and who never physically attend school for instruction or training. [Eff]
(Auth: HRS §§302A-1162, 321-9, 321-11, 321-31, 325-13) (Imp: HRS §§302A-1162, 321-1, 321-9, 321-31, 325-76)

§11-164.2-24 TB clearance requirements for child care facility personnel. (a) Prior to starting employment or volunteer service at a child care facility, child care facility personnel shall present to the child care facility operator and the department of human services a TB clearance obtained within twelve months prior to the date of employment or volunteer service, and shall obtain a TB clearance annually.

(b) Every child care facility shall maintain a copy of each employee's or volunteer's TB clearance while they are employed by or providing service to the child care facility, and shall make that copy available for inspection by the department of health and the department of human services.
[Eff] Auth: HRS §§321-9, 321-11, 321-31, 325-13) (Imp: §§321-1, 321-9, 321-31, 325-76)

§11-164.2-25 TB clearance requirements for child care facility attendance. (a) Prior to attending a

child care facility in the State, a child shall present to the child care facility administrator and the department of human services a TB clearance; provided that if a TB clearance was obtained before the child was twelve months of age, the child shall obtain a new TB clearance after the child is twelve months of age and present it to the child care facility before the child is sixteen months of age or the child shall be excluded from the child care facility until a TB clearance is presented.

(b) Every child care facility shall maintain a copy of each child's TB clearance while the child is attending the child care facility, and shall make that copy available for inspection by the department of health and the department of human services.

[Eff _____] (Auth: HRS §§321-9, 321-11, 321-31, 325-13) (Imp: HRS §§321-1, 321-9, 321-31, 325-76)

§11-164.2-26 TB clearance requirements for persons living or working in health care facilities or residential care settings licensed or otherwise regulated by the department.

(a) Employees, contract workers, and volunteers working more than ten hours per week in health care facilities or residential care settings licensed or otherwise regulated by the department and residents of health care facilities or residential care settings licensed or otherwise regulated by the department shall obtain a TB clearance within twelve months prior to the date of employment, contract start date, volunteer service, or entry into a health care facility or residential care setting licensed or otherwise regulated by the department, and shall obtain a TB clearance annually.

(b) A person who does not meet the requirements of subsection (a) who requires urgent or unexpected admission into a health care facility or residential care setting licensed or otherwise regulated by the department may be temporarily admitted by providing the following:

- (1) Documentation of a chest x-ray taken within the preceding thirty days that excludes a diagnosis of communicable TB disease; or
- (2) If a chest x-ray is not available, evidence that a practitioner has completed a TB risk assessment on the person and determined that the person has no TB symptoms.

The person shall obtain a TB clearance within two weeks of the admission or may be discharged.

(c) A person who does not meet the requirements of subsections (a) or (b) who requires urgent or unexpected admission into a health care facility or residential care setting licensed or otherwise regulated by the department may not be admitted.

(d) The following persons shall be exempt from the requirements of this section:

- (1) Persons who are not in contact with, or who have not shared air space with patients or residents of the facilities (e.g., telephone operators who work in a separate office from patients or residents), or who will never be in contact with clinical specimens that may contain *Mycobacterium tuberculosis*;
- (2) Patients of acute inpatient facilities; and
- (3) Infants under twelve months of age.
[Eff _____] (Auth: HRS §§321-9, 321-11, 321-31, 325-13) (Imp: HRS §§321-1, 321-9, 321-31, 325-76)

§11-164.2-27 TB clearance requirements for food handlers. (a) Prior to starting employment as a food handler, a person shall present to the employer:

- (1) A TB clearance obtained within twelve months prior to the start date; or
- (2) A TB clearance obtained after age sixteen.

(b) Persons engaged in food handling only at carnivals, fairs, or other temporary activities lasting less than fifteen days shall be exempt from this section.

(c) Every employer shall maintain a copy of each food handler's TB clearance while the food handler is

employed at the food establishment, and shall make that copy available for inspection by the department." [Eff _____] (Auth: HRS §§321-9, 321-11, 321-31, 325-13) (Imp: HRS §§321-1, 321-9, 321-31, 325-76)

3. The repeal of chapter 11-164 and the adoption of chapter 11-164.2, Hawaii Administrative Rules, shall take effect ten days after filing with the Office of the Lieutenant Governor.

I certify that the foregoing is a copy of the rules, drafted in the Ramseyer format pursuant to the requirements of section 91-4.1, Hawaii Revised Statutes, which were adopted on _____ and filed with the Office of the Lieutenant Governor.

VIRGINIA PRESSLER, M.D., Director
Department of Health

APPROVED AS TO FORM:

Deputy Attorney General