



STATE OF HAWAII
DEPARTMENT OF HEALTH
OFFICE OF HEALTH CARE ASSURANCE
601 KAMOKILA BOULEVARD, ROOM 337
KAPOLEI, HAWAII 96707

In reply, please refer to
file:

November 5, 2021

Raymond Embry
Chief Executive Officer
Embry Health
4717 E. Hilton Avenue, Suite 250
Phoenix, Arizona 85034

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED
7017 2620 0000 4645 6428

Dear Mr. Embry:

**RE: ORDER TO CEASE AND DESIST OPERATIONS AND
PAY ADMINISTRATIVE PENALTY FOR OPERATING A
COLLECTING DEPOT OR COLLECTING DEPOTS WITHOUT A
CLIA CERTIFICATE AND WRITTEN STATE OF HAWAII
DEPARTMENT OF HEALTH APPROVAL**

The State of Hawaii Department of Health (DOH) hereby orders Embry Health to immediately cease and desist the operations of all Embry operated collecting depots in the State of Hawaii and is ordered to pay an administrative penalty of \$207,000.00 as determined herein for operating a collecting depot or collecting depots without a State of Hawaii license or permit or written approval. This action is taken by the DOH Office of Health Care Assurance (OHCA) under the authority of federal and state statutes and regulations on clinical laboratories pursuant to Clinical Laboratory Improvement Amendments of 1988 (CLIA), sections 321-11 and 321-13, Hawaii Revised Statutes (HRS), and chapter 11-110.1, Hawaii Administrative Rules (HAR).

Statutes and Rules

Section 321-13(b), HRS, states, "[i]t shall be unlawful for any person to engage in or to attempt to engage in or to follow any of the occupations or practices referred to in this section, unless the person first obtains and hold a valid unrevoked certificate of registration or permit under such rules or regulations as the department shall prescribe." Such rules are promulgated under chapter 11-110.1, HAR.

Under section 11-110.1-6(a), HAR, it requires that "[n]o person shall establish, conduct, maintain, or operate a clinical laboratory in the State without a valid and effective clinical laboratory permit or license issued by the department." HAR 11-110.1-18(a) requires that "[a] clinical laboratory certified under 42 C.F.R. part 493 subpart A may operate collecting depots after first obtaining written approval from the department for the establishment of each depot."

Further, HAR 11-110.1-19(b), mandates that “[n]o establishment other than a clinical laboratory certified under 42 C.F.R. part 493 subpart A or a collecting depot conducted in conformity with section 11-110.1-18 shall receive specimens for the purpose of laboratory examination to obtain information for diagnosis, prevention, or treatment of a disease or the assessment of a medical condition.”

Finally, an administrative penalty is authorized pursuant to section 321-13(a), HRS and sections 11-110.1-20(a)(1) and 11-110.1-37, HAR. Specifically, HAR 11-110.1-37 states that “[a]nyone who violates the provisions of this subchapter may be fined not more than \$1000 for each day of violation.”

Nature of the Violation

On September 19, 2021, the Hawaii news media reported that Embry Health intended to open a testing site at Kahala Mall, Suite UB-U2 Hawaii on September 20, 2021.¹ On September 22, 2021, DOH received a complaint that Embry Health was operating a testing site at Kahala Mall in Honolulu, Hawaii. In addition, a September 22, 2021 DOH Disease Outbreak Control Division (DOCD) Weekly Operations Report reported in Section IX Electronic Lab Reporting, "Ready-To-Go-Live: American Institute of Toxicology, Inc. a HealthTrack Rx company will be reporting electronic lab reports (ELR) for PCR test results. Current specimen location is Kahala mall. Specimens are sent to their lab in Texas for testing."

On September 24, 2021, a review of DOH records determined there was no contact between Embry Health and the DOH State Laboratories Division (SLD) or between Embry Health and the DOH OHCA to request written approval to operate any collecting depots in the State of Hawaii; and specifically, to operate a collecting depot at Kahala Mall.

On September 27, 2021, a representative of the DOH OHCA confirmed that Embry Health had established a site at Kahala Mall and witnessed nasal samples being collected from an individual while other individuals waited within the Embry Health location.

On September 28, 2021, further review of DOH OHCA records verified no Embry Health Laboratory was listed in state permit or CLIA databases.

