DEPARTMENT OF REGULATORY AGENCIES

Office of Natural Medicine Licensure

NATURAL MEDICINE LICENSURE RULES AND REGULATIONS

4 CCR 755-1

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

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1: GENERAL

1.4 Definitions

"Adverse Health Event" means any untoward or unexpected health condition or medical occurrence associated with the use of natural medicine or natural medicine product–this could include any unfavorable and unintended sign (including a hospitalization, emergency department visit, medical visit, abnormal laboratory finding, outbreak, death [non-motor vehicle]), symptom, or disease temporally associated with the use of a natural medicine product, and may include concerns or reports on the quality, labeling, or possible adverse reactions to natural medicine or natural medicine product transferred by or manufactured at a Natural Medicine Business. An adverse health event may also include any of the previous signs, symptoms, or disease temporally associated with the use of a natural medicine product that is administered to a participant by a licensed facilitator. An adverse event or suspected adverse reaction is considered "life-threatening" if its occurrence places the participant at immediate risk of death. It does not include an adverse event or suspected adverse reaction that, had it occurred in a more severe form, might have caused death. An adverse event or suspected adverse reaction is considered "serious" if it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

"Approved Facilitator Training Program" means a program of study which the Director has determined meets the minimum requirements of the curriculum mandated by DORA in section 4 of these Rules.

"Natural medicine harm reduction" is defined as a set of practical strategies and ideas aimed at reducing negative consequences to physical, mental or social well-being associated with the use of natural medicines.

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6: STANDARDS OF PRACTICE

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6.22 Data Collection

A. Basis and Purpose

Rule 6.22 is intended to establish requirements for all facilitators to collect and provide data to the Director upon request. Data collection is necessary to further the goals articulated in the Natural Medicine Health Act of 2022, including but not limited to the following expectations set forth in the Act: Board review of research related to the efficacy and regulation of natural medicine and natural medicine product, including recommendations related to product safety, harm reduction, and cultural responsibility (section 12-170-106(5)(b)), development of research related to the safety and efficacy of each natural medicine (section 12-170-106(5)(f)), current research, studies, and real-world data related to natural medicine to make recommendations as to whether natural medicine, natural medicine product, natural medicine services, and associated services should be covered under health first Colorado or other insurance programs as a cost-effective intervention for various mental health conditions (section 12-170-106(6)).

B. Authority

This rule is adopted pursuant to the authority in sections 12-20-204; 12-170-105(1)(a)(IV) and (V); 12-170-105(1)(j); 12-170-105(3), and 24-4-103, C.R.S.

C. Requirements for Data Collection

1. For each participant to whom a facilitator provides services, and for each administration of regulated natural medicine to the participant, each facilitator must collect and submit the following de-identified data:

a. A unique participant identification number;

b. Whether the services were provided in the Denver, Colorado Springs, or Grand Junction metro areas or a rural area. If services were provided in a rural area, whether the services were provided in Northeast, Northwest, Southeast, or Southwest Colorado;

c. Demographic information regarding the participant, including age, sex assigned at birth, gender identity, race/ethnicity; state of residence, veteran status; income range, and equity status;

d. Data from Risk Factor Screening Form;

e. Reasons the participant sought natural medicine services, including whether the participant had any diagnosed physical or behavioral health condition for which the participant sought natural medicine services;

f. Data from Mental Health Screening Form;

g. Fees charged for services, and if applicable, any discounts, scholarships, or other reduction in fees charged;

h. Whether the administration session was an individual or group session, the number of participants and whether the administration session took place outdoors, indoors, or both;

i. Whether the goal of facilitation was for clinical or experiential purposes (or both);

j. Confirmation of completion of the following records: touch contract, safety plan, transportation plan, and informed consent processes;

k. Data regarding the date and start and end times for every preparation, administration, and integration session;

l. Identification of the natural medicine products consumed by each participant, the unique identifier of the product, the amount consumed, and whether the consumption occurred in a single or multiple doses;

m. Whether the participant self-identified a benefit from the use of natural medicine and any other outcome-related information collected by the facilitator;

n. If known to the facilitator, whether an adverse health event occurred, and to the extent known, the date and time of onset, and duration and type of adverse health event; and

o. Whether a clinical facilitator provided services under a secondary license to the participant.

