



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:

December 7, 2021

Dr. Darshan Shah
Next Health Hawaii Inc.
3900 Wailea Alanui Drive
Kihei, Hawaii 96753

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED
7018 0680 0002 0558 2927

Dear Dr. Darshan Shah:

**RE: ORDER TO CEASE AND DESIST OPERATIONS AND
PAY ADMINISTRATIVE PENALTY FOR OPERATING A
CLINICAL LABORATORY WITHOUT A STATE OF HAWAII
DEPARTMENT OF HEALTH ("DOH") CLINICAL LABORATORY
CLASS I CLINICAL LABORATORY PERMIT AND A
CLIA CERTIFICATE OF WAIVER**

The State of Hawaii Department of Health (DOH) hereby orders NextHealth to immediately cease and desist the operations of all NextHealth operated clinical laboratory or clinical laboratories in the State of Hawaii and is ordered to pay an administrative penalty of \$58,000.00 as determined herein for operating a clinical laboratory or clinical laboratories without a DOH Clinical Laboratory Class I Clinical Laboratory permit. This action is taken by the DOH Office of Health Care Assurance (DOH 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 [DOH OHCA]." Further, sections 11-110.1-7(a) and (b), HAR, states:

- (a) A person intending to operate a clinical laboratory may apply for a class I permit if the laboratory:

- (1) Performs only waived or provider performed microscopy procedures, or both, pursuant to 42 C.F.R. part 493 subpart A, on its premises;
 - (2) **Is certified as a clinical laboratory under 42 C.F.R. part 493 subpart A;** and
 - (3) Remits applicable fees.
- (b) A person applying for an initial class I clinical laboratory permit and renewal **shall complete application forms provided by the department.**

Emphases added. A "clinical laboratory" is defined as "a facility where the microbiological, serological, chemical, hematological, biophysical, toxicological, cytological, pathological, or other examinations of specimens taken from the human body are performed to obtain information for diagnosis, prophylaxis, or treatment of a disease or assessment of a medical condition." Section 11-110.1-2, HAR.

Under section 11-110.1-19(b), HAR, "[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." Emphasis added. Non-compliance under this section is considered an unlawful practice.

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 November 8, 2021, DOH OHCA received a complaint that NextHealth was conducting Rapid Antigen COVID-19 testing and Rapid PCR COVID-19 testing at the Four Seasons Resort Maui at Wailea located at 3900 Wailea Alanui Dr., Kihei, Hawaii.

On November 16, 2021, a review of NextHealth's website at <https://www.next-health.com/pages/hawaii-four-seasons> confirmed that NextHealth was offering the BD Veritor Rapid Antigen COVID-19 tests and ThermoFisher Accula SARS COV-2 PCR tests at the Four Seasons Resort Maui.

On November 16, 2021, a review of DOH records determined that NextHealth was not listed in any state DOH permit or CLIA databases.

Beginning November 18, 2021 through November 22, 2021, a representative of the DOH OHCA exchanged a series of phone calls, voice mails, emails and U.S. mail with Megan Retterath, APRN, NP-C, NextHealth Chief Medical Officer, regarding NextHealth operating a clinical laboratory and conducting COVID-19 testing which requires a permit from DOH OHCA.

On November 23, 2021, a review of CLIA database records also found that NextHealth possessed a CLIA certificate of waiver in California (CLIA #05D1051930) under the clinical laboratory name Beautologie Cosmetic Surgery Inc. However, the California clinical laboratory

did not apply for or receive approval for multiple sites, temporary testing locations in Hawaii. Further, DOH OHCA has no record of receiving an application for a certificate, permit, license or certificate of waiver from NextHealth or Beautologie Cosmetic Surgery Inc. to operate in Hawaii and no DOH OHCA Clinical Laboratory Class I permit or CLIA Certificate of Waiver was issued to NextHealth to operate any clinical laboratory to include performing or conducting laboratory testing in the State of Hawaii.