On October 5, 2021, DOH SLD referred a mobile laboratory information request from Dr. Aubrey Anderson to DOH OHCA. During an October 6, 2021 phone conversation with DOH OHCA, Dr. Anderson identified herself from the Mana Clinic and her email address as danderson@themanaclinic.com. She inquired about operating a mobile laboratory to collect specimens in Hawaii to send to the U.S. mainland for testing. Regulatory requirements on collecting depots under chapter 11-110.1, HAR, were provided to Dr. Anderson by email on October 6, 2021.

Beginning on or about October 6, 2021, an exchange of phone calls and emails ensued among Tedric Abe, Field Operations Manager, Embry Health, and various representatives of DOH. In an email on October 6, 2021, Mr. Abe identified Dr. Anderson as an Embry Health employee. On Friday, October 8, 2021, a Microsoft Teams virtual meeting was held between representatives of Embry Health and Hawaii DOH. The meeting included Steffan Embry,

¹ <https://www.khon2.com/coronavirus/embry-health-offering-free-covid-tests-at-kahala-mall/>. By Ray Anne Galzote, posted on September 19, 2021.

Director of Special Projects, Embry Health, John Moore, Chief Commercial Officer, HealthTrack Rx, Tedric Abe, Embry Field Operations Manager, and others from or invited by Embry Health, and Keith Ridley, Chief, OHCA, Diane Kumashiro, OHCA CLIA Medical Technologist, and others from the DOH. The purpose of the meeting was to inform Embry Health of the regulatory requirements to operate a collecting depot or depots in Hawaii and to encourage their rapid cooperation to meet regulatory requirements so that Embry's depot operations could continue to serve Hawaii's public.

Between October 8, 2021 and October 18, 2021, emails were exchanged between Embry and DOH OHCA that indicated Embry would comply with Hawaii DOH's collecting depot requirements. John Moore from HealthTrack Rx, emailed a CLIA Certificate of Accreditation #45D2009077 for American Institute of Toxicology, Inc., to DOH OHCA on October 8, 2021.

On October 12, 2021, DOH OHCA emailed John Moore the DOH OHCA collecting depot documentation requirements along with the chapter 11-110.1, HAR rule excerpt on Collecting Depots. DOH OHCA also inquired if the American Institute of Toxicology, Inc. was conducting business as HealthTrack Rx. John Moore responded the same day by email that the HealthTrack Rx/Embry team would ensure that all of DOH OHCA's requirements would be addressed by Thursday, October 14, 2021, if not sooner.

On October 13, 2021, Steffan Embry emailed DOH OHCA stating that Embry was under a contract with HealthTrack Rx to serve as a collection depot station for the HealthTrack Rx Laboratory. DOH OHCA responded back by email requesting documentation verifying Embry's COVID-19 testing and reporting agreement or relationship with American Institute of Toxicology, Inc. and HealthTrack Rx. Following a phone conversation with DOH OHCA, Carmen Hill-Mekoba, Chief Nursing Officer (CNO), Embry Health emailed DOH OHCA that all pending Embry Health documentation would be submitted by close of business on October 15, 2021. On October 15, 2021, Carmen Hill-Mekoba emailed DOH OHCA that Embry's information was awaiting her review and that all documents including CLIA certificates, the CMS-116 CLIA Application for Certification form, OHCA 1513 Disclosure of Ownership form, current manual of methods, procedures and test result reporting, and a list of current testing sites with start dates would be submitted by Monday, October 18, 2021. On Monday, October 18, 2021, Carmen Hill-Mekoba emailed DOH OHCA a manual entitled "procedure Binder7.pdf" and a list of collecting depot sites with start dates. The collecting depot sites included Wahiawa District Park, Waipahu District Park, Kahala Mall, Kaimana Beach Hotel Waikiki, and Mauna Kea Resort (Big Island). The list of sites did not include Patsy T. Mink Central Oahu Regional Park (CORP) in Waipahu. Other documents listed in her October 15, 2021 email were not submitted to DOH OHCA.

On October 19, 2021, DOH OHCA received an email from Carmen Hill-Mekoba, Embry Health, "requesting that the application for the collecting depot be withdrawn."

