

Neuada State Board of Pharmacy

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December 9, 2021

NOTICE OF INTENT TO ACT UPON A REGULATION

Notice of Hearing for the Adoption and Amendment of Regulations of the Nevada State Board of Pharmacy

The Nevada State Board of Pharmacy will conduct a Public Hearing on Thursday, January 13, 2022, at 9:00 a.m. Public access for the meeting is:

Pursuant to Governor Steve Sisolak's Emergency Directive 044 and AB 253, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South 7740 Las Vegas Blvd. South Las Vegas, NV 89123

Via Videoconference at Zoom: https://zoom.us/j/5886256671

or

Via Teleconference at 1 (669) 900-6833 Meeting ID: 588 625 6671

The purpose of the hearing is to receive comments from all interested persons regarding the adoption and amendment of regulations that pertain to Chapters 453 and/or 639 of the Nevada Administrative Code.

The following information is provided pursuant to the requirements of NRS 233B.060:

- A. Amendment of Nevada Administrative Code (NAC 639). The proposed amendments will add a new section to implement the provisions of Senate Bill 190, requiring the Board to adopt regulations that establish a protocol to allow a pharmacist to dispense a self-administered hormonal contraceptive to any patient. (LCB File R036-21)
 - 1. The need for and the purpose of the proposed regulation or amendment.

The proposed regulations will authorize a pharmacist to dispense self-administered hormonal contraceptives to a patient without a prescription under a protocol. Implementing these regulations will expand access to hormonal contraceptives particularly for women in rural areas.

2. Either the terms or the substance of the regulations to be adopted and amended.

A copy of the proposed regulation amendment is attached to this notice.

3. The estimated economic effect of the regulation on the business which it is to regulate and on the public:

(a) Both adverse and beneficial effects.

There should be no adverse economic impact from these regulations on the regulated entities or on the public. The beneficial effects will be expanded access to hormonal contraceptives, particularly for women in rural areas.

(b) Both immediate and long-term effects.

Both the immediate and long-term economic effects on regulated entities and on the public will be expanded access to hormonal contraceptives particularly for women in rural areas.

4. The estimated cost to the agency for enforcement of the proposed regulation.

There will be no additional or special costs incurred by the Board of Pharmacy for enforcement of this regulation amendment.

5. A description of and citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include the name of the regulating federal agency.

The Board of Pharmacy is not aware of any similar regulations of any other state or local governmental agency that the proposed regulation amendment overlaps or duplicates.

6. If the regulation is required pursuant to federal law, a citation and description of the federal law.

This regulation is not required by federal law.

7. If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

The Board of Pharmacy is not aware of any similar federal regulation amendments of the same activity in which the state regulation is more stringent.

8. Whether the proposed regulation establishes a new fee or increases an existing fee.

This regulation does not provide a new or increase of fees.

B. Amendment of Nevada Administrative Code (NAC) 639.501 Inspections; provision of self-assessment form. The proposed amendment to NAC 639.501 will remove the requirement to complete an assessment of workplace and modifies the requirement of an annual inspection.

(LCB File R165-20)

1. The need for and the purpose of the proposed regulation or amendment.

The proposed amendment will remove the requirement that a pharmacy perform a self-assessment relating to the volume of work and prescriptions, workflow, personnel, and technology before the annual inspection and requires the Executive Secretary to develop and implement a program for the inspection of each licensed pharmacy annually or at any other time deemed necessary. The self-assessment is not functional and does not add value to the inspection process. Removing the self-assessment will allow inspectors to focus on other aspects of the pharmacy operation for the protection, health and safety of the public.

2. Either the terms or the substance of the regulations to be adopted and amended.

A copy of the proposed regulation amendment is attached to this notice.

- 3. The estimated economic effect of the regulation on the business which it is to regulate and on the public:
- (a) Both adverse and beneficial effects.

There should be no adverse economic impact from this regulation amendment on the regulated entities or on the public. The beneficial effects of the amendment will allow inspectors to focus on inspecting other aspects of the pharmacy operation.

