

No. R. 1156

20 November 2000

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

The Minister of Health has, in consultation with the South African Pharmacy Council, in terms of sections 33 and 34 of the Pharmacy Act, 1974 (Act 53 of 1974), as amended, made the regulations in the Schedule.

**SCHEDULE****1. Definitions** – in these regulations, unless the context otherwise indicates -

“**Act**” means the Pharmacy Act, 1974, (Act 53 of 1974), as amended, and regulations;

“**additional qualification**” means a qualification obtained as part of continuing professional development which is recognised by council for purposes of registration;

“**assessor**” means any pharmacist registered by council in accordance with criteria determined and published for this purpose by council to measure outcomes of pharmacy education and training;

“**certificate of approval**” means a certificate issued by council to a person or institution that complies with the criteria determined and published by council for the approval of providers;

“**certificate of qualification**” means documentary evidence of a qualification required for registration as a pharmacist’s assistant;

“**community pharmacy**” means a pharmacy wherein or from which some or all of the services as prescribed in regulation 18 of the Regulations Relating to the Practice of Pharmacy are provided to persons requiring pharmaceutical services, but excludes an institutional pharmacy;

“**continuing professional development**” means the process by which natural persons registered with council continuously enhance their knowledge, skills and personal qualities throughout their professional careers, and encompasses a range of activities including continuing education and supplementary training;

“**contract**” means a contract approved by council which lays down the conditions of an internship of a pharmacist intern or the in-service training of a pharmacist’s assistant (learner basic) or pharmacist’s assistant (learner post-basic);

“**direct personal supervision**” means guidance and support by a pharmacist whilst physically present in a pharmacy;

“**in-service training**” means the training undertaken by a pharmacist’s assistant (learner basic) or pharmacist’s assistant (learner post-basic) under the direct personal supervision of a tutor at a pharmacy approved by council for purposes of such training;

**“internship”** means the practical training undertaken by a pharmacist intern in terms of a contract under the direct personal supervision of a tutor in a pharmacy approved by council for purposes of such training or at an institution registered as a provider of a qualification in pharmacy;

**“institutional pharmacy”** means a pharmacy situated in –

- (a) a public health facility wherein or from which some or all of the services as prescribed in regulation 18 of the Regulations Relating to the Practice of Pharmacy are provided to persons requiring pharmaceutical services, from or at that public health facility; or
- (b) a private health facility wherein or from which some or all of the services as prescribed in regulation 18 of the Regulations Relating to the Practice of Pharmacy are provided to persons requiring pharmaceutical services from or at that private health facility,

but excludes a community pharmacy;

**“manufacturing pharmacy”** means a pharmacy wherein or from which some or all of the services as prescribed in regulation 16 of the Regulations Relating to the Practice of Pharmacy are provided and who shall sell medicine only to a wholesale pharmacy or a community pharmacy or an institutional pharmacy or to persons who are authorised to purchase medicines in terms of the Medicines Act or to an organ of State;

**“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); or
- (e) pharmacy student;

**“pharmacist intern”** means a person registered as such and who is undergoing an internship;

**“primary care drug therapy”** means diagnosing a health need, prescribing and supplying of medicine to meet the health needs of a patient or group of patients or, where necessary, the referral to another health care provider by a pharmacist who has received the necessary authorisation from the council;

**“private health facility”** means any hospital, institution or facility at which provision is made for diagnostic interventions, medical or surgical treatment, and nursing or other health care which is not owned or controlled by an organ of State;

**“provider”** means any person or institution approved by and registered with council to provide education and training for purposes of conferring a qualification in pharmacy or a certificate of qualification or for purposes of continuing professional development;

**“public health facility”** means any hospital, institution or facility at which provision is made for diagnostic interventions, medical or surgical treatment and nursing or other health care which is owned or controlled by an organ of State;

**“qualification in pharmacy”** means a qualification prescribed for purposes of registration as a pharmacist;

**“supplementary training”** means training approved by council which empowers a registered person to perform acts or provide services, in terms of the Act or any other law, which fall outside the scope of practice of the category in which he or she is registered;