On November 29, 2021, a DOH OHCA representative conducted an unannounced onsite investigation at the NextHealth location at the Four Seasons Resort Maui located at 3900 Wailea Alanui Dr., Kihei, Hawaii, to determine if the allegations of the complaint received on November 8, 2021, and information contained on the NextHealth website were accurate. The representative observed laboratory personnel perform BD Veritor Rapid Antigen COVID-19 testing on two individuals while on-site. The representative also observed laboratory personnel making a ThermoFisher Accula SARS COV-2 PCR test appointment for a guest of a nearby hotel. The DOH OHCA representative also discovered that NextHealth did not have a Hawaii state licensed clinical laboratory director pursuant to HAR 11-110.1-23(a). The investigation concluded that the allegations from the complaint and website information were correct and it was confirmed that NextHealth was operating in the state of Hawaii without a CLIA Certificate of Waiver and a State of Hawaii Clinical Laboratory Class I Permit as required under 42 C.F.R. Part 493 Subpart A and 11-110.1-6(a) HAR for the establishment of a clinical laboratory as required by law.

Determination of Violation Time Period

As a result of NextHealth's failure to obtain a State of Hawaii Class I Clinical Laboratory permit from DOH OHCA to operate a clinical laboratory prior to performing laboratory services in the State of Hawaii, DOH OHCA has determined that NextHealth is operating a clinical laboratory without obtaining a CLIA Certificate of Waiver under 42 C.F.R. Part 493 Subpart A and without obtaining a Clinical Laboratory Class I permit from DOH OHCA under 11-110.1-6(a) HAR for the establishment of a clinical laboratory as required by law. NextHealth has been in violation of the law for a minimum of fifty eight (58) days based on the summary of evidence below.

Based on the DOH OHCA representative's onsite review of patient test logs, interviews of NextHealth testing personnel, and observations during the unannounced onsite investigation on November 29, 2021, at the NextHealth's location at the Four Seasons Resort Maui, it was determined that NextHealth began performing the BD Veritor Rapid Antigen COVID-19 testing and ThermoFisher Accula SARS COV-2 PCR testing on the premises of the Four Seasons Resort Maui on October 11, 2021. Starting from October 11, 2021, through November 29, 2021, approximately 982 patients were tested and there was no indication that NextHealth would cease to offer or perform testing services. Therefore, the violation time period is determined to be from October 11, 2021, to the date of this cease and desist letter, inclusive, for a total of fifty eight (58) days. The violation time period may be determined to be greater if testing continues to be offered or conducted beyond the date of this cease and desist letter.

Determination of Administrative Penalty

The total number of days NextHealth is determined to have operated a Class I Clinical Laboratory in the State of Hawaii without demonstrating it is a clinical laboratory certified under 42 C.F.R. Part 493 Subpart A and without obtaining a Class I Clinical Laboratory permit from DOH OHCA for the establishment of a clinical laboratory pursuant to 11-110.1-6(a) HAR at the

Four Seasons Resort Maui located at 3900 Wailea Alanui Dr., Kihei, Hawaii, is fifty eight (58) days. An administrative penalty is hereby assessed at **\$58,000.00** based on fifty eight (58) days at \$1,000 per day pursuant to HRS 321-13(a) and HAR 11-110.1-37. The administrative penalty may be determined to be greater if the violation time period is determined to be greater as noted above. DOH OHCA reserves the right to assess an additional administrative penalty based on the additional violation time period.

ORDER

NextHealth is hereby ordered to immediately:

1. Cease and desist operating a Class I Clinical Laboratory at the Four Season Resort Maui located at 3900 Wailea Alanui Dr., Kihei, Hawaii and any and all other clinical laboratory locations within the State of Hawaii;
2. Pay an administrative penalty totaling **\$58,000.00**;
3. Notify DOH OHCA in writing of all clinical laboratories operated by NextHealth within the State of Hawaii and confirm the date that operations ceased; and
4. Not open or operate any clinical laboratory in the State of Hawaii without a valid State of Hawaii Class I Clinical Laboratory permit from DOH OHCA.

Pursuant to HAR 11-110.1-37, NextHealth "may have recourse to an administrative hearing in accordance with chapter 91, HRS." As a result, **this Order becomes final and enforceable twenty (20) days after your receipt of this Order unless you submit a written request for a hearing.** The written request for a hearing must be mailed to: Hearings Officer, Department of Health, 1250 Punchbowl Street, Third Floor, Honolulu, Hawaii 96813. Your written request for a hearing must occur **before the twenty (20) days expire.** Include a copy of this Order with your hearing request.

Sincerely,



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

c: Ben Shank, General Manager
Four Seasons Resort Maui at Wailea

Robby Delaney, Resort Manager
Four Seasons Resort Maui at Wailea

Elizabeth A. Char, M.D.
Director of Health

Danette Wong Tomiyasu, M.B.A.
Deputy Director, Health Resources Administration