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MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 303

2013

REGULATIONS RELATING TO IMPAIRED REGISTERED PERSONS: PHARMACY ACT, 2004

Under section 66 of the Pharmacy Act, 2004 (Act No. 9 of 2004), read with section 56(4) of that Act, and on the recommendation of the Pharmacy Council of Namibia, I have made the regulations set out in the Schedule.

R. N. KAMWI
MINISTER OF HEALTH AND SOCIAL SERVICES

Windhoek, 28 October 2013

SCHEDULE

Definitions

1. In these regulations a word or expression to which a meaning has been assigned in the Act bears that meaning, and unless the context otherwise indicates -

“assessment” means the assessment of the physical, medical or psychological condition of a registered person by a medical examiner to determine whether that registered person is impaired;

“Committee” means the Committee appointed by the Council under section 56(5) of the Act;

“medical examiner” means a person registered under the Medical and Dental Act, 2004 (Act No 10. of 2004), the Allied Health Professions Act, 2004 (Act No. 7 of 2004), the Nursing Act, 2004 (Act No. 8 of 2004) or the Social Work and Psychology Act, 2004 (Act No. 6 of 2004) and appointed in terms of regulation 6(1);

“registered person” includes a person registered as a specialist, intern or student;

“the Act” means the Pharmacy Act, 2004 (Act No. 9 of 2004).

Health Assessment Committee

2. The Committee appointed under section 56(5) of the Act is known as the Health Assessment Committee and must conduct investigations, assessments and inquiries in respect of impaired persons.

Reporting allegation of impairment

3. (1) When an allegation is made to the registrar that a registered person appears to be impaired or if the registrar becomes aware of such an allegation, the registrar must report in writing the allegation to the chairperson of the Committee and submit all the information relating to the allegation to the chairperson of the Committee.

(2) On receipt of the report referred to in subregulation (1), the chairperson of the Committee must convene, in concurrence with the registrar, a meeting of the Committee to discuss and evaluate the allegation and information referred to in subregulation (1).

Evaluation of allegation of impairment

4. If the Committee, after having discussed and evaluated the allegation and information referred to in regulation 3(1) at the meeting conducted under regulation 3(2), considers –

- (a) that the allegations are without grounds and must not be proceeded with, the Committee must take a decision to that effect; or
- (b) that the allegations raises a question of impairment, the Committee must take a decision to that effect.

When question of impairment is raised

5. (1) If the Committee has under regulation 4(b) decided that the allegations in question raises a question of impairment, the chairperson must direct the registrar to -

- (a) notify the registered person concerned of the allegations;
- (b) invite the registered person to submit to the registrar, before a date specified in that invitation, a written reply to the allegations, including any observations, particulars or evidence relating to the alleged impairment that the registered person wishes to bring to the attention of, or make available to, the Committee;
- (c) invite the registered person to submit to an assessment by medical examiner or medical examiners appointed under regulation 6(1) for that purpose, and inform him or her of the venue, date and time of the assessment determined by the Committee; and
- (d) notify the registered person that if he or she fails to submit to the assessment referred to in paragraph (c), he or she commits an act of unprofessional conduct as contemplated by section 45 of the Act.

- (2) A notification by the registrar under subregulation (1) to the registered person must -
- (a) be in writing;
 - (b) include a summary of the allegations of impairment referred to in subregulation 3(1), without disclosing the identity of the person who made the allegations;
 - (c) be sent by prepaid registered post, addressed to the postal address of the registered person as it appears in the register or be delivered to the registered person by hand; and
 - (d) be posted not less than 30 days or delivered not less than 21 days before the date of the assessment contemplated under subregulation (1)(c).
- (3) The Committee, on good cause shown and subject to conditions that it may determine, may -
- (a) grant to a registered person an extension of time to submit to the assessment referred to in subregulation (1)(c); or
 - (b) condone a failure by a registered person to comply with any of these regulations.

Assessment of registered person

- 6.** (1) The Committee must -
- (a) appoint one or more medical examiners who must assess the condition of the registered person with reference to the allegations referred to in regulation 3(1) at the venue and on the date and at the time contemplated under regulation 5(1)(c);
 - (b) furnish the medical examiner or medical examiners with particulars relating to the allegations referred to in regulation 3(1);
 - (c) request the medical examiner or medical examiners referred to in paragraph (a) to -
 - (i) assess the physical or mental or the physical and mental, state and condition of the registered person, with reference to the allegations referred to in regulation 3(1); and
 - (ii) report to the Committee in the manner and before the date specified by the Committee in the request -
 - (aa) the alleged impairment of the registered person; and
 - (bb) the fitness and capability of the registered person to practise his or her profession.
- (2) The medical examiner or medical examiners appointed in terms of subregulation (1) must -
- (a) conduct the assessment on the date and at the time referred to in regulation 5(1)(c) and
 - (b) comply with a request by the Committee under subregulation (1)(c)(i) and (ii), before the date specified in that request.