**“tutor”** means the pharmacist approved by council to supervise the internship of a pharmacist intern or the in-service training of a pharmacist’s assistant;

**“unit standards”** means the education and training outcomes prescribed for the various categories of persons, for purposes of registration in terms of the Act;

**“wholesale pharmacy”** means a pharmacy wherein or from which some or all of the services as prescribed in regulation 17 of the Regulations Relating to the Practice of Pharmacy are provided and who shall sell medicine only to a wholesale pharmacy or a community pharmacy or an institutional pharmacy or to persons who are authorised to purchase medicines in terms of the Medicines Act or to an organ of State;

## **CHAPTER I**

### **Standards of education and training of pharmacists**

#### **Minimum curriculum**

2. The unit standards for a qualification in pharmacy are set out in Annexure A.
3. A person or an institution that holds a certificate of approval for a qualification in pharmacy may provide education and training for purposes of conferring a qualification in pharmacy -
  - (1) in accordance with the minimum curriculum as set out in the Regulations Relating to the Minimum Requirements for the Curriculum for a Degree in Pharmacy with respect to persons who commence such studies before January 2002; or
  - (2) in accordance with a curriculum that ensures the required outcomes of the unit standards set out in Annexure A.

#### **Course for a qualification in pharmacy**

4. The course for a qualification in pharmacy must extend over a minimum period of four years: provided that if the course for a qualification in pharmacy includes practical training to the satisfaction of 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 course must extend over a minimum period of five years.

#### **General requirements and conditions for internship**

5. Any person who holds a qualification in pharmacy must prior to registration as a pharmacist, undertake an internship to the satisfaction of council for a period of not less than one year or periods of not less than one year in the aggregate: provided that the council may exempt him or her partially or in full from this requirement on submission of documentary evidence to the satisfaction of council that he or she has undertaken practical training for a period of not less than one year or periods of not less than one year in the aggregate as part of his or her undergraduate studies under the supervision of a person or an institution registered as a provider of a qualification in pharmacy.
6. The internship referred to in regulation 5 must be undertaken-
  - (1) in terms of a contract;
  - (2) in a community pharmacy, institutional pharmacy, manufacturing pharmacy, or at a provider of a qualification in pharmacy, approved by council for the purposes of such training; and
  - (3) under the direct personal supervision of a tutor approved by council.
7. No person must commence an internship unless-
  - (1) he or she is duly registered as a pharmacist intern in terms of the Regulations Relating to the Registration of Persons and the Maintenance of Registers;
  - (2) a contract is entered into by and between the tutor and the prospective pharmacist intern;
  - (3) the pharmacy or institution registered as a provider of a qualification in pharmacy at which the internship will take place has been approved by council; and
  - (4) the tutor has been approved by council.
8. No pharmacist, pharmacy or institution registered as a provider of a qualification in pharmacy must 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 regulation 6 and 7 have been complied with and such pharmacist, pharmacy or institution registered as a provider of a qualification in pharmacy has been notified by the registrar in writing thereof.
9. Council may condone any non-compliance with the requirements of these regulations as a result of a *bona fide* administrative error in the office of the registrar during the registration of the pharmacist intern.
10. The internship undertaken at an institution registered as a provider of a qualification in pharmacy or in a manufacturing pharmacy must include as part of such internship a period of not less than 400 hours of practical training as determined by council at a community or institutional pharmacy approved by council for such training: provided that-
  - (1) the tutor referred to in sub-regulation 6(3) must make the necessary arrangements for and keep the necessary records of such training; and
  - (2) such periods of practical training must be done on a basis of periods each of which must be at least 5 consecutive days in an approved community or institutional pharmacy.