(b) Both immediate and long-term effects.

Both the immediate and long-term economic effects on regulated entities and on the public will be more efficient and effective regulatory oversight of pharmacy operations.

4. The estimated cost to the agency for enforcement of the proposed regulation.

There will be no additional or special costs incurred by the Board of Pharmacy for enforcement of this regulation amendment.

5. A description of and citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include the name of the regulating federal agency.

The Board of Pharmacy is not aware of any similar regulations of any other state or local governmental agency that the proposed regulation amendment overlaps or duplicates.

6. If the regulation is required pursuant to federal law, a citation and description of the federal law.

This regulation is not required by federal law.

7. If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

The Board of Pharmacy is not aware of any similar federal regulation amendments of the same activity in which the state regulation is more stringent.

8. Whether the proposed regulation establishes a new fee or increases an existing fee.

This regulation does not provide a new or increase of fees.

Persons wishing to comment upon the proposed action of the Board may appear at the scheduled public hearing or may address their comments, data, views, or arguments, in written form, to the Board at pharmacy.nv.gov or to the Nevada State Board of Pharmacy, 985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521. Written submissions must be received by the Board on or before January 13, 2022. If no person who is directly affected by the proposed action appears to request time to make an oral presentation, the Board may proceed immediately to act upon any written submissions.

This notice and the text of the proposed regulation are also available in the State of Nevada Register of Administrative Regulations which is prepared and published monthly by the Legislative Counsel Bureau pursuant to NRS 233B.0653, and on the Internet at http://www.leg.state.nv.us. Copies of this notice and the proposed regulation will also be mailed to members of the public upon request.

Pursuant to NRS 233B.064(1), upon adoption of any regulation, the Board, if requested to do so by an interested person, either before adoption or within 30 days thereafter, will issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

This notice has been posted at <u>www.notice.nv.gov</u> and <u>www.bop.nv.gov</u> pursuant to Governor's Declaration of Emergency Directive 006.

REVISED PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R036-21

November 17, 2021

EXPLANATION - Matter in *italics* is new, matter in brackets omitted is material to be omitted.

AUTHORITY: §§ 1-6, NRS 639.070 and section 2.5 of Senate Bill No. 190, chapter 504, Statutes of Nevada 2021, at page 3268.

A REGULATION relating to contraceptives; establishing a protocol and certain other requirements for a pharmacist to dispense self-administered hormonal contraceptives without a prescription; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Effective January 1, 2022, existing law authorizes a pharmacist to dispense a selfadministered hormonal contraceptive to a patient under a protocol established by regulation of the State Board of Pharmacy, regardless of whether the patient has obtained a prescription from a practitioner. Existing law requires a pharmacist to provide a risk assessment questionnaire prescribed by regulation of the Board to a patient who requests a self-administered hormonal contraceptive before dispensing the self-administered hormonal contraceptive to the patient under the protocol. (Sections 2.5 and 3 of Senate Bill No. 190, chapter 504, Statutes of Nevada 2021, at pages 3268 and 3269) Section 2 of this regulation requires a pharmacist who wishes to dispense self-administered hormonal contraceptives under the protocol to: (1) complete certain education concerning self-administered hormonal contraceptives; and (2) notify the Board of his or her intent to dispense self-administered hormonal contraceptives under the protocol. Section 3 of this regulation adopts by reference certain federal guidelines concerning the use of contraceptives. Section 4 of this regulation prescribes the protocol for a pharmacist to dispense self-administered hormonal contraceptives, which includes: (1) providing the risk assessment questionnaire to the patient and discussing the results with the patient; (2) utilizing a treatment algorithm which includes evaluating the patient using the federal guidelines adopted by reference in section 3; (3) providing certain records to the patient; (4) dispensing a self-administered hormonal contraceptive to the patient if it is safe to do so; (5) providing information to the patient concerning use of the contraceptive; (6) the maintenance of certain records by the pharmacy; (7) limitations on the amount of a self-administered hormonal contraceptive that may be dispensed; and (8) certain requirements relating to refills. Section 5 of this regulation prescribes the risk assessment questionnaire that must be provided to a patient who requests the dispensing of a self-administered hormonal contraceptive under the protocol.