(3) The report of the medical examiner or medical examiners referred to in subregulation (1)(c)(ii) must include the medical examiner or medical examiners recommendations, if any, relating to the conditions and restrictions that must apply to the registered person when practising his or her profession.

(4) A registered person who fails to submit to an assessment in terms of these regulations commits an act of unprofessional conduct as contemplated by section 45 of the Act.

Evaluation of assessment by Committee

7. (1) The Committee -

(a) must evaluate and consider the report of the medical examiner or medical examiners submitted under regulation 6(1)(c)(ii); and

(b) may -

(i) request the medical examiner or medical examiners to elaborate on or furnish further particulars relating to anything mentioned in the report referred to in paragraph (a); or

(ii) consult with the medical examiner or medical examiners in order to clarify any vagueness or any issue not covered by the report.

(2) If the Committee under subregulation (1)(a) is satisfied that the registered person appears to be impaired, the Committee must convene an inquiry into the impairment of the registered person.

Temporary suspension of registered person

8. (1) If the Committee, after evaluating and considering the reports in terms of regulation 7(1)(a), is of the opinion that the registered person is impaired to such an extent that he or she is not fit to practise his or her profession or that the impairment may constitute a danger to his or her patients, the Committee may make a recommendation to the Council that the registered person must -

(a) practise his or her profession under the supervision of a person designated by the Council for that purpose, or

(b) be suspended from practising his or her profession,

until such time as the Committee has conducted an inquiry under regulation 9.

(2) The Council may -

(a) confirm the recommendation made under subregulation (1); or

(b) reject the recommendation made under subregulation (1), in which case the recommendation has no effect.

(3) If the Council under subregulation (2) confirms the recommendation by the Committee, the chairperson of the Council must direct the registrar to notify the registered person contemplated in subregulation (1) in writing of -

(a) the conditions determined by the Council under subregulation 2(a); or

- (b) his or her suspension from practising his or her profession.
- (4) A notice under subregulation (3), must -
 - (a) be in the form and contain the particulars that the Council determine;
 - (b) notify the registered person that if he or she fails to comply with any decision of the Council under subregulation (2), that he or she commits an offence and is liable to the penalties prescribed by subregulation (6); and
 - (c) be served on the registered person by the registrar or by a person designated by the registrar in writing for that purpose.
- (5) If the registrar or the person designated under subregulation (4)(c), certifies that the registered person referred to in that subregulation -
 - (a) cannot be traced; or
 - (b) refuses to accept service of the notice; or
 - (c) refuses to sign an acknowledgement of receipt relating to the service of the notice,the registrar may send that notice by prepaid registered post to that registered person, addressed to his or her postal address as it appears in the register.
- (6) A registered person who fails to comply or practises his or her profession in contravention of a decision by the Council under subregulation (2) and who has received a notice under subregulation (4)(c) -
 - (a) commits an offence and is liable upon conviction to a fine not exceeding N\$4 000 or to imprisonment for a period not exceeding 12 months or to both such fine and such imprisonment; and
 - (b) commits an act of unprofessional conduct as contemplated by section 45 of the Act.

Inquiry by Committee

- 9.** (1) For the purposes of an inquiry referred to in regulation 7(2), the Committee may appoint a person to act as a member of the Committee at the inquiry.
- (2) The registrar must notify the registered person in respect of whom an inquiry is conducted in terms of these regulations, of the venue, date and time of the inquiry not less than 21 days before the date determined for commencement of the inquiry.
- (3) A notice to a registered person under subregulation (2) must -
 - (a) be in the form and contain the information that Committee determine;
 - (b) set out in full the allegations of impairment made against that registered person;
 - (c) specify the venue, date and time of the inquiry to be conducted;
 - (d) inform the registered person that he or she -
 - (i) must be present at the inquiry to answer to the allegations of impairment and that if he or she fails to be so present that the inquiry may be conducted in his or her absence; and

- (ii) may be represented by a legal practitioner at the inquiry, only if the registered person himself or herself is present at the inquiry;
 - (e) be served on that registered person by the registrar or by a person designated by the registrar in writing for that purpose.
- (4) If the registrar or the person designated under subregulation (3)(e), certifies that the registered person referred to in that subregulation -
- (a) cannot be traced; or
 - (b) refuses to accept service of the notice; or
 - (c) refuses to sign an acknowledgement of receipt relating to the service of the notice,
- the registrar may send that notice by prepaid registered post, not less than 21 days before the commencement date of the intended inquiry, to that registered person, addressed to his or her postal address as it appears in the register.
- (5) If the registered person served with a notice under subregulation (3), or to whom a notice has been sent under subregulation (4), is not present at the commencement of the inquiry without good cause, the Committee may conduct the inquiry in the absence of that registered person.
- (6) For the purpose of an inquiry under this regulation, the registrar must notify in writing and in the form determined by the Committee -
- (a) all or any of the medical examiner or medical examiners who submitted reports to the registrar relating to the registered person under regulation 6(1)(c)(ii) -
 - (i) of the venue, date and time of the inquiry; and
 - (ii) that his or her or their presence at the inquiry is or are required for the purpose of giving evidence on his or her or their report or reports; and
 - (b) the person or persons who made the allegations of impairment under regulation 3(1) of the inquiry.
- (7) The medical examiner or medical examiners referred to in subregulation 6(a), and the person or persons referred to in subregulation (6)(b), must testify before the Committee on the allegations of impairment and the assessment of the registered person respectively.
- (8) For the purpose of subregulation (7), the chairperson must appoint a person to lead the evidence of the persons referred to in that subregulation, when testifying before the Committee.
- (9) The registered person appearing before the Committee may -
- (a) examine any person testifying before the Committee under subregulation (7);
 - (b) testify and call witnesses to testify, on his or her behalf; and
 - (c) address the Committee on any matter that the Committee must decide on.
- (10) The Committee may cross-examine any person referred to in subregulation (9)(b) testifying before the Committee.
- (11) Any person testifying before the Committee -