11. No internship undertaken at an institution registered as a provider of a qualification in pharmacy shall be recognised in terms of the Act, unless the prospective tutor has submitted to the registrar-
- (1) full particulars of the proposed post-graduate study or research to be undertaken by the prospective pharmacist intern and the post-graduate study or research has been approved by council; and
  - (2) acceptable documentary evidence that the prospective pharmacist intern is registered at such institution for the post-graduate study or research referred to in subregulation 11(1), which post-graduate study or research will lead to the awarding by such institution of at least a master's degree.
12. If a pharmacist intern, undergoing an internship at an institution registered as a provider of a qualification in pharmacy, discontinues his or her studies or research for any reason or ceases to be registered at that provider, he or she shall receive recognition only for the period(s) of practical training duly completed at a community or institutional pharmacy referred to in regulation 10.
13. The internship of a pharmacist intern at an institution registered as a provider of a qualification in pharmacy, shall be regarded to be completed upon successful completion of the required period of practical training referred to in regulation 10 and the submission of acceptable documentary evidence to the registrar that the pharmacist intern has satisfied the requirements of the institution for the awarding of at least a master's degree.

#### **Cession of contract**

14. A contract may be ceded in the event of –
- (1) the death of a tutor, the sequestration of his or her estate, his or her conviction of a serious offence, his or her suspension or the removal of his or her name from the register of pharmacists;
  - (2) the discontinuation of practice of the tutor or the resignation of the tutor from the pharmacy or provider approved for the internship of the pharmacist intern;
  - (3) the closure of the pharmacy or provider approved for the internship of the pharmacist intern;
  - (4) mutual consent between the tutor and the pharmacist intern for a reason which is acceptable to the registrar; or
  - (5) for any other reason that the council may deem fit,

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

#### **Approval of the contract of cession**

15. A pharmacist intern intending to cede a contract to another tutor must at least 7 days before such cession occurs -

- (1) submit to the registrar:
  - (a) a duly completed application on a form as approved and provided by council;
  - (b) a duly completed and signed contract of cession for the conducting of an internship approved and provided by council;
  - (c) acceptable documentary evidence -
    - (i) of the approval by council of the pharmacy or provider where the internship of the pharmacist intern will occur after cession of the contract;
    - (ii) of the approval by 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 for a course of study which will lead to the awarding of at least a master's degree; and
- (2) pay the cession fee as determined by council.

#### **Delegation of training by an approved tutor**

16. (1) A pharmacist shall not act as a tutor to more than one pharmacist intern;
- (2) Notwithstanding sub-regulation (1) –
  - (a) a tutor practising in a pharmacy in which other pharmacists practise on a full-time basis may act as tutor to more than one pharmacist intern, in which event he or she must delegate the actual practical training of all such additional pharmacist interns to such other pharmacists: provided that -
    - (i) there must not be less than one pharmacist for each additional pharmacist intern;
    - (ii) the responsibility for the effective practical training of all such pharmacist interns will remain with the tutor;
    - (iii) the tutor informs council in writing of such delegation or of any changes to such delegation; and
    - (iv) the internship is conducted in accordance with the provisions of these regulations; and
  - (b) a tutor may act as tutor to a second pharmacist intern when a pharmacist intern already under training with such tutor has completed his or her ninth month of internship; or
  - (c) a tutor in an institution approved by council as a provider of a qualification in pharmacy may, with the prior approval of the council, act as a tutor to more than one pharmacist intern.

17. The approved tutor in terms of sub-regulation 6(3) must –
- (1) submit to the registrar:
    - (a) assessment forms as approved and provided by 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 stating that the training has been completed satisfactorily in accordance with council's requirements for an internship and that the pharmacist intern is a fit and proper person to be registered as a pharmacist;
  - (2) if applicable, submit to the registrar an affidavit at the end of the period of internship referred to in regulation 10 to confirm that the prescribed period of 400 hours has been completed satisfactorily in accordance with council's requirements for an internship at an institution registered as a provider of a qualification in pharmacy or in a manufacturing pharmacy.
18. The successful undertaking of a pre-registration examination(s) or evaluation(s) conducted by council may be imposed by council as a pre-requisite for registration as a pharmacist in terms of the Act: provided that if a person requiring registration should fail such examination(s) or evaluation(s) the council may require –
- (1) such person to be re-evaluated or re-examined at a time and date as determined by council; or
  - (2) such person's period of practical training to be extended by an additional period or periods as the council may determine.

