

DEPARTMENT OF HEALTH

NO. 5458

25 October 2024

PHARMACY ACT, 1974 (ACT NO. 53 OF 1974)

REGULATIONS RELATING TO THE REGISTRATION OF SPECIALIST PHARMACISTS

The Minister of Health hereby, in consultation with the South African Pharmacy Council, in terms of section 49 (1) (mB) of Pharmacy Act (Act No. 53 of 1974), makes regulations in the Schedule.

Interested persons are invited to submit substantiated comments or representations in writing on the proposed amendments to the Regulations, to the Director-General: Health, Private Bag X828, Pretoria, 0001 (for the attention of the Director: Public Entities Governance, Ms M Mushwana, mihloti.mushwana@health.gov.za and godfrey.tsebe@health.gov.za), within three months of the date of publication of this Notice.



DR PA MOTSOALEDI, MP
MINISTER OF HEALTH

DATE: 7/10/2024

SCHEDULE

GENERAL EXPLANATORY NOTE:

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

[] Words in brackets indicate deletion in existing enactments

1. DEFINITIONS

In these Regulations, unless the context otherwise indicates –

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

“**Provider**” means any person or institution approved by and registered with Council to provide education and training for the purposes of conferring a Bachelor of Pharmacy qualification or a certificate of qualification or for purposes of continuing professional development.

“**specialist pharmacist**” means a pharmacist who is registered as such in terms of the Act;

“**specialist pharmacist resident**” means a pharmacist who is registered as such in terms of these regulations

“**specialist pharmacist student**” means a pharmacist who is registered as such in terms of these regulations

“**speciality**” means a specialist qualification in one of the fields of pharmacy approved and published in rules made by council;

“**tutor**” means a specialist pharmacist registered as a tutor by Council to supervise specialist pharmacist resident as determined by Council from time to time;

2. CATEGORIES OF SPECIALIST PHARMACISTS

For purposes of registration in terms of the Act, read together with section 2 of the *Regulations relating to the registration of persons, recording of pharmacies and the maintenance of registers*, there shall be the following categories of specialist pharmacists:

- a) Specialist Pharmacist Student
- b) Specialist Pharmacist Resident
- c) Pharmacokineticist;
- d) Radiopharmacist;
- e) Clinical pharmacist;
- f) Public Health pharmacist;
- g) Industrial pharmacist; or
- h) Any other sub-category of specialist pharmacist as may be determined and published by Council from time to time.

CHAPTER II – SCOPE OF PRACTICE

3 Scope of Practice of a Pharmacokineticist

The following services or acts shall for purposes of the Act be regarded to be services or acts pertaining to the scope of practice of a pharmacokineticist:

- a) the acts specially pertaining to the profession of a pharmacist as prescribed in regulations 3 and 4 of the *Regulations relating to the practice of pharmacy* (GNR 1158 of 20 November 2000, as amended);
- b) provide pharmacokinetic consultations to a variety of specialities;
- c) take a leading role in identifying drug groups that require pharmacokinetic monitoring due to their increased risk of toxicity, narrow therapeutic index and challenges with adherence or efficacy;

- d) take a leading role in identifying patients that need a pharmacokinetic consultation due to a high risk of non-adherence, experiencing adverse drug reactions or drug toxicity due to their specific condition or diagnosis;
- e) take a leading role in requesting and interpreting drug concentrations in patients at risk;
- f) act as a leading pharmaceutical partner within a multi professional health care team;
- g) appraise information, make informed decisions with the drug concentrations available and be able to justify the decisions;
- h) advise on dosing adjustment and patient monitoring based on drug concentrations;
- i) take a leading role in pharmacokinetic input for clinical protocol and guideline development;
- j) provide education and training related to pharmacokinetics; or
- k) perform research and publish in pharmacokinetics.

4 SCOPE OF PRACTICE OF A RADIOPHARMACIST

The following services or acts shall for purposes of the Act be regarded to be services or acts pertaining to the scope of practice of a radiopharmacist:

- a) the acts specially pertaining to the profession of a pharmacist as prescribed in regulations 3 and 4 of the *Regulations relating to the practice of pharmacy* (GNR 1158 of 20 November 2000, as amended);
- b) take a leading pharmaceutical role in protocol and guideline development in nuclear medicine;
- c) act as a leading pharmaceutical partner within a multi professional health care team in nuclear medicine;
- d) develop, implement, evaluate and provide strategic leadership for radiopharmacy services;

- e) appraise information, make informed decisions regarding supply and use of radiopharmaceuticals with the evidence available and be able to justify/defend the decisions;
- f) develop policies and procedures specifically for the specialty area;
- g) provide education and training related to radiopharmacy; or
- h) perform research, teach and publish in radiopharmacy.

5 SCOPE OF PRACTICE OF A CLINICAL PHARMACIST

The following services or acts shall for purposes of the Act be regarded to be services or acts pertaining to the scope of practice of a clinical pharmacist:

- a) the acts specially pertaining to the profession of a pharmacist as prescribed in regulations 3 and 4 of the *Regulations relating to the practice of pharmacy* (GNR 1158 of 20 November 2000, as amended);
- b) provide advanced clinical services to a variety of specialities;
- c) take a pharmaceutical leadership role in clinical protocol and guideline development;
- d) lead clinical audits of medicine use;
- e) act as a leading pharmaceutical partner within a multi professional health care team;
- f) develop, implement, evaluate and provide strategic leadership for clinical pharmacy services;
- g) appraise clinical pharmacy information, make informed decisions with the evidence available and be able to justify/defend the decisions;
- h) develop policies and procedures specifically for clinical pharmacy;
- i) provide education and training related to clinical pharmacy; or
- j) perform research, teach and publish in clinical pharmacy.

6 SCOPE OF PRACTICE OF A PUBLIC HEALTH PHARMACIST

The following services or acts shall for purposes of the Act be regarded to be services or acts pertaining to the scope of practice of a public health and management pharmacist:

- a) the acts specially pertaining to the profession of a pharmacist as prescribed in regulations 3 and 4 of the *Regulations relating to the practice of pharmacy* (GNR 1158 of 20 November 2000, as amended);
- b) lead and manage surveillance and assessment of the pharmaceutical services;
- c) lead projects to protect and promote health and well-being, including communicable disease control and environmental health;
- d) manage, analyse and interpret information and statistics;
- e) develop and analyse pharmaceutical public health policy for the better use of existing and new medicines technologies and rational use of all medicines, to improve health services;
- f) provide strategic leadership for medicine supply management;
- g) provide education and training related to public health and management;
- h) manage knowledge and transfer of research evidence into practice;
- i) develop policies and procedures for public health and management;
- j) manage, analyse, interpret and advice on pharmaco-economic information for rational use of medicines; or
- k) perform research, teach and publish in the field of public health management.

7 SCOPE OF PRACTICE OF AN INDUSTRIAL PHARMACIST

The following services or acts shall for purposes of the Act be regarded to be services or acts pertaining to the scope of practice of an industrial pharmacist:

- a) the acts specially pertaining to the profession of a pharmacist as prescribed in regulations 3 and 4 of the *Regulations relating to the practice of pharmacy* (GNR 1158 of 20 November 2000, as amended);

- b) control both intrinsic and extrinsic quality of a product taking into account patient health and safety;
- c) manage knowledge and transfer of research evidence into practice;
- d) provide strategic leadership for manufacture of medicine, warehousing and supply chain management;
- e) design, develop and interpret quality systems for implementation of good manufacturing practices;
- f) provide education and training relating to industrial pharmacy;
- g) provide pharmaceutical leadership and guidance in directing the business;
- h) take a leading role in pharmaceutical research and development;
- i) take a leading role in the development of and contribution to regulatory guidelines and relevant legislation; and
- j) appraise pharmaceutical information, make informed decisions with the evidence available and be able to justify/defend the decisions.

CHAPTER III – QUALIFICATIONS FOR REGISTRATION

8 Qualification for purposes of registration as a specialist pharmacist

- (1) For purposes of registration as a pharmacokineticist the qualification shall be-
 - (a) at least a master's degree in the speciality of pharmacokinetics at a university in the Republic; or
 - (b) has obtained an equivalent post-graduate qualification in the speciality of pharmacokinetics and that the subject contents and standard of such qualification and the institution where the qualification was obtained are acceptable to the Council;
- (2) For purposes of registration as a radiopharmacist, the qualification shall be-
 - (a) A professional master's degree in radiopharmacy as determined by Council and published from time to time, or

- (b) A [postgraduate] qualification in radiopharmacy deemed to be the equivalent or higher than a professional master's degree in radiopharmacy as assessed by Council.
- (3) For purposes of registration as a Clinical pharmacist, the qualification shall be –
 - (a) A professional master's degree in clinical pharmacy as determined by Council and published from time to time; or
 - (b) A postgraduate qualification in clinical pharmacy deemed to be the equivalent or higher than a professional master's degree in clinical pharmacy as assessed by Council.
- (4) For purposes of registration as a public health pharmacist, the qualification shall be –
 - (a) A professional master's degree in public health pharmacy and pharmaceutical management as determined by Council and published from time to time; or
 - (b) A postgraduate qualification in public health pharmacy and pharmaceutical management deemed to be the equivalent or higher than a professional master's degree in public health pharmacy as assessed by Council.
- (5) For purposes of registration as an industrial pharmacist, the qualification shall be –
 - (a) A professional master's degree in industrial pharmacy as determined by Council and published from time to time; or
 - (b) A postgraduate qualification in industrial pharmacy deemed to be the equivalent or higher than a professional master's degree in industrial pharmacy.

9 PRACTICAL EXPERIENCE REQUIRED FOR PURPOSES OF REGISTRATION AS A SPECIALIST PHARMACIST RESIDENT

- (1) Any person who holds a professional master's qualification in a category of specialist pharmacist, as provided in regulation 2, and who applies for registration in a particular category of specialist pharmacist shall complete no less than twenty-four months (24) practical experience at an appropriate pharmacy premises specifically approved by Council for purposes of such practical experience relevant to the category of specialist pharmacy;
- (2) Any person who is required to complete the practical experience as required in sub-section (1), shall be registered as a specialist pharmacist resident;
- (3) The practical experience as prescribed in sub-section (1) shall be completed under the supervision of a tutor duly registered as a specialist pharmacist in the same category of specialist pharmacy as the intended applicant.
- (4) The practical experience as prescribed in sub-section (1) shall be recorded by way of –
 - (a) A duly completed and signed contract approved and provided by Council for the undertaking of such practical experience;
 - (b) Submission of a portfolio of evidence verified by the tutor, as determined by Council from time to time.

CHAPTER IV REGISTRATION REQUIREMENTS

10 Requirements and conditions for registration as a specialist pharmacist student

1. A pharmacist who applies for registration as a specialist pharmacist student must be registered as a pharmacist and –
 - (a) submit to the registrar:
 - (i) a duly completed application on a form approved and provided by council;
 - (ii) a certified copy of his or her identity document or passport; and

- (iii) acceptable documentary evidence from the provider concerned that he or she has been admitted to the professional master's degree in the relevant category of specialist pharmacist; and
 - (b) pay the registration fee as determined by the council.
- 2. Any person who complies with the requirements in regulation 10 must be registered as a specialist pharmacy student and issued with a registration certificate by the registrar.

11 REMOVAL FROM THE REGISTER

- (1) Except as provided for in terms of sections 23, 24 and 39 of the Act, the registrar may remove from the register of specialist pharmacy students the name of a student—
 - (a) who has complied with the requirements for a qualification in the category of specialist pharmacist;
 - (b) who no longer complies with the requirements and conditions for registration as a specialist pharmacist student; or
 - (c) who is deceased.
- (2) A person in respect of whose entry a removal as contemplated in sub-regulations (1) (a) and (b) has been made, must be notified thereof and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice has so been given.

12 RESTORATION TO THE REGISTER

- 1. A specialist pharmacy student whose name was removed from the register in terms of regulation 12 may, if applicable, have his or her name restored to the register by—
 - (a) submitting to the registrar:
 - (i) a duly completed application for restoration of his or her name to the relevant register on a form as approved and provided by the council; and

- (ii) acceptable documentary evidence from the provider concerned to the effect that he or she has been re-admitted for continued studies for a qualification for registration of a specialist pharmacist in pharmacy; and
 - (b) paying the prescribed restoration fee.
2. if the registrar is satisfied that he or she is a fit and proper person to be restored, registrar may restore such person to the relevant register. If the registrar is not satisfied that he or she is a fit and proper person to be restored to the relevant register, the registrar must submit the application concerned to the council for a decision.

13 REQUIREMENTS AND CONDITIONS FOR REGISTRATION AS A SPECIALIST

PHARMACIST RESIDENT

- 1.1. Any person who holds a qualification as prescribed in terms of regulation 8 may register as a specialist pharmacist resident with the council: provided that no person shall be registered as a specialist pharmacist resident, unless he or she complies with regulation 15.
- 1.2 Any person who applies for registration as a pharmacist resident must—
- (1) submit to the registrar:
 - (a) a duly completed application on a form as approved and provided by the council;
 - (b) a certified copy of his or her identity document or passport;
 - (c) a duly completed and signed contract approved and provided by the council for the undertaking of a specialist pharmacy residency; and
 - (d) acceptable documentary evidence—
 - (i) of the approval by the council of the pharmacy where the residency will be undertaken;
 - (ii) of the approval by council of the tutor under whom such residency will take place;
 - (iii) that he or she holds a qualification as prescribed in regulation 3; and

- 1.3. pay the registration fee as determined by council.
- 1.4. Every person who complies with the requirements in regulation 15 must be registered as a specialist pharmacist resident and issued with a registration certificate by the registrar.

14. REMOVAL FROM THE REGISTER

- (1) Except as provided for in terms of sections 23, 24 and 39 of the Act, the registrar may remove from the register of specialist pharmacist residence, the name of a specialist pharmacist resident—
 - (a) who has completed his or her residency to the satisfaction of the council;
 - (b) who has not completed his or her residency to the satisfaction of the council;
 - (c) who has discontinued his or her residency with the consent of the council;
 - (d) who no longer complies with the requirements and conditions for registration as a specialist pharmacist resident; or
 - (e) who is deceased.
- (2) A person in respect of whose entry a removal as contemplated in sub-regulations (1) (a) to (d) has been made, must be notified thereof and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice has so been given.

15. RESTORATION TO THE REGISTER

1. A specialist pharmacist resident whose name was removed from the register in terms of regulation 17 may if applicable, have his or her name restored to the register by—
 - (a) submitting to the registrar—
 - (i) a duly completed application for restoration of his or her name to the register on a form as approved and provided by the council;

- (ii) acceptable documentary evidence that he or she complies with the conditions under which he or she may be registered as a specialist pharmacist resident; and
 - (iii) acceptable documentary evidence from a tutor to the effect that he or she has resumed his or her residency; and
 - (b) paying the prescribed restoration fee.
2. if the registrar is satisfied that he or she is a fit and proper person to be restored, registrar may restore such person to the relevant register. If the registrar is not satisfied that he or she is a fit and proper person to be restored to the relevant register, the registrar must submit the application concerned to the council for a decision.

16. REQUIREMENTS AND CONDITIONS FOR REGISTRATION AS A SPECIALIST PHARMACIST

1. A pharmacist who applies for registration as a specialist pharmacist must—
- (a) submit to the registrar:
 - (i) a duly completed application on a form approved and provided by council;
 - (ii) a certified copy of his or her identity document or passport;
 - (iii) acceptable documentary evidence that he or she has obtained a qualification as prescribed in terms of regulation 2 or has complied with the requirements for registration in terms of the Act.
 - 1.2 submit acceptable documentary evidence to the registrar that he or she has obtained practical experience in the field of speciality as prescribed in regulation 9 for which registration as a specialist pharmacist is being applied for;
 - 1.3 give notice to the registrar of the speciality in which he or she intends to practise;
 - 1.4 successfully complete the pre-registration examination as determined by council from time to time; and
 - 1.5 pay the registration fee as determined by the council.

1.6 A pharmacist who complies with the requirements of regulation 19 must be registered as a specialist pharmacist and be issued with a registration certificate by the registrar, indicating his or her speciality.

17. REMOVAL FROM THE REGISTER

(1) Except as provided for in terms of sections 23, 24 and 39 of the Act, the registrar may remove from the register of specialist pharmacists the name of a specialist pharmacist who—

- (a) no longer complies with the requirements and conditions for registration as a specialist pharmacist; or
- (b) who is deceased.

(2) A person in respect of whose entry a removal as contemplated in sub-regulation (1) (a) has been made, must be notified thereof and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice has so been given.

18. RESTORATION TO THE REGISTER

1. A specialist pharmacist whose name was removed from the register of specialist pharmacists in terms of regulation 21 may, if applicable, have his or her name restored to the register by—

- (a) submitting to the registrar:
 - (i) a duly completed application for restoration of his or her name to the register of specialist pharmacists on a form as approved and provided by the council; and
 - (ii) acceptable documentary evidence that he or she complies with the conditions under which he or she may be registered as a specialist pharmacist; and
- (b) paying the prescribed restoration fee.

2. if the registrar is satisfied that he or she is a fit and proper person to be restored, registrar may restore such person to the relevant register. If the registrar is not satisfied that he or she is a fit and proper person to be restored to the relevant register, the registrar must submit the application concerned to council for a decision.

19. PRACTISING MORE THAN ONE SPECIALITY

A pharmacist may register more than one speciality: provided that he or she may only practise in one speciality.

20. REPEAL

Insofar as, as it relates to Regulations 23-27, Regulations relating to the registration of persons and the maintenance of registers, GNR 1160, published on 20 November 2000, as amended, are hereby repealed.

21. SHORT TITLE

These Regulations are called Regulations relating to registration of specialist pharmacists, 2024.