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November 6, 2023

Kenneth S. Fink, MD, MGA, MPH Director, Department of Health 1250 Punchbowl Street Honolulu, Hawaii 96813

RULEMAKING PETITION

Dear Director Fink,

Attached please find a Petition for Rulemaking that addresses the need to change the department's current policy of allowing two-year certifications and registrations.

I have an interest in this matter because of the negative impact that two-year certifications are having upon medical cannabis patients because of the lack of follow up care and medical supervision that is resulting from this practice.

Thank you for considering this request.

Aloha,

Clifton Otto, MD cliftonotto@hotmail.com



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PROPOSED AMENDMENT:

HAR § 11-160-12 Written certifications.

(c) Unless revoked or voided, a written certification shall be valid for one year from the time of signing by the physician or advanced practice registered nurse[; provided that, as recommended by the certifying physician or certifying advanced practice registered nurse, the written certification may be valid for up to two years if the qualifying patient's debilitating medical condition is chronic in nature], provided that existing two-year certifications shall remain valid until they expire.

JUSTIFICATION:

State law requires that patients have a bona fide physician-patient or advanced practice registered nurse (APRN)-patient relationship with their certifying provider.

HRS §329-123 Registration requirements; qualifying patients; primary caregivers.

(a) Physicians or advanced practice registered nurses who issue written certifications shall provide, in each written certification, the name, address, patient identification number, and other identifying information of the qualifying patient. The department of health shall require, in rules adopted pursuant to chapter 91, that all written certifications comply with a designated form completed by or on behalf of a qualifying patient. The form shall require information from the applicant, primary caregiver, and physician or advanced practice registered nurse as specifically required or permitted by this chapter. The form shall require the address of the location where the cannabis is grown and shall appear on the registry card issued by the department of health. The certifying physician or advanced practice registered nurse shall be required to have a bona fide physician-patient relationship or bona fide advanced practice registered nurse-patient relationship, as applicable, with the qualifying patient. All current active medical cannabis permits shall be honored through their expiration date.

Department rules define the bona fide physician/APRN-patient relationship, which requires an ongoing responsibility to provide follow up care:

Rulemaking Petition November 6, 2023 Page 2

HAR §11-160-2 Definitions.

"Bona fide physician-patient relationship" means a relationship in which the physician has <u>ongoing responsibility for the assessment, care</u>, and treatment of a qualifying patient's debilitating medical condition with respect to the medical use of cannabis which means:

(2) The physician <u>provides follow up care</u> and treatment as medical appropriate to the qualifying patient and assesses the qualifying patient's condition during the course of the qualifying patient's medical use of cannabis;

The department's <u>website</u> reinforces the importance of this relationship:

A "bona fide physician/APRN-patient relationship" means a relationship in which the physician/APRN has ongoing responsibility for the assessment, care, and treatment of a qualifying patient's debilitating medical condition with respect to the medical use of cannabis which means:

- 1. The physician/APRN has completed a full assessment of the qualifying patient's medical history and current medical condition, including conducting a review of the qualifying patient's medical records related to the debilitating condition, as medically appropriate, and conducting an in-person physical examination;
- The physician/APRN provides follow up care and treatment, as medically appropriate, to the qualifying patient and assesses the qualifying patient's condition <u>during the course of the qualifying patient's medical use of cannabis</u>; and
- 3. The physician/APRN maintains records of the qualifying patient's treatment and condition in accordance with medically accepted standards.

And state law gives the department discretion over allowing multi-year certifications:

HRS §329-121 Definitions. As used in this part:

"Written certifications" are valid for one year from the time of signing; provided that the <u>department of health may allow</u> for the validity of any written certification for up to three years if the qualifying patient's physician or advanced practice registered nurse states that the patient's debilitating medical condition is chronic in nature.

Two-year certifications, or certifications that are longer than one year, not only go against the intent of state law and department rules, but they also deprive patients of the necessary ongoing follow up that is standard of care for patients with debilitating medical conditions. This is especially true for patients with chronic diseases that typically get worse with age. Annual certification ensures ongoing medical supervision and provides the opportunity for reassessing new medication drug interactions, discussing changes to state law, and reviewing the ever-changing array of dispensary products that patients are being exposed to. Follow up care does not occur with a vast majority of two-year certifications, which is why going back to an annual Written Certification is so important. Rulemaking Petition November 6, 2023 Page 3

The proposed amendment would also eliminate the current situation where patients are able to pay for a two-year registration online without even consulting with their certifying provider, which can result in loss of \$38.50 if the certifying provider does not agree to a two-year certification, because these fees are non-refundable.

Allowing patients to pay for a two-year certification before talking with their certifying provider can also coerce providers into going ahead with a two-year certification just to avoid confrontation with patients. Patients often feel entitled to a two-year certification because they have not received adequate education from the department on what should be expected from their provider-patient relationship, which makes it difficult for patients to understand the value of ongoing medical supervision. Continually explaining to patients why a two-year certification is not appropriate wastes significant amounts of time for the certifying provider.

The argument that a two-year certification is necessary because there are not enough certifying providers available is nonsensical and potentially self-serving for commercial interests that are not directly involved in patient care. There are now <u>plenty</u> of physicians and APRNs who are providing this service. Renewals can also be conducted via tele-health.

Cannabis is also still an illegal controlled substance. If the current federal situation with cannabis did not exist, then medical cannabis evaluations could be billed to insurance, and providers would probably be conducting these visits much more often. However, because all costs for the medical use of cannabis are still out of pocket, patients cannot afford to pay for a medical cannabis evaluation several times a year. Under the current circumstances, annual certification ensures a minimum standard for ongoing care.

Petitioner has an interest in this matter because of the negative impact that two-year certifications and the resulting lack of provider follow up are having upon the care of our medical cannabis patients.

AUTHORITY:

HRS §91-6 and HAR §11-1-51.

PETITIONER:

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