#### **Qualification in pharmacy entitling pharmacists to registration**

19. A qualification in pharmacy listed in the Regulations Relating to Qualifications obtained in the Republic entitling Pharmacists to Registration shall entitle the holder thereof to registration in terms of the Act as a pharmacist: provided that:
- (1) he or she has complied with the requirements for practical training in terms of these regulations; and
  - (2) he or she has complied with all statutory requirements for registration as a pharmacist.

## **CHAPTER II**

#### **Standards of education and training of pharmacists' assistants**

20. The unit standards for a certificate of qualification are set out in Annexure B.
21. A provider may provide learning programmes for purposes of conferring a certificate of qualification in accordance with a curriculum that must ensure the required outcomes of the unit standards set out in Annexure B.
22. A provider that holds a certificate of approval is entitled to provide education and training for purposes of conferring a certificate of qualification.

**Entry assumptions for a pharmacist's assistant in the categories pharmacist's assistant (learner basic) and pharmacist's assistant (learner post-basic)**

23. The minimum entry requirements for admission to a learning program to obtain a certificate of qualification shall be the entry assumptions as determined by council from time to time: provided that a candidate may be admitted to a learning program to obtain a certificate of qualification by the recognition of prior learning obtained by such person and the provision of documentary evidence of competency and skills acquired to the satisfaction of the provider.
24. The council must, 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.
25. The learning programme for a certificate of qualification may be determined by a provider: provided that a minimum period of twelve months of in-service training must occur.

**General requirements and conditions for in-service training**

26. The in-service training referred to in regulation 25 must be undertaken -
  - (1) at a community pharmacy, institutional pharmacy, manufacturing pharmacy or wholesale pharmacy approved by council for purposes of such in-service training; and
  - (2) under the supervision of a tutor approved by council.
27. No person must commence in-service training unless-
  - (1) he or she is duly registered as a pharmacist's assistant in the category pharmacist's assistant (learner basic) or pharmacist's assistant (learner post basic), as the case may be, in terms of the Regulations Relating to the Registration of Persons and the Maintenance of Registers;
  - (2) the pharmacy at which the in-service training will take place has been approved by council for such in-service training; and
  - (3) the tutor has been approved by council.

**Delegation of in-service training**

28. A tutor may delegate the actual in-service training of a pharmacist's assistant to another pharmacist practising in a full-time capacity in the same pharmacy: provided that the tutor will be responsible to ensure that the in-service training is completed in accordance with the provisions of these regulations and that council is informed in writing of such delegation.
29. No pharmacist must employ any person as a pharmacist's assistant (learner basic) or pharmacist's assistant (learner post-basic) or in any other capacity which may imply or lead such person to believe that he or she is undertaking a period of in-service training, unless the provisions of regulations 26 and 27 have been complied with and such pharmacy and pharmacist have been notified by the registrar in writing thereof.



### **Supervision of pharmacy support personnel undergoing in-service training**

30. No pharmacist may undertake to act as a tutor to more than three pharmacist's assistants (learner basic) or more than two pharmacist's assistants (learner post-basic) undergoing in-service training.
31. Notwithstanding regulation 30, the council may approve a written application for an increase in the ratio as stipulated in regulation 30: provided that-
- (1) each application is treated on its own merit;
  - (2) the motivation for such application is to the satisfaction of the council;
  - (3) any increase in the ratio approved by council shall apply in that specific circumstance or situation only and be subject to such conditions as council may determine.

