

DEPARTMENT OF HEALTH

NO. 658

12 JUNE 2020

**PHARMACY ACT, 1974 (ACT NO. 53 OF 1974)
REGULATIONS RELATING TO PHARMACY EDUCATION AND TRAINING:
AMENDMENT REGULATIONS, 2019**

The Minister of Health intends, in consultation with the South African Pharmacy Council, in terms of sections 33 and 49 of the Pharmacy Act, 1974 (Act No. 53 of 1974), to make the regulations in the Schedule.

The proposed amendments to these Regulations enable:

- a) the establishment of a new category of pharmacy support personnel – pharmacy technician – with a new scope of practice;
- b) the categorisation of pharmacy technicians as a type of pharmacist's assistant to enable these persons to handle medicines in accordance with the provisions of the Medicines and Related Substances Act, 1965, (Act 101 of 1965);
- c) the retention of the categories of pharmacy support personnel - pharmacist's assistants (basic) and pharmacist's assistants (post-basic) - with amendments to the scope of practice;
- d) two routes for the education and training and subsequent registration of pharmacy technicians – one via the Occupational Qualifications Sub-framework (OQSF), and the other via the Higher Education Qualifications Sub-framework (HEQSF);
- e) registration of persons undertaking a pharmacy technician qualification which falls under the HEQSF, as a pharmacy technician (student) and completion of a traineeship whilst registered as a pharmacy technician (trainee);

- f) registration of persons undertaking a pharmacy technician qualification which falls under the QQSF as a pharmacy technician (learner) and the option to exit as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic) after completion of part qualifications. NOTE: There is no traineeship or internship required after completing these part-qualifications or the whole qualification;
- g) upskilling of current pharmacist's assistants, whilst enabling those who are unable to undergo further education and training to continue to practise in the category in which they are registered.

Further information is available on the websites of the National Department of Health and the South African Pharmacy Council

Any person wishing to comment on or make representation with regard to the proposed amendments to the Regulations is hereby invited to do so within three (3) months of the date of publication of this notice.

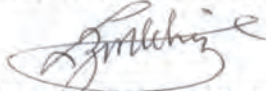
All such comments and representations must be submitted in writing using the format outlined in the attached template (available on www.health.gov.za), marked for the attention of Ms Mhloti Mushwana, Director: Public Entities Governance in any one of the following ways:

(a) By electronic mail: regulationcomments@health.gov.za

(b) Hand delivered to:

Director-General: Health
National Department of Health
222 Thabo Sehume Street
Pretoria
0001

Comments received after the closing date may not be considered. Enquiries may be made to Mandie Bhembe on (012) 395 8288/8130 or regulationcomments@health.gov.za.


DR. ZWELINI LAWRENCE MKHIZE, MP
MINISTER OF HEALTH

DATE 24/03/2020

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Education Regulations

**TEMPLATE FOR COMMENT ON THE AMENDMENTS TO THE REGULATIONS RELATING TO PHARMACY EDUCATION
AND TRAINING MADE IN TERMS OF THE PHARMACY ACT, 1974 (ACT 53 OF 1974)**

Name of Organisation / Individual:			
Date of submission:			

Comment no.	Regulation, subregulation or paragraph			Comment and Rationale	Proposed Revised Text Bold underlined – additions [square brackets bold] – deletions
	Reg	Subreg	Par.		
Example: 1	4	(1)	(a)(i)	Provide a rationale for the comment.	Provide a revised text example.

ADD MORE ROWS TO TABLE AS REQUIRED

GENERAL EXPLANATORY NOTE:

_____ Words underlined with a solid line indicate insertions in existing enactments.

SCHEDULE**Definition**

1. In this Schedule the "Regulations" means the Regulations Relating to Pharmacy Education and Training, published under Government Notice No. R. 1156 of 20 November 2000, as corrected by Government Notice No. R. 1321 of 8 December 2000.