- **Section 1.** Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 5, inclusive, of this regulation.
- Sec. 2. 1. Except as otherwise provided in subsection 7 of section 4 of this regulation, a pharmacist who wishes to dispense self-administered hormonal contraceptives under the protocol prescribed in section 4 of this regulation must:
- (a) Complete a course of education concerning self-administered hormonal contraceptives that:
 - (1) Consists of at least 2 hours of instruction;
- (2) Includes, without limitation, instruction concerning the assessment of risks to the patient and contraindications; and
- (3) Is approved by the Accreditation Council for Pharmacy Education or the American College of Obstetricians and Gynecologists, or their successor organizations, or provided by a school of pharmacy accredited by the Accreditation Council for Pharmacy Education, or its successor organization; and
- (b) Notify the Board of his or her intent to dispense self-administered hormonal contraceptives under the protocol in the form prescribed by the Board.
- 2. A pharmacist who complies with the provisions of subsection 1 shall maintain in an easily retrievable location a written or electronic record of his or her completion of the course required by paragraph (a) of subsection 1:
- (a) While the pharmacist is dispensing self-administered hormonal contraceptives under the protocol prescribed in section 4 of this regulation; and
- (b) For at least 2 years after ceasing to dispense self-administered hormonal contraceptives under the protocol.

- Sec. 3. 1. Except as otherwise provided in subsection 2, the <u>United States Medical</u>

 Eligibility Criteria for Contraceptive Use published by the Centers for Disease Control and

 Prevention of the United States Department of Health and Human Services is hereby adopted

 by reference. A copy of this publication may be obtained free of charge at the Internet address

 https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html, or, if that

 Internet website ceases to exist, from the Board.
- 2. Except as otherwise provided in this subsection, the most current version of the publication adopted by reference in subsection 1 which is published will be deemed to be adopted by reference. The Board will periodically review and determine, within 30 days after the review, whether any change made to the publication listed in subsection 1 is appropriate for application in this State. If the Board does not disapprove a change to the publication within 30 days after the review, the change is deemed to have been approved by the Board.
- Sec. 4. 1. The protocol prescribed pursuant to section 2.5 of Senate Bill No. 190, chapter 504, Statutes of Nevada 2021, at page 3268, consists of compliance with subsections 2 to 8, inclusive.
- 2. Before initially dispensing a self-administered hormonal contraceptive to a patient under the protocol, a pharmacist must:
- (a) Provide the patient with the risk assessment questionnaire prescribed in section 5 of this regulation in accordance with subsection 2 of section 3 of Senate Bill No. 190, chapter 504, Statutes of Nevada 2021, at page 3269, and, if the patient completes the questionnaire, discuss the results of the questionnaire with the patient; and

- (b) Utilize a treatment algorithm to determine whether it is safe to dispense a self-administered hormonal contraceptive to the patient. The treatment algorithm must include, without limitation:
- (1) Training and education of the patient concerning the self-administered hormonal contraceptive and possible alternatives to the self-administered hormonal contraceptive;
- (2) Assessing any risks to the patient posed by the self-administered hormonal contraceptive;
- (3) Evaluating the patient using the criteria adopted by reference in section 3 of this regulation;
 - (4) Conducting a health and history screening of the patient;
 - (5) Screening to determine whether the patient is or may be pregnant;
 - (6) Screening the patient for disease;
- (7) Determining whether the patient is taking other medications and, if so, evaluating the potential interaction between the self-administered hormonal contraceptive and the other medications:
 - (8) Taking the blood pressure of the patient;
 - (9) Soliciting and considering the preferences of the patient concerning treatment; and
- (10) Formulating a plan for treatment of the patient and discussing the plan with the patient.
- 3. If, after satisfying the requirements of subsection 2, a pharmacist determines that it is unsafe to dispense a self-administered hormonal contraceptive to the patient, the pharmacist must not dispense the self-administered hormonal contraceptive and must:

- (a) Refer the patient to his or her attending provider of health care or another qualified provider of health care for further consultation and treatment; and
- (b) Provide the patient with a copy of the record required by subsection 4 of section 3 of Senate Bill No. 190, chapter 504, Statutes of Nevada 2021, at page 3269.
- 4. If, after satisfying the requirements of subsection 2, a pharmacist determines that it is safe to dispense a self-administered hormonal contraceptive to the patient, the pharmacist must:
- (a) Provide the patient with information concerning the self-administered hormonal contraceptive being dispensed, which must include, without limitation, the information described in paragraph (b) of subsection 3 of section 3 of Senate Bill No. 190, chapter 504, Statutes of Nevada 2021, at page 3269, and information concerning:
 - (1) Proper dosage of the self-administered hormonal contraceptive;
 - (2) The effectiveness of the self-administered hormonal contraceptive;
- (3) The importance of obtaining recommended tests and screening from the attending provider of health care of the patient or another qualified provider of health care who specializes in women's health;
- (4) The effectiveness of long-acting, reversible contraceptives as an alternative to self-administered hormonal contraceptives;
- (5) When to seek emergency medical services as a result of administering a selfadministered hormonal contraceptive; and
 - (6) The risk of acquiring a sexually transmitted infection and ways to reduce that risk;
- (b) Provide the patient with a copy of the record required by subsection 4 of section 3 of Senate Bill No. 190, chapter 504, Statutes of Nevada 2021, at page 3269; and

- (c) Dispense an appropriate self-administered hormonal contraceptive to the patient in a container with a label that clearly shows:
 - (1) The date on which the self-administered hormonal contraceptive was dispensed;
 - (2) The name and address of the patient;
- (3) The serial number assigned to the record of the self-administered hormonal contraceptive in accordance with paragraph (a) of subsection 8;
- (4) The number of recommended doses of the self-administered hormonal contraceptive that are being dispensed in the container;
 - (5) Specific directions for use of the self-administered hormonal contraceptive;
 - (6) The proprietary or generic name of the self-administered hormonal contraceptive;
 - (7) The strength of the self-administered hormonal contraceptive; and
 - (8) The expiration date of the self-administered hormonal contraceptive.
- 5. A pharmacy that initially dispenses self-administered hormonal contraceptives under the protocol shall maintain:
- (a) A written or electronic record of each risk assessment questionnaire completed by a patient of the pharmacy pursuant to paragraph (a) of subsection 2 for at least 2 years after the date of completion; and
 - (b) The written or electronic record required by subsection 8.
- 6. A pharmacist who dispenses a self-administered hormonal contraceptive under the protocol shall not dispense to a patient more than a 12-month supply of the self-administered hormonal contraceptive. If the pharmacist initially dispenses to the patient less than a 12-month supply, the pharmacist may refill the self-administered hormonal contraceptive under the protocol until the patient has received a 12-month supply. If the patient requests a refill

after the patient has received a 12-month supply, the pharmacist must comply with the requirements of the protocol set forth in subsections 2, 3 and 4.

- 7. Subject to the limitations set forth in subsection 6, a pharmacist who has not complied with the requirements of section 2 of this regulation may refill the supply of a self-administered hormonal contraceptive initially dispensed under the protocol if the pharmacist has access to an electronic record of the risk assessment questionnaire completed pursuant to paragraph (a) of subsection 2. When dispensing the refill, such a pharmacist shall:
 - (a) Review and discuss the results of the risk assessment questionnaire with the patient;
- (b) Answer any questions that the patient may have concerning the self-administered hormonal contraceptive; and
 - (c) Take the actions described in paragraphs (a) and (c) of subsection 4.
- 8. A pharmacy that dispenses a self-administered hormonal contraceptive under the protocol, including, without limitation, a pharmacy that refills the supply of a self-administered hormonal contraceptive pursuant to subsection 7, shall maintain a written or electronic record of each self-administered hormonal contraceptive dispensed by the pharmacy for at least 2 years after the date on which the self-administered hormonal contraceptive was dispensed. The record must:
 - (a) Be assigned a serial number,
- (b) Include, without limitation, the information required by paragraph (a) of subsection 3 of Senate Bill No. 190, chapter 504, Statutes of Nevada 2021, at page 3269; and
- (c) Be maintained in the same manner as other records of prescriptions dispensed by the pharmacy.