Determination of Uncertified Status

As a result of Embry Health's withdrawal of the application for the collecting depot or depots in the State of Hawaii, DOH OHCA has determined that Embry Health is operating a collecting depot or depots without demonstrating it is a clinical laboratory certified under 42 C.F.R. Part 493 Subpart A and without the written approval of DOH OHCA for the establishment of each depot as required by law and has determined Embry Health has been in violation of the law for a minimum of two hundred seven (207) days based on the summary of evidence below.

Determination of Uncertified Time Period

As stated above, on September 27, 2021, a representative of the DOH OHCA confirmed that Embry Health had established a site at Kahala Mall and witnessed nasal samples being collected from an individual while other individuals waited within the Embry Health location. This is a total of at least forty (40) days as of the date of this letter.

In addition, on October 25, 2021, DOH OHCA received confirmation from the City and County of Honolulu that Embry Health was issued City Department of Parks & Recreation facility permits to operate free COVID-19 testing for the time periods and locations identified below. It must also be noted that the City and County of Honolulu permits require that the permittee "shall comply with all state and federal laws." Refer to Facility Permit, Terms and Conditions, paragraph 3. Laws and Rules.

- Beginning October 7, 2021, through November 11, 2021, at the Patsy T. Mink Central Oahu Regional Park (CORP) Parking Lot Tennis-A and Tennis-B, located at 94-801 Kamehameha Hwy, Waipahu, HI 96797, permit number 195947, for a total of thirty-seven (37) days;
- Beginning September 22, 2021, through November 21, 2021, at Wahiawa District Park, located at 1139-A Kilani Avenue, Wahiawa, HI 96786, permit number 195771, for a total of sixty (60) days;
- Beginning October 10, 2021, at Waipahu District Park, located at 94-230 Paiwa Street, Waipahu, HI 96797, permit number 195749, for one (1) day;
- Beginning September 22, 2021 through November 21, 2021, at Waipahu District Park, located at 94-230 Paiwa Street, Waipahu, HI 96797, permit number 195750, for a total of sixty (60) days.

Based on the four (4) City and County of Honolulu Department of Parks & Recreation permits, Embry Health illegally operated four (4) collecting depots for a total of at least one hundred fifty-eight (158) days in violation of state laws and rules.

On October 22, 2021, DOH OHCA confirmed that Embry Health illegally operated a collecting depot at the Mauna Kea Beach Resort on Hawaii Island beginning October 18, 2021, twice a week, for at least a total of six (6) days.

According to the Embry Health website at <https://embryhealth.com/honolulu-az-kai-kaimanabeachhotelwaikiki/>, Embry is also illegally operating a COVID-19 PCR Diagnostic Test site at Kaimana Beach Hotel Waikiki, 2863 Kalakaua Avenue, Honolulu, HI 96815, every Monday. Total days are preliminary determined as three (3) days.

Determination of Administrative Penalty

The total minimum number of days Embry Health is determined to have or is scheduled to illegally operate collecting depots in the State of Hawaii without demonstrating it is a clinical laboratory certified under 42 C.F.R. Part 493 Subpart A and without the written approval of DOH OHCA for the establishment of each collecting depot is two hundred seven (207) days. An administrative penalty is hereby assessed at **\$207,000.00** based on 207 days at \$1,000 per day pursuant to HRS 321-13(a) and HAR 11-110.1-37.

Order

Embry Health is hereby ordered to immediately:

1. Cease and desist operating the above listed collecting depots and any and all other collecting depots within the State of Hawaii;
2. Pay an administrative penalty totaling \$207,000;
3. Notify DOH OHCA in writing of all collecting depot locations operated by Embry Health within the State of Hawaii and confirm the date that operations ceased; and
4. Not open or operate any collecting depot in the State of Hawaii without a valid state certificate or permit or without obtaining prior written approval from DOH OHCA.

Sincerely,



KEITH R. RIDLEY, M.B.A.
Chief, Office of Health Care Assurance

c: The Honorable Rick Blangiardi
Mayor of the City and County of Honolulu

The Honorable Laura H. Thielen
Director of the Department of Parks & Recreation
City and County of Honolulu

The Honorable Clare E. Connors
State of Hawaii Attorney General
Department of the Attorney General

Elizabeth A. Char, M.D.
Director of Health
State of Hawaii, Department of Health

Danette Wong Tomiyasu, M.B.A.
Deputy Director, Health Resources Administration
State of Hawaii, Department of Health