Amendment of regulation 1 of Regulations

2. Regulation 1 of the Regulations is hereby amended by—

- (a) the deletion of the definition of "certificate of qualification" after the definition of "certificate of approval"
- (b) the substitution for the definition of "continuing professional development" of the following definition:

"continuing professional development" means the process by which persons registered under this Act maintain and enhance their competence throughout their professional careers, and encompasses a range of activities including continuing education and supplementary training;

- (c) the substitution for the definition of "contract" of the following definition:

"'contract' means a written contract approved by the council which lays down the conditions of the —

- (a) internship of a pharmacist intern;
- (b) in-service training of a pharmacist's assistant (learner basic) or pharmacist's assistant (learner post-basic); or
- (c) traineeship of a pharmacy technician (trainee);"
- (d) the substitution for the definition of "direct personal supervision" of the following definition:

"'direct personal supervision' means guidance and support provided by a pharmacist whilst physically present in a pharmacy, in accordance with rules relating to good pharmacy practice published in terms of section 35A of the Act;"
- (e) substitution for the definition of "pharmacist's assistant" of the following definition:

"pharmacist's assistant" means a natural person registered in one of the following categories:

- (a) pharmacist's assistant (learner basic);
- (b) pharmacist's assistant (basic);
- (c) pharmacist's assistant (learner post-basic);
- (d) pharmacist's assistant (post-basic);
- (e) pharmacy technician (learner);
- (f) pharmacy technician (student);
- (g) pharmacy technician (trainee);
- (h) pharmacy technician; or

(i) pharmacy student;

which constitute the various categories of pharmacy support personnel registered as such in terms of the Act';

(f) the insertion after the definition of "pharmacist's assistant" of the following definitions:

" 'pharmacy technician' means a person registered as such in terms of the Act;

'pharmacy technician (learner)' means a person registered as such in terms of the Act;

'pharmacy technician (student)' means a person registered as such in terms of the Act;

'pharmacy technician (trainee)' means a person registered as such in terms of the Act;";

(g) the substitution for the definition of "provider" of the following definition:

" 'provider' means any person or institution approved by and registered with the council in terms of the Act to provide education and training approved by the council for purposes of:

(a) registration as a pharmacist;

(b) registration as a pharmacist's assistant (basic), pharmacist's assistant (post-basic) or pharmacy technician;

(c) registration of a speciality;

(d) continuing professional development;

(e) supplementary training; or

a course determined by the Council in terms of the Medicines Act;";

(h) the deletion of the definition of "qualification in pharmacy" after the definition of public health facility;

(i) the insertion after the definition of "supplementary training" of the following definition:

“ ‘traineeship’ means practical training, as determined by the council from time to time, undertaken by a pharmacy technician (trainee) in terms of a contract under the direct personal supervision of a tutor in a pharmacy approved by the council in terms of the Act for purposes of such training;”;

- (j) the substitution for the definition of “tutor” of the following definition:

“‘tutor’ means a pharmacist registered with the council as a tutor, to supervise the internship of a pharmacist intern, the traineeship of a pharmacy technician (trainee) or the in-service training of a pharmacist’s assistant (learner basic) or pharmacist’s assistant (learner post-basic);”;

- (k) the deletion of the definition of “unit standards” after the definition of “tutor”

- (l) the insertion after the definition of “wholesale pharmacy” of the following definition:

“ ‘work-based training’ means education and training undertaken by a pharmacist’s assistant (learner basic); pharmacist’s assistant (learner post-basic), or pharmacy technician (learner) in a pharmacy under the auspices of a provider, as part of an education and training programme approved by the council for purposes of registration as a pharmacist’s assistant (basic); pharmacist’s assistant (post-basic), or pharmacy technician. ”

Substitution of regulation 2 of Regulations

3. The following regulation is hereby substituted for regulation 2 of the Regulations:

“2. Education and training programmes for purposes of registration as a pharmacist shall be approved by the council.”