Sec. 5. The risk assessment questionnaire described in paragraph (a) of subsection 2 of section 2.5 of Senate Bill No. 190, chapter 504, Statutes of Nevada 2021, at page 3268, must be in substantially the following form:

HORMONAL CONTRACEPTIVE RISK ASSESSMENT QUESTIONNAIRE FOR PATIENT COMPLETION

Note to patient: Complete this questionnaire and bring to your pharmacy for self-administered hormonal contraceptives. You should call your pharmacy first to make certain the pharmacy is able to provide this service. You may also obtain the questionnaire from participating pharmacies.

Patient Name: Date: Date:
Date of Birth: Height: Height:
Email address:
What was the date of your last women's health clinical visit?/_/_
Any allergies to medications? Yes \(\sigma \) No \(\sigma \)
If yes, list them here:
Do you have a preferred method of birth control that you would like to use?
A daily pill \Box A weekly patch \Box A monthly vaginal ring \Box Injectable (every 3 months) \Box

I	Do you think you could be pregnant now?	Yes 🗆	No □
2	What was the starting date of your last menstrual period?	i.	
3	Have you ever taken birth control pills or used a birth control patch, ring, shot or injection?	Yes □	No □
	- If yes, have you previously had contraceptives dispensed to you by a pharmacist?	Yes 🗆	No □
4	Have you ever experienced a bad reaction to using hormonal birth control?	Yes □	No □
	- If yes, what kind of reaction occurred?		
5	Are you currently using birth control pills or a birth control patch, ring, shot or injection?	Yes □	No □
6	Have you ever been told by a medical professional not to take hormones?	Yes □	No □
7	Do you smoke cigarettes?	Yes 🗆	No □
8	Have you had a recent change in vaginal bleeding that worries you?	Yes □	No □
9	Have you given birth within the past 21 days?	Yes □	No □
	- If yes, what was the date of the birth?/_/_	163 🚨	110 🗆
10	Are you currently breastfeeding?	Yes □	No 🗆
11	Do you have diabetes?	Yes □	No 🗆
12	Do you get migraine headaches?	Yes □	No □
	- If yes, have you ever had headaches that start with warning signs or symptoms, such as flashes of light, blind spots or tingling in your hand or face that goes completely away before the headache starts?	Yes □	No □
13	Do you have high blood pressure, hypertension or high cholesterol? (Please indicate yes even if your hypertension is controlled by medication.)	Yes □	No □
14	Have you ever had a heart attack or stroke or been told by a medical professional that you have heart disease?	Yes □	No □
15	Have you ever had a blood clot?	Yes 🗆	No □
16	Have you ever been told by a medical professional that you are		
	at a high risk of developing a blood clot?	Yes 🗆	No 🗆
17	Have you ever had bariatric surgery or stomach reduction surgery?	Yes □	No □
18	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes □	No □
19	Do you plan to have restricted mobility for a long period of time? (e.g. a long airplane trip, etc.)	Yes □	No 🗆
20	Do you have or have you ever had breast cancer?	Yes 🗆	No □

21	Do you have or have you ever had hepatitis, liver cancer or gall bladder disease, or do you have jaundice (yellow skin or		
	eyes)?	Yes 🗆	No □
22	Do you have lupus, rheumatoid arthritis or any blood disorders?	Yes □	No □
23	Do you take medication for seizures, tuberculosis (TB), fungal infections or human immunodeficiency virus (HIV)?	Yes □	No □
	- If yes, list the medications here:		
24	Do you have any other medical problems or take regular medication(s)?	Yes □	No □
	- If yes, list problems or medications here:		
25	Do you take any herbal or vitamin supplements?	Yes 🗆	No 🗆
	- If yes, list supplements here:		
	ent Signature:		
	This regulation becomes affective upon the later of		

Sec. 6. This regulation becomes effective upon the later of:

- 1. January 1, 2022; or
- 2. The date on which this regulation is filed with the Secretary of State.