### **Evaluation prior to registration of a person in the category pharmacist's assistant (basic) or pharmacist's assistant (post basic)**

32. Any provider approved to offer a certificate of qualification must submit to the registrar upon the successful assessment of a pharmacist's assistant in the category pharmacist's assistant (learner basic) or pharmacist's assistant (learner post-basic), as the case may be, notification of each unit standard which has been assessed successfully.
33. The successful undertaking of an assessment or evaluation conducted by council may be imposed by council as a pre-requisite for registration in the category pharmacist's assistant (basic) or pharmacist's assistant (post-basic).

### **Certificate of qualification entitling pharmacists' assistants to registration**

34. A certificate of qualification entitles the holder thereof to registration as a pharmacist's assistant in the category pharmacist's assistant (basic) or pharmacist's assistant (post-basic), as the case may be, in terms of the Act: provided that he or she has complied with the requirements for in-service training in terms of these regulations.

## **CHAPTER III**

### **Approval of tutors and premises for purposes of education and training**

#### **Approval of a tutor**

35. A pharmacist who wants to apply to be appointed as a tutor must:
- (1) submit to the registrar a duly completed application on a form as approved and provided by council for-
    - (a) the approval of the tutor under whom an internship or in-service training, as the case may be, is contemplated;
    - (b) the approval of the pharmacy or provider at which an internship or in-service training is contemplated; and
  - (2) pay the evaluation fee as determined by council, if applicable.

### **Approval of premises**

36. Upon receipt of the application and the fee referred to in regulation 35, the registrar must within 14 days appoint an inspector to inspect the pharmacy or the provider: provided that an inspector appointed must –
- (1) be a pharmacist conversant with the practice of pharmacy;
  - (2) have been registered as a pharmacist for a period of not less than three years;
  - (3) not have a direct or indirect beneficial interest in the pharmacy or provider to be inspected; and
  - (4) in the case of an inspector appointed to inspect a provider be in possession of at least a master's degree in a pharmaceutical field of study.
37. Such an inspector, must within 14 days of the receipt of the registrar's request, satisfy him- or herself by a physical inspection of such pharmacy or provider that it conforms to the minimum criteria determined by council for the training of pharmacist interns and pharmacists' assistants and must, within seven days submit to the registrar a written report on a form as approved and provided by council.
38. The responsible pharmacist or the pharmacist who applied for approval to act as tutor must co-operate fully with the inspector appointed by council and must assist him or her as may be necessary for him or her to carry out his or her inspection.
39. A pharmacy or provider may be inspected whenever an application is made for an internship or in-service training to be undertaken at such pharmacy or provider.
40. An inspector appointed by council must be remunerated by council in accordance with a fee as determined by council from time to time and reimbursed for his or her expenses.

## **CHAPTER IV**

### **Approval of providers of pharmacy education and training**

#### **Approval of providers**

41. The council may approve providers of education and training for purposes of –
- (1) conferring a qualification in pharmacy or a certificate of qualification;
  - (2) registration of specialities, additional qualifications or supplementary training; or
  - (3) continuing professional development.

#### **Minimum criteria and conditions for approval**

42. The approval of providers in terms of regulation 41 must be subject to –
- (1) minimum criteria for the approval of providers as determined and published by council; and

- (2) such conditions as the council may determine and for such period or periods of time as the council may determine,

Provided that:

- (a) providers of education and training for purposes of conferring a certificate of qualification or for purposes of continuing professional development may be approved for a maximum period of three years; and
- (b) providers of education and training for purposes of conferring a qualification in pharmacy may be approved for a maximum period of six years.