Substitution of regulation 3 of Regulations

4. The following regulation is hereby substituted for regulation 3 of the Regulations:

“3. Only a provider that holds a certificate of approval for an education and training programme approved for purposes of registration as a pharmacist may provide such education and training ”

Substitution of regulation 4 of Regulations

5. The following regulation is hereby substituted for regulation 4 of the Regulations:

4. An education and training programme approved by the council for purposes of registration as a pharmacist must extend over a minimum period of four years: provided that if such programme includes practical training to the satisfaction of the council of not less than one year or periods of not less than one year in the aggregate, as part of the undergraduate studies, under the supervision of the provider concerned, such programme must extend over a minimum period of five years.

Insertion of new Chapter II

6. The following new Chapter II is hereby inserted after regulation 4 of the Regulations:

“CHAPTER II

Substitution of regulation 5 of Regulations

7. The following regulation is hereby substituted for regulation 5 of the Regulations:

Requirements and conditions for pharmacy internship

5.(1) A person who has completed an education and training programme approved by the council for purposes of registration as a pharmacist must, prior to registration as a pharmacist, undertake an internship in accordance with this Chapter for a period or aggregate period specified in subregulation (3);

(2) The council may exempt a person referred to in subregulation (1), partially or in full, from the requirement of subregulation (1) on submission of documentary evidence to the satisfaction of the council that the person has undertaken other relevant practical training for a period or aggregate period equivalent to the period specified in subregulation (3).

(3) The period of internship contemplated in subregulation (1) must be for a period or aggregate period of at least 12 months.

Substitution of regulation 6 of Regulations

8. The following regulation is hereby substituted for regulation 6 of the Regulations:

6. The internship contemplated in regulation 5 must be undertaken—

- (a) in terms of a contract;
- (b) under the direct personal supervision of a tutor;
- (c) in a community pharmacy, institutional pharmacy, manufacturing pharmacy, or wholesale pharmacy which provides a minimum number of services pertaining to the scope of practice of a pharmacist as may be determined by the council in terms of the Act, and which is approved by the council in terms of the Act for purposes of such training; or

- (d) at a provider who holds a certificate of approval for an education and training programme approved by the council for purposes of registration as a pharmacist.

Substitution of regulation 7 of Regulations

9. The following regulation is hereby substituted for regulation 7 of the Regulations:

7. No person may commence an internship unless—

- (a) such person has been registered as a pharmacist intern in terms of the Act;
- (b) a contract has been entered into between the pharmacist intern and the tutor concerned;
- (c) the pharmacy or provider at which the internship will take place has been approved by the council in terms of section 34 of the Act; and
- (d) the tutor has been registered as such.

Substitution of regulation 8 of Regulations

10. The following regulation is hereby substituted for regulation 8 of the Regulations:

8. No pharmacist, pharmacy or provider of an education and training programme approved by the council for purposes of registration as a pharmacist, may employ any person as a pharmacist intern or in any other capacity which may imply or lead such person to believe that he or she is undertaking an internship, unless the requirements in regulations 6 and 7 have been complied with.

11. Deletion of regulation 9 of Regulations

Regulation 9 of the Regulations is hereby deleted

Substitution of regulation 10 of Regulations

12. The following regulation is hereby substituted for regulation 10 of the Regulations:

10. An internship undertaken at a provider of an education and training programme approved by the council for purposes of registration as a pharmacist, or in a manufacturing pharmacy or a wholesale pharmacy, must include a period of not less than 400 hours of practical training at a community or institutional pharmacy approved by the council for such training in terms of the Act: Provided that—

- (a) the tutor, referred to in regulation 6(b), must—
 - (i) make arrangements for the keeping of the necessary records of such training;
and
 - (ii) inform the council of the community or institutional pharmacy where the practical training will be undertaken;
- (b) such periods of practical training must be undertaken on the basis of periods, each of which must be at least five consecutive days;
- (c) there is a tutor at the pharmacy where practical training is undertaken who must keep records of such training;
- (d) the responsibilities of all the parties regarding such practical training must be clearly documented and included in the internship contract.

