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SOUTH AFRICAN PHARMACY COUNCIL

COMPETENCY STANDARDS FOR A SPECIALIST PHARMACIST WHO PROVIDES CLINICAL PHARMACY SERVICES IN SOUTH AFRICA

The South African Pharmacy Council hereby publishes for **implementation,** the **Competency standards for a specialist pharmacist who provides clinical pharmacy services in South Africa** in terms of Sections 33(o) of the Pharmacy Act, 53 of 1974.

SCHEDULE

(a) Competency standards for a specialist pharmacist who provides clinical pharmacy services in South Africa

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COMPETENCY STANDARDS FOR A SPECIALIST PHARMACIST WHO PROVIDES CLINICAL PHARMACY SERVICES IN SOUTH AFRICA

TABLE OF CONTENTS

ACRONYMS

The following acronyms have been included; however, the list is not exhaustive –

CAPA Corrective Action and Preventative Action

GCP Good Clinical Practice

GXP Good Practice Guidelines and Regulations e.g., Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good Wholesaling Practice (GWP) and Good Radiopharmacy Practice (GRPP) and other pharmaceutical practices

HTA Health Technology Assessment

IPC Infection, Prevention and Control

IVDs *In-vitro* Diagnostics

PTC Pharmacy and Therapeutics Committee

SOP Standard Operating Procedure

TDM Therapeutic Drug Monitoring

UHC Universal Health Coverage

DEFINITIONS

"Change control report" is a document that records the process of coordinated activities through which a desired change is implemented in an existing function, process, or product in the pharmaceutical industry.

"Clinical Pharmacist" is a pharmacist registered with Council to offer clinical pharmacy services.

"Specialist pharmacist student" means a pharmacist who is registered as such in terms of the Pharmacy Act 53 of 1974 (the Act).

"Specialist pharmacist resident" means a pharmacist who is registered as such in terms of the Pharmacy Act 53 of 1974 (the Act).

"Specialist pharmacist" means a pharmacist who is registered as such in terms of the Pharmacy Act 53 or 19754 (the Act).

"Speciality" means a specialist qualification in one of the fields of pharmacy approved and published in rules made by Council.

For purposes of this document, the terms drug and medicine are used interchangeably.

1. INTRODUCTION

Clinical pharmacy is aimed at the development and promotion of rational and appropriate use of medicines and pharmaceutical care, in the interest of the patient and the community. Patients with advanced disease have multiple symptoms, and treatment becomes complicated. This makes it difficult for patients and/or their carers to manage their medicines which leads to symptoms being inadequately controlled and a low level of therapeutic compliance. Pharmacists have the responsibility to identify, resolve, and prevent each patient's therapeutic problems. These responsibilities are met by using the caring paradigm in a patient-centred manner.

Pharmaceutical care mandates that pharmacists should not only dispense medicines but also assume the responsibility of improving the quality of life of patients and improving therapy outcomes.

Pharmaceutical care within a clinical pharmacy context as practiced within a multidisciplinary team involves the implementation of the following steps:

(a) Assessment of patient health and formulation of treatment plans.

(b) Monitoring of patient's response to therapy to ensure optimum therapeutic outcomes.

(c) Performing medicine reviews to detect and resolve medicine-related problems.

(d) Documentation of the care provided and provision of advice to patients in a way that patients understand.

2. BACKGROUND

In 2018, the South African Pharmacy Council published the reviewed competency standards for pharmacists. Competency standards have been developed and used as the basis for pharmacy education and practice since 2006. The competency standards for a pharmacist providing clinical pharmacy services are based on the competency standards for pharmacists. These competency standards for a clinical pharmacist are developed to encompass the scope of practice of a clinical pharmacist as a specialist pharmacist.