REVISED PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R165-20

October 14, 2021

EXPLANATION - Matter in italies is new; matter in brackets [omitted material] is material to be omitted

AUTHORITY: §§ 1 and 2, NRS 639.070.

A REGULATION relating to pharmacy; requiring the Executive Secretary of the State Board of Pharmacy to develop and implement a program for the inspection of each licensed pharmacy; removing the requirement that a pharmacy perform a self-assessment relating to the volume of work and other matters at the pharmacy; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations pertaining to the practice of pharmacy and requires a pharmacy to comply with the regulations of the Board. (NRS 639.070, 639.100, 639.215) Existing law requires the Board to employ an Executive Secretary who is not a member of the Board and is required to perform certain duties. (NRS 639.040) Existing law entitles the members of the Board and certain staff to free access to all places where drugs, medicines or poisons are held. (NRS 639.090)

Under existing regulations, a member of the staff of the Board is required to inspect each licensed pharmacy annually and at any other time deemed necessary by the staff of the Board. (NAC 639.501) Before the annual inspection occurs, a pharmacy must perform a self-assessment concerning: (1) statutory and regulatory compliance; and (2) its volume of work, prescriptions, workflow, personnel and technology. (NAC 639.501)

Section 1 of this regulation requires the Executive Secretary of the Board to develop and implement a program for the inspection of each licensed pharmacy annually or at any other time deemed necessary by the staff of the Board. Section 1 removes the requirement for the pharmacy to perform a self-assessment concerning its volume of work and prescriptions, workflow, personnel and technology before the annual inspection. Section 2 of this regulation makes a conforming change by removing a section that is no longer necessary because of the removal of the requirement for a self-assessment in section 1. (NAC 639.5012)

Section 1. NAC 639.501 is hereby amended to read as follows:

- 639.501 1. Before the Board will issue a new license to operate a pharmacy to any person, a satisfactory inspection of the premises of the pharmacy must be conducted by a member of the staff of the Board.
- 2. [A member of the staff of the Board] The Executive Secretary shall [inspect] develop and implement a program for the inspection of each licensed pharmacy annually [and] or at any other time deemed necessary. [by the staff of the Board.]
- 3. Before an annual inspection of a licensed pharmacy, the Board will provide a self-assessment form to the pharmacy that includes !:
- (a) A a questionnaire concerning statutory and regulatory compliance pursuant to which the pharmacy must assess its physical plant and operations to assure that the pharmacy is in compliance with all applicable statutes and regulations. I; and
- (b) An assessment of the workplace pursuant to which the pharmacy must assess its volume of work and prescriptions, personnel, workflow and technological devices that assist in the work of the pharmacy.]
- 4. The managing pharmacist of a pharmacy or the designee of the owner of the pharmacy may obtain self-assessment forms from the Board in addition to the form provided pursuant to subsection 3 at any time for his or her own use.
 - Sec. 2. NAC 639.5012 is hereby repealed.

TEXT OF REPEALED SECTION

639.5012 Confidentiality and use of self-assessment and accompanying documentation. (NRS 639.070)

- 1. An assessment of the workplace completed by a pharmacy as part of the self-assessment, and all documentation accompanying the assessment, that are submitted to a member of the staff of the Board pursuant to NAC 639.5016 are confidential. The Board will destroy such an assessment of the workplace and all accompanying documentation within 6 months after the Board receives the assessment and documentation.
- 2. The staff of the Board may compile and analyze such data provided in assessments of the workplace as the Board deems appropriate, except that the staff shall not provide to any member of the Board or otherwise publish any compilation or analysis completed by the staff unless the staff has redacted from the compilation or analysis all information by which an individual pharmacy could be identified. The Board will not use data provided in an assessment of the workplace against the pharmacy that completed the assessment for any disciplinary purpose.