Substitution of regulation 11 of Regulations

13. The following regulation is hereby substituted for regulation 11 of the Regulations:

11. No internship undertaken at a provider of an education and training programme approved by the council for purposes of registration as a pharmacist may be recognised in terms of the Act, unless the prospective tutor has submitted to the registrar—

(a) full particulars of the proposed post-graduate study or research to be undertaken by the prospective intern and the post-graduate study or research has been approved by the council in terms of the Act; and

(b) documentary evidence that the prospective intern is registered at such provider for the post-graduate study or research referred to in subregulation (a).

Substitution of regulation 12 of Regulations

14. The following regulation is hereby substituted for regulation 12 of the Regulations:

12. If an intern undergoing an internship at a provider of an education and training programme approved by the council for purposes of registration as a pharmacist, contemplated in regulation 11, discontinues his or her studies or research for any reason, or ceases to be registered at that provider, he or she must receive recognition only for the period of practical training duly completed at a community or institutional pharmacy referred to in regulation 10.

Substitution of regulation 13 of Regulations

15. The following regulation is hereby substituted for regulation 13 of the Regulations:

13. The internship of a pharmacist intern at a provider of an education and training programme approved by the council for purposes of registration as a pharmacist, must be regarded as completed upon successful completion of the required period of practical training referred to

in regulation 10 and the submission of documentary evidence to the registrar that the intern has satisfied the requirements of the provider for the awarding of at least a master's degree.

Substitution of regulation 14 of Regulations

16. The following regulation is hereby substituted for regulation 14 of the Regulations:

Cession of contract of pharmacy internship

14. A contract contemplated in regulation 6(a) may be ceded in the event of—

- (a) the death of a tutor, his or her conviction of a serious offence or suspension or removal of his or her name from the register of pharmacists during the contract;
- (b) the discontinuation of practice of the tutor or the resignation of the tutor from the pharmacy or provider approved for the internship;
- (c) the closure of the pharmacy or provider approved for the internship;
- (d) mutual consent of the tutor and the pharmacist intern for a reason which is acceptable to the registrar; or
- (e) any other reason the registrar may consider to be acceptable;

Provided that the period of internship undertaken by the pharmacist intern under the original tutor must be recognised by the council for the purposes of internship and the prospective tutor accepts the delegation of the rights, obligations and interests in terms of such a contract.

Substitution of regulation 15 of Regulations

17. The following regulation is hereby substituted for regulation 15 of the Regulations:

Approval of contract of cession

15. (1) A pharmacist intern intending to cede a contract to another tutor must, at least seven days before such cession occurs, submit to the registrar—

- (a) a duly completed application on a form, as approved and provided by the council;
- (b) a duly completed and signed contract of cession for the conducting of an internship approved and provided by the council;
- (c) documentary evidence—
 - (i) of the approval by the council of the pharmacy or provider where the internship of the pharmacist intern will occur after cession of the contract;
 - (ii) of the registration with the council of the tutor under whose direct personal supervision such internship will take place;
 - (iii) where applicable, that he or she is registered at an institution approved as a provider of a course of study which will lead to the awarding of at least a master's degree; and

- (iv) an affidavit by the previous tutor, where possible, affirming that partial internship was successfully performed.

(2) The pharmacist intern contemplated in subregulation (1) must pay the cession fee as may be determined by the council in terms of the Act.

Substitution of regulation 16 of Regulations

18. The following regulation is hereby substituted for regulation 16 of the Regulations:

Delegation of training by tutor

16.(1) Subject to subregulations (2), (4) and (5), a pharmacist may not act as a tutor to more than one pharmacist intern at the same time.

(2) A tutor practising in a pharmacy where other pharmacists practise on a full-time basis may act as tutor to more than one pharmacist intern, in which event, the tutor may delegate the actual practical training of all such additional pharmacist interns to such other pharmacists, subject to subregulation (3).