- (a) must do so under oath or affirmation; and
- (b) is entitled to all the privileges that a witness testifying before the High Court of Namibia is entitled to.

(12) A person appointed under these regulations to act as a member of the Committee may advise the Committee on any matter before the Committee and take part in the deliberations of the Committee, but may not cast a vote on any issue that the Committee takes a vote on.

(13) Subject to Article 12 of the Namibian Constitution, an inquiry by the Committee under these regulations must be conducted *in camera*.

Findings of Committee

10. (1) The Committee, after having conducted an inquiry under regulation 9 in respect of a registered person, may make a finding that on the evidence before the Committee -

- (a) it is of the opinion that the registered person in respect of whom the inquiry has been conducted -
 - (i) is not an impaired registered person and that he or she may practise his or her profession without any restrictions;
 - (ii) is an impaired registered person and that -
 - (aa) the impairment is of a serious nature that renders him or her incompetent to practise his or her profession; or
 - (bb) the impairment is not of a serious nature and that he or she is a fit and proper person to practise his or her profession subject to certain conditions and restrictions; or
- (b) it is not able to determine whether the registered person is an impaired person.

(2) If the Committee has made a finding under subregulation (1), the Committee must submit that finding to the Council together with any recommendation to the Council as it considers necessary.

(3) The recommendations of the Committee to the Council in respect of a finding under subregulation (1)(a)(ii) may include conditions with regard to -

- (a) the scope of the registered person's practice;
- (b) permission to handle scheduled substances;
- (c) prohibition on the use or abuse of dependence producing substances;
- (d) suspension of registered person subject to conditions and for a specified time;
- (e) ensuring and securing treatment and rehabilitation of the impaired registered person; or
- (d) securing supervision of the fitness to practise and performance of registered person.

(4) The registrar must submit to the Council the findings of the Committee in terms of this regulation.

Decision of Council

11. (1) On receipt of the findings and recommendations of the Committee under regulation 10, the Council -

- (a) may take a decision confirming the finding of the Committee under regulation 10(1)(a)(ii)(aa), and may -
 - (i) suspend the registered person from practising his or her profession with immediate effect, until the finalisation of an inquiry by the Council as contemplated by subparagraph (ii);
 - (ii) must conduct an inquiry under Part VI of the Act into the conduct of that registered person;
- (b) may take a decision confirming the finding of the Committee under regulation 10(1)(a)(ii)(bb), and impose conditions the Council may consider necessary including conditions recommended by the Committee and instruct the registrar to inform the registered person -
 - (i) of the conditions and restrictions so determined; and
 - (ii) that if he or she fails to comply with those conditions and restrictions that -
 - (aa) he or she commits an act of unprofessional conduct as contemplated in section 45 of the Act; and
 - (bb) the Council may conduct a professional conduct inquiry under Part VI of the Act into his or her failure to comply with the conditions and restrictions;
- (c) may take a decision confirming the findings of the Committee under regulation 10(1)(a)(i); and
- (d) must, if the Committee makes a finding referred to in regulation 10(1)(b), conduct an inquiry under Part VI of the Act.

(2) The Council may under subregulation (1)(b)(i) impose conditions that the impaired registered person -

- (a) may practise his or her profession -
 - (i) in a hospital, clinic or private practice; and
 - (ii) under the direct supervision, and on the instructions, of the registered person or persons,
that the Council may identify;
- (b) may not acquire, possess or prescribe any scheduled substance;
- (c) must receive the appropriate treatment for the appropriate period of time in or at the appropriate facility to remedy, rectify or cure the impairment.

(3) The impaired registered person is liable for the payment of all the expenses pertaining to the treatment contemplated by subregulation (2)(c).

(4) The registrar must notify the registered person concerned of the finding of the Council under this regulation.

(5) The notification under subregulation (4) must be –

(a) in writing; and

(b) be sent by prepaid registered post, addressed to the postal address of the registered person as it appears in the register or be delivered to the registered person by hand.