6.23 Requirements for Reporting Adverse Health Events

A. Statement of Basis and Purpose and Authority

The purpose of this Rule is to establish requirements for facilitators to report adverse health events to the Director.

The authority for this Rule is found in sections 12-20-404; 12-170-105(1)(a)(I), 12-170-105(1)(a)(II); 12-170-105(1)(a)(IV), and 12-170-105(1)(a)(V); 12-170-109; and 24-4-103, C.R.S.

B. A facilitator must report to the Director every adverse health event that is life-threatening or serious within 24 hours.

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8: DISCIPLINARY VIOLATIONS and UNLICENSED PRACTICE

8.1 Grounds for Discipline

A. Statement of Basis and Purpose

The purpose of these Rules is to clarify acts that constitute grounds for discipline pursuant to these Rules and Article 170 of Title 12, C.R.S.

The authority for these Rules is found in sections 12-20-404; 12-170-105(1)(a)(I), 12-170-105(1)(a)(II), 12-170-105(1)(a)(IV), and 12-170-105(1)(a)(V); 12-170-108(2); 12-170-109; and 24-4-103, C.R.S.

B. The Director may initiate disciplinary or other action as authorized in these Rules, as authorized in section 24-4-104(4), C.R.S., and as authorized in section 12-20-404, C.R.S., when the Director has reasonable grounds to believe that the licensee has engaged in any of the following:

1. Violated a provision of Article 170, C.R.S. or any of these Rules promulgated pursuant to Article 170;

2. Has been convicted of or has entered a plea of nolo contendere to a felony. In considering the conviction of or the plea to any such crime, the director shall be governed by the provisions of sections 12-20-202(5) and 24-5-101, C.R.S. Pursuant to sections 12-20-404(8) and 12-30-121, C.R.S., the director will not consider legally protected marijuana convictions and legally protected health-care activities.

3. Made any misstatement on an application for a license to practice pursuant to Article 170, C.R.S. or attempted to obtain a license to practice by fraud, deception, or misrepresentation;

4. Committed an act or failed to perform an act necessary to meet the generally accepted professional standards of conduct to practice a profession licensed pursuant to Article 170, C.R.S. or promulgated by rule pursuant to 12-170-105(1)(a)(II)(D), including performing services outside of the person's area of training, experience, or competence;

5. Excessively or habitually uses or abuses alcohol or controlled substances;

6. Violated any of the provisions of Article 170, C.R.S., an applicable provision of Article 20 of title 12, C.R.S., or any valid order of the director;

7. Is guilty of unprofessional or dishonest conduct;

8. Advertises by means of false or deceptive statement;

9. Fails to display the license as provided in section 12-170-108(2), C.R.S.;

10. Fails to comply with the Rules promulgated by the director pursuant to Article 170, C.R.S.;

11. Is guilty of willful misrepresentation;

12. Fails to disclose to the director within forty-five days a conviction for a felony or any crime that is related to the practice as a facilitator;

13. Has violated or has aided or knowingly permitted any person to violate any provision of this article 170, or applicable provisions of article 20 or 30 of this title 12.

14. Fails to timely respond to a complaint sent by the director pursuant to section 12-170-110.

15. Fails to report an adverse event to the Director within 24 hours, as required by Rule 6.23.

16 Has acted in a manner that is inconsistent with the health or safety of persons under their care.

17 Has had a license related to facilitation or clinical facilitation, suspended or revoked in any jurisdiction. A certified copy of the order of suspension or revocation is prima facie evidence of the suspension or revocation.

C. “Unprofessional or dishonest conduct,” includes the following:

1. Conviction of certain felony or misdemeanor offenses, including the following:

a. A conviction or plea of nolo contendere of any felony or misdemeanor crime related to the practice of facilitation, as defined in section 12-170-104(5), C.R.S.;

b. A conviction or plea of nolo contendere of any felony or misdemeanor crime involving dishonesty or willful misrepresentation;

c. In considering a conviction or plea pursuant to this paragraph 8.1(C)(1) and (2), the Director’s determination must be made in accordance with sections 12-20-202(5) and 24-5-101, C.R.S. Pursuant to sections 12-20-404(8) and 12-30-121, C.R.S., the director will not consider legally protected marijuana convictions and legally protected health-care activities.