(3) In the event of subregulation (2)—

- (a) there must be one pharmacist for each additional pharmacist intern;
- (b) the tutor may not delegate the training of more than four pharmacist interns;

- (c) the responsibility for the internship of all such pharmacist interns must remain with the tutor;
- (d) the tutor must inform the council, in writing, of a delegation or of any changes to such delegation; and
- (e) the internship must be conducted in accordance with the provisions of these Regulations.

(4) A tutor may act as tutor to a second pharmacist intern when the pharmacist intern already under training with such tutor has completed his or her ninth month of internship.

(5) A tutor at a provider of an education and training programme approved by the council for purposes of registration as a pharmacist, may, with the prior approval of the registrar, act as a tutor to no more than five pharmacist interns at the same time.

Substitution of regulation 17 of Regulations

19. The following regulation is hereby substituted for regulation 17 of the Regulations:

Assessment and completion of pharmacist internship

17. The tutor of a pharmacist intern must submit to the registrar—

- (a) assessment forms, obtainable from the council, on the progress of the pharmacist intern during the period of internship; and
- (b) an affidavit, at the end of the period of internship, affirming that—

- (i) the training has been completed satisfactorily in accordance with council's requirements for internship;
- (ii) the pharmacist intern is a fit and proper person to be registered as a pharmacist;
and
- (iii) where the internship has been completed at a provider of an education and training programme approved by the council for purposes of registration as a pharmacist, a manufacturing pharmacy or a wholesale pharmacy, proof that the period of 400 hours practical training in a community pharmacy or institutional pharmacy has been completed in accordance with all the necessary requirements

Substitution of regulation 18 of Regulations

20. The following regulation is hereby substituted for regulation 18 of the Regulations:

Pre-registration evaluations

18. A person may be required to undertake a pre-registration evaluation, which may be conducted by the council, as a pre-requisite for registration as a pharmacist in terms of the Act: Provided that if such person fails such evaluation, the council may require—

- (a) the person to be re-evaluated at a time and date as may be determined by the council; or

(b) the person's period of practical training to be extended by an additional period as the council may determine."

21. Deletion of regulation 19 of Regulations

Regulation 19 of the Regulations is hereby deleted

Substitution of title of existing Chapter II of Regulations

22. The following title is hereby substituted for the existing title "**CHAPTER II Standards of education and training of pharmacists' assistants**" of the Regulations:

"CHAPTER III

Standards of education and training of pharmacist's assistants (basic) and pharmacist's assistants (post-basic)"

Substitution of regulation 20 of Regulations

23. The following regulation is hereby substituted for regulation 20 of the Regulations:

"20. Education and training programmes for purposes of registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic) shall be approved by the council."

Substitution of regulation 21 of Regulations

24. The following regulation is hereby substituted for regulation 21 of the Regulations:

"21. Only a provider that holds a certificate of approval for an education and training programme approved for purposes of registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic) may provide such education and training ".

Deletion of regulation 22 of Regulations

25. Regulation 22 of the Regulations is hereby deleted.

Deletion of regulation 23 of the Regulations

26. Regulation 23 of the Regulations is hereby deleted.

Substitution of regulation 24 of the Regulations

27. The following regulation is hereby substituted for regulation 24 of the Regulations:

24. Evaluation of prior learning. The council may, when it is deemed necessary by council, provide for an evaluation of prior learning by which a person shall be assessed prior to registration in the category pharmacist's assistant (learner basic) or pharmacist's assistant (learner post-basic): provided that the evaluation must be conducted in accordance with a procedure as determined by council from time to time and on payment of the evaluation fee as determined by council

Substitution of regulation 25 of Regulations

28. The following regulation is hereby substituted for regulation 25 of the Regulations:

"25. A learning programme approved by the council for purposes of registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic), may be determined by a

provider provided that a minimum period of twelve months of in-service training must be completed."