### **Inspection of providers**

43. The council shall have the right to inspect providers to measure compliance with the requirements determined by council for the provision of pharmacy education and training at least every three years or at intervals as determined by council from time to time.
44. A person(s) appointed by council to perform an inspection referred to in regulation 43 must –
- (1) be conversant with pharmacy education and training;
- (2) not have a direct or indirect beneficial interest in the provider to be inspected; and
- (3) where applicable, provide documentary evidence to the satisfaction of the registrar of expert knowledge in an area being evaluated.
45. A person appointed to inspect a provider must submit a written report on a form as approved and provided by council to the registrar on the findings of the inspection within 30 days of the date of such investigation.
46. A person appointed to inspect a provider shall be remunerated by council in accordance with a fee as determined by council from time to time and reimbursed for his or her expenses.
47. The council may amend or withdraw the approval of a provider should it be determined, following an inspection by council, that the requirements determined by council for the provision of pharmacy education and training have not been adhered to, after:
- (1) giving due notice to the provider; and
- (2) affording such provider an opportunity to furnish reasons why the approval of such provider should not be withdrawn.
48. The institutions as set out in Annexure C, shall be deemed to be approved and registered to provide education and training for a qualification in pharmacy at the commencement of these regulations.

### **Approval of courses for purposes of continuing professional development**

49. The council may approve courses for purposes of continuing professional development, subject to such conditions as the council may determine.

**Repeal**

The regulations published under Government Notice No. R. 378 of 3 March 1978; Government Notice No. R. 642 of 2 April 1982; Government Notice No. R. 2794 of 23 December 1983; Government Notice No. R. 1979 of 6 September 1985; Government Notice No. R. 2047 of 13 September 1985 are hereby repealed.

**ANNEXURE A****Unit standards for pharmacists**

The following unit standards are prescribed for pharmacists in terms of section 33 of the Act.

- (i) Unit EL 1 – Organise the manufacturing, compounding and packaging of pharmaceutical products;
- (ii) Unit EL 2 – Organise the procurement, storage and distribution of pharmaceutical products;
- (iii) Unit EL 3 – Dispense and ensure the optimum use of medicine prescribed to the patient;
- (iv) Unit EL 4 – Provide pharmacist initiated care to the patient and ensure the optimum use of medicine;
- (v) Unit EL 5 – Provide education and information on health care and medicine;
- (vi) Unit EL 6 – Promote community health and provide related information and advice;
- (vii) Unit EL 7 – Participate in research to ensure the optimal use of medicine.

**ANNEXURE B****Unit standards for pharmacist's assistants in the category pharmacist's assistant (basic) and pharmacist's assistant (post-basic)**

The following unit standards are prescribed for pharmacist's assistants in terms of section 33 of the Act.

**(a) Pharmacist's assistant (basic):**

- (i) Unit BL 1 – Provision of health advice, information and pharmacy products directly to the consumer;
- (ii) Unit BL 2 – Provision of pharmacy products in hospital pharmacy;
- (iii) Unit BL 3 – Pharmacy marketing;
- (iv) Unit BL 4 – Stock control;
- (v) Unit BL 5 – Manufacturing/compounding of pharmaceutical products;
- (vi) Unit BL 6 - Packaging and/or pre-packing of pharmaceuticals;
- (vii) Unit BL 7 – Control and distribution of finished pharmacy products;
- (viii) Unit BL 8 – Collect information for research purposes.

**(b) Pharmacist's assistant (post-basic):**

- (i) Unit PBL 1 – Issuing of pharmacy products;
- (ii) Unit PBL 2 – Stock control;
- (iii) Unit PBL 3 – Manufacturing/compounding of pharmaceutical products;
- (iv) Unit PBL 4 - Packaging and/or pre-packing of pharmaceuticals;
- (v) Unit PBL 5 – Control and distribution of finished pharmacy products;
- (vi) Unit PBL 6 – Collect information for research purposes.

**ANNEXURE C**

The following institutions in the Republic shall be regarded to be providers approved and registered to provide education and training for purposes of conferring a qualification in pharmacy:

- (a) University of Durban-Westville;
- (b) University of the North;
- (c) Potchefstroom University for Christian Higher Education;
- (d) Rhodes University;
- (e) University of the Western Cape;
- (f) University of Port Elizabeth;
- (g) University of the Witwatersrand; and
- (h) Medical University of Southern Africa in collaboration with the Technikon Pretoria.

**ME Tshabalala-Msimang**  
**Minister of Health**

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