2. The following adverse actions:

a. Disciplinary or other actions taken against facilitation licenses held in another state;

b. Disciplinary or other actions taken against a secondary license (in Colorado or another jurisdiction) held by a clinical facilitator.

3. Performs services outside the scope of the licensees secondary or other license.

8.2 Duty to Report Criminal Convictions and Unprofessional or Dishonest Conduct

A. Statement of Basis and Purpose and Authority

The purpose of these Rules is to clarify the procedures for reporting convictions and unprofessional or dishonest conduct pursuant to section 12-170-109(1)(I), C.R.S. and these Rules.

The authority for these Rules is set forth in sections in sections 12-20-404; 12-170-105(1)(a)(I), 12-170-105(1)(a)(II), 12-170-105(1)(a)(IV), and 12-170-105(1)(a)(V); 12-170-108(2); 12-170-109; and 24-4-103, C.R.S.

B. Any licensee, Facilitator licensee, Clinical Facilitator licensee, Distinguished Educator licensee, or Training licensee, must inform the Director, in writing or in another manner set forth by the Director, within forty-five days of any criminal conviction or other action meeting the definition of unprofessional or dishonest conduct.

C. The notice to the Director must include the following information:

1. If the event is an action by a government agency: the name of the agency, its jurisdiction, the case name, the docket, proceeding or case number by which the event is designated, and a copy of the consent decree, order, or decision;

2. If the event is a felony conviction or a conviction or a crime involving dishonest or wilful misrepresentation, or a crime related to the practice of facilitation: the court, its jurisdiction, the case name, the case number, a description of the matter or a copy of the indictment or charges, and any plea or verdict entered by the court. The facilitator must also provide to the Director a copy of the imposition of sentence related to the felony conviction and the completion of all terms of the sentence within 90 days of such action; and

3. If the event concerns a civil action or arbitration proceeding: the court or arbiter, the jurisdiction, the case name, the case number, a description of the matter or a copy of the complaint, and a copy of the verdict, the court or arbitrational decision, or, if settled, the settlement agreement and court’s order of dismissal.

C. The facilitator may submit a written statement with any notice under these Rules to be included in the facilitator’s records.

D. These Rules apply to all criminal convictions and unprofessional or dishonest conduct events that occur on or after the effective date of this Rule.

8.3 Unlicensed Practice

A. Statement of Basis and Purpose and Authority

The purpose of these Rules is to clarify the procedures for the Director to prevent against the unlicensed practice of natural medicine facilitation services, pursuant to section 12-170-105(1)(g), C.R.S. and these Rules.

The authority for these Rules is set forth in sections 12-20-404; 12-170-105(1)(a)(I), 12-170-105(1)(a)(II), 12-170-105(1)(a)(IV), and 12-170-105(1)(a)(V); 12-170-108(2); 12-170-109; and 24-4-103, C.R.S.

B. If it appears to the Director that a person without a license is engaged in the provision of facilitation*, i.e.*, the performance and supervision of natural medicine services for a participant, the Director may issue an order to cease and desist their conduct in accordance with section 12-20-405(1)(a), C.R.S. Any individual who receives an order directing them to cease and desist the unlicensed practice of natural medicine facilitation services may request a hearing pursuant to sections 12-20-405(1)(b), 24-4-104, and 24-4-105, C.R.S.

1. A person may be engaged in the provision of facilitation if that individual refers to themself as a "facilitator," "clinical facilitator," "distinguished educator licensee," or "training licensee."

2. A person may be engaged in the provision of facilitation if that individual seeks remuneration for services that are otherwise within the scope of the practice of facilitation.

C. An individual who is not licensed may perform a bona fide religious, culturally traditional, or spiritual ceremony, if the individual informs all persons engaging in the ceremony that the individual is not a licensed facilitator and that the ceremony is not associated with commercial, business, or for-profit activity.

Editor's Notes

History

Annotations