Amendment of regulation 27 of Regulations

29. Regulation 27 of the Regulations is hereby amended by the substitution for subregulation (3) of the following subregulation:

"(3) the tutor has been registered as such."

Deletion of regulation 28 of Regulations

30. Regulation 28 of the Regulations is hereby deleted.

Substitution of regulation 30 of Regulations

31. The following regulation is hereby substituted for regulation 30 of the Regulations:

"30. Supervision of pharmacy support personnel undergoing in-service training. A pharmacist may at the same time, act as the tutor to no more than three pharmacist's assistants (learner basic) or pharmacist's assistants (learner post-basic), per category or a combination thereof, undergoing in-service training."

Substitution of regulation 32 of Regulations

32. The following regulation is hereby substituted for regulation 32 of the Regulations:

"32. A provider approved to offer an education and training programme for purposes of registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic), must, upon

the successful assessment of the pharmacist's assistant in the said categories, submit to the registrar a notification of completion of such qualification, in a manner determined by the council."

Substitution of regulation 33 of Regulations

33. The following regulation is hereby substituted for regulation 33 of the Regulations:

"33. A person may be required to undertake an assessment or evaluation, which may be conducted by the council, as a prerequisite for registration in the category pharmacist's assistant (basic) or pharmacist's assistant (post-basic)."

Deletion of regulation 34 of the Regulations

34. Regulation 34 of the Regulations is hereby deleted.

Insertion of new Chapter IV in Regulations

35. The following new Chapter IV, together with the regulations made thereunder, is hereby inserted after regulation 34 of the Regulations:

"CHAPTER IV

Standards of education and training of pharmacy technicians

34A. Education and training programmes for purposes of registration as a pharmacy technician shall be approved by council."

34B. Only a provider that holds a certificate of approval for an education and training programme approved for purposes of registration as a pharmacy technician may provide such education and training."

34C.(1) A person who has completed an education and training programme approved by the council for purposes of registration as a pharmacy technician must, prior to registration as a pharmacy technician, undertake a traineeship contemplated in this Chapter for a period or aggregate period of six months.

(2) The council may exempt a person referred to in subregulation (1), partially or in full, from the traineeship requirement contemplated in subregulation (1) on submission of documentary evidence to the satisfaction of the council that the person has undertaken work-based training as part of an education and training programme approved by the council for purposes of registration as a pharmacy technician.

34D.(1) The traineeship referred to in regulation 34D must be undertaken –

- (a) in terms of a contract;
- (b) under the direct supervision of a tutor;
- (c) in a community pharmacy, institutional pharmacy, manufacturing pharmacy or wholesale pharmacy which provides a minimum number of services pertaining to the scope of practice of a pharmacy technician, as may be determined by the council in terms of the Act, and which is approved by the council in terms of the Act for purposes of such training.

(2) A traineeship undertaken in terms of subregulation (1)(c) in a manufacturing pharmacy or a wholesale pharmacy must include, as part of such traineeship, a period of not less than 200 hours

of practical training at a community or institutional pharmacy approved by council, in terms of the Act, for such training: Provided that—

- (a) the tutor referred to in subregulation (1)(b) must –

 - (i) make the arrangements for the keeping of necessary records of such training; and
 - (ii) inform the council of the community or institutional pharmacy where the practical training will be undertaken;
- (b) such periods of practical training must be undertaken at an approved community or institutional pharmacy and on the basis of periods each of which must be at least five consecutive days;
- (c) there is a tutor at the pharmacy where practical training is undertaken who must keep records of such training;
- (d) the responsibilities of all the parties regarding such practical training must be clearly documented and included in the terms of the traineeship contract; and
- (e) under the direct personal supervision of a tutor registered by the council in terms of the Act.

34E. No person must commence a traineeship unless he or she is duly registered as a pharmacy technician (trainee) in terms of the Regulations Relating to the Registration of Persons and the Maintenance of Registers made in terms of the Act.