2.1 THE SCOPE OF PRACTICE FOR A CLINICAL PHARMACIST

In addition to the acts and services which form part of the scope of practice of the pharmacist as prescribed in terms of Regulations 3 and 4 of the Regulations relating to the practice of Pharmacy; a pharmacist who has completed a master's degree in clinical pharmacy must be allowed to provide the following services or acts pertaining to the scope of practice of a clinical pharmacist:

(a) Provide advanced clinical services to medical specialities;

(b) Take a pharmaceutical leadership role in clinical protocol and guideline development;

(c) Lead clinical audits of medicine use;

(d) Act as a leading pharmaceutical partner within a multi-professional healthcare team;

(e) Develop, implement, evaluate and provide strategic leadership for clinical pharmacy services;

(f) Appraise clinical pharmacy information, make informed decisions with the evidence available and be able to justify/defend the decisions;

(g) Develop policies and procedures specifically for clinical pharmacy;

(h) Provide education and training related to clinical pharmacy; or

(i) Perform research, teach, and publish in clinical pharmacy.

The scope of practice of a specialist pharmacist student is the same as the scope of practice of a specialist pharmacist practiced under the auspices of a provider.

The scope of practice of a specialist pharmacist resident is the same as the scope of practice of a specialist pharmacist practiced under the supervision of a specialist pharmacist.

3. RATIONALE FOR DEVELOPMENT OF COMPETENCY STANDARDS FOR A CLINICAL PHARMACIST

The rationale is to train advanced-level clinical pharmacists who can register with Council as specialists and contribute to capacity building in the field of clinical pharmacy as well as create specialists in the field of pharmacy, for the advancement of health care in South Africa in line with Universal Health Coverage (UHC).

Additionally, according to Van Mil (2004) "*if we want to try to prove that the structured provision of pharmaceutical care has an effect on outcomes, we must first of all make sure that the care provided matches the needs of the patients in that specific health system".*

Historically, the role of the pharmacist, regardless of the health setting, was to ensure prompt and efficient medicine supply, adequate stock, accurate dispensing, compounding, storage and transport, and to ensure that medicines are easily accessible to patients who need them. The pharmacist is also responsible for the selection of medicines, dosage forms, and monitoring of patient compliance.

Clinical pharmacists are required to understand the provision of pharmaceutical care that matches the patient's specific health needs. These pharmacists focus on disease prevention and treatment, including evidence-based medicine use and related care that improve both short and long-term outcomes for patients.

The competency standards have been developed to encompass the changes and developments including new technologies, work processes, changes in legislation and international trends. This is to primarily ensure the production and promotion of prudent and proper medicine usage and pharmaceutical care, in both the patient's and the public's best interests.

4. REGISTRATION OF CLINICAL PHARMACISTS

Clinical pharmacists are obliged to be registered with Council for the purposes of offering the acts related to their scope of practise as follows:

(a) Specialist pharmacist student.

(b) Specialist pharmacist resident.

(c) Specialist pharmacist.

5. QUALIFICATIONS OF A CLINICAL PHARMACIST

For purposes of registration as a clinical pharmacist, a pharmacist must have obtained -

(a) a professional master's degree in clinical pharmacy as determined by Council and published from time to time, or

(b) a qualification deemed to be equivalent or higher than the professional Master's degree in clinical pharmacy as assessed by Council.

6. STRUCTURE OF THE COMPETENCY STANDARDS AND DOMAINS

A competency framework consisting of six (6) domains suitable for the South African context was developed together with several associated competencies. A domain represents an organised cluster of competencies within a framework and the domains with associated competencies, as summarised in Table 1. The behavioural statements indicating how individuals working within a competency framework should behave in practice have also been drafted.

TABLE 1: SUMMARY OF CLINICAL PHARMACY COMPETENCY STANDARDS

DOMAIN	COMPETENCY STANDARD
1. Public Health	1.1 Promotion of clinical pharmacy services. 1.2 Pharmacoeconomics.
2. Safe and rational use of Medicine and Medical devices	2.1 Patient consulting. 2.2 Patient medicines review and management. 2.3 Medicines, medical devices and IVD safety.
3. Supply of Medicines and Medical devices	3.1 Medicine compounding. 3.2 Supply chain management. 3