34F. No pharmacist or pharmacy may employ any person as an pharmacy technician (trainee) or in any other capacity which may imply or lead such person to believe that he or she is undertaking a traineeship, unless the requirements in regulations 34D and 34E have been complied with.

Cession of contract of traineeship

34G. (1) A contract contemplated in regulation 34D(1)(a) may be ceded in the event of –

- (a) the death of a tutor, his or her conviction of a serious offence or suspension or removal of his or her name from the register of pharmacists during the contract;
- (b) the discontinuation of practice of the tutor or the resignation of the tutor from the pharmacy approved for the traineeship;
- (c) the closure of the pharmacy approved for the traineeship;
- (d) mutual consent of the tutor and the pharmacy technician (trainee) for a reason, which is acceptable to the registrar; or
- (e) any other reason the registrar may consider to be acceptable;

Provided that the period of traineeship undertaken by the pharmacy technician (trainee) under the original tutor must be recognised by the council for the purposes of traineeship and that the prospective tutor accepts the delegation of the rights, obligations and interests in terms of such a contract.

Approval of contract of cession

34H.(1) A pharmacy technician (trainee) intending to cede a contract to another tutor must, at least seven days before such cession occurs, submit to the registrar

(a) a duly completed application on a form as approved and provided by the council;

(b) a duly completed and signed contract of cession for the conducting of a traineeship approved and provided by the council;

(c) documentary evidence—

(i) of the approval by the council of the pharmacy where the traineeship of the pharmacy technician (trainee) will occur after cession of the contract;

(ii) of registration of the tutor under whose direct personal supervision such traineeship will take place;

(iii) in the form of an affidavit by the previous tutor, where possible, affirming that partial traineeship was successfully performed.

(2) The pharmacy technician (trainee) contemplated in subregulation (1) must pay the cession fee as may be determined by the council in terms of the Act.

34I. A pharmacist may act as a tutor to no more than one pharmacy technician (trainee) at a time, unless the pharmacy technician (trainee) already under training with such tutor has

completed his or her fifth month of traineeship, in which case the tutor may act as tutor to one other pharmacy technician (trainee) for the remainder of the traineeship period.

Assessment and completion of pharmacy technician traineeship

34J.(1) The tutor of a pharmacy technician (trainee) must submit to the registrar—

- (a) assessment forms, obtainable from the council, on the progress of the pharmacy technician (trainee) during the period of traineeship; and
- (b) an affidavit, at the end of the period of traineeship, affirming that—
 - (i) the training has been completed satisfactorily in accordance with council's requirements for traineeship; and
 - (ii) the pharmacy technician (trainee) is a fit and proper person to be registered as a pharmacy technician.

Pre-registration evaluations

34K. A person may be required to undertake a pre-registration evaluation, which may be conducted by the council, as a pre-requisite for registration as a pharmacy technician in terms of the Act: Provided that if a person requiring registration fails such evaluation, the council may require—

- (a) such person to be re-evaluated at a time and date as may be determined by the council; or

- (b) the person's period of traineeship to be extended by an additional period as the council may determine.

Substitution of title of existing Chapter III of the Regulations

36. The following title is hereby substituted for the existing title "CHAPTER III Approval of tutors and premises for purposes of education and training" of the Regulations:

"CHAPTER V

Registration of tutors and approval of premises for purpose of education and training

Registration of a tutor

Substitution of regulation 35 of Regulations

37. The following regulation is hereby substituted for regulation 35 of the Regulations:

"35.(1) A pharmacist who wishes to be registered as a tutor must submit to the registrar—

- (a) a duly completed application for registration as a tutor of persons undergoing an internship, traineeship or in-service training, on a form obtainable from the council;
- (b) in the case of a pharmacist who wishes to act as a tutor of a pharmacist intern, proof that he or she has been registered as a pharmacist for a period of at least three years, which period may include the performance of pharmaceutical community service; and
- (c) proof of successful completion of continuing professional development in terms of the Act.

(2) A pharmacist contemplated in subregulation (1) must pay the necessary application fee as may be determined by the council in terms of the Act."

Substitution of existing title Chapter IV of Regulations

38. The following title is hereby substituted for the existing title "CHAPTER IV" of the Regulations:

"CHAPTER VI

Substitution of regulation 41 of Regulations

39. The following regulation is hereby substituted for regulation 41 of the Regulations:

"41.(1) Any provider intending to provide education and training for purposes of —

- (a) registration as a pharmacist;
- (b) registration as a pharmacist's assistant (basic), pharmacist's assistant (post-basic) or pharmacy technician;
- (c) registration of a speciality;
- (d) continuing professional development
- (e) supplementary training; or
- a course determined by the council in terms of the Medicines Act,"

must apply to the council for approval.

(2) The application contemplated in subregulation (1) must be made on an application form obtainable from the council for such purpose."

Substitution of regulation 42 of Regulations

40. The following regulation is hereby substituted for regulation 42 of the Regulations:

"Conditions for approval

42.(1) Any provider contemplated in regulation 41 must be approved, subject to the following conditions:

- (a) providers of education and training for purposes of registration as a pharmacist may be approved for a maximum period of six years;
- (b) providers of education and training for purposes of registration as a pharmacist's assistant (basic), pharmacist's assistant (post-basic) or pharmacy technician may be approved for a maximum period of five years; and
- (c) providers of continuing professional development courses, supplementary training and courses determined in terms of the Medicines Act, may be approved for a maximum period of three years.

(2) The pharmacy education and training programmes must be conducted in accordance with—

- (a) good pharmacy education standards;
- (b) good pharmacy practice;
- (c) the code of conduct as published by council in rules in terms of the Act; and

(d) the provisions of other applicable legislation."

Insertion of regulation 42A into Regulations

41. The following regulation is inserted after regulation 42 of the Regulations:

"Appointment and duties of designated pharmacist

42A. (1) A provider of pharmacy education and training must appoint and register a designated pharmacist for each approved institution.

(2) The designated pharmacist must be responsible to the council for complying with the provisions of the Act and other legislation relating to pharmacy education and training.

(3) The designated pharmacist must—

(a) ensure that the provider complies with all the requirements for approval including the payment of applicable fees;

(b) ensure that learners registered with the provider have complied with all the requirements for registration;

(c) furnish the registrar with information that the registrar may require from time to time;

(d) participate in the decision making process of the provider affecting pharmacy education and training;

(e) notify the council immediately upon receiving knowledge that his or her status as designated pharmacist has changed or will be changed;

- (f) inform the registrar of any instruction or order from the institution with regard to the pharmacy education and training which could amount to a contravention of legislation applicable to pharmacy;
- (g) take corrective measures in respect of deficiencies with regard to inspection reports emanating from monitoring and accreditation inspections; and
- (h) ensure that there is compliance with good pharmacy education standards and practice and the code of conduct as published by the council in rules in terms of the Act.

Substitution of regulation 43 of Regulations

42. The following regulation is hereby substituted for regulation 43 of the Regulations:

"Inspection of providers

43. The council must inspect providers to measure compliance with the requirements determined by council for the provision of pharmacy education and training at intervals as determined by council from time to time."

Amendment of regulation 44 of Regulations

43. Regulation 44 of the Regulations is hereby amended by the addition of the following subregulation:

"(4) have the minimum of a Master's degree."

Substitution of regulation 48 of Regulations

44. The following regulation is hereby substituted for regulation 48 of the Regulations:

"48. The council must publish the names of providers that have been approved and registered to provide education and training in terms of the Act."

Deletion of Annexures

Annexure A, Annexure B and Annexure C are hereby deleted.

Short Title

45. These Regulations are called the Amendment Regulations relating to the pharmacy education and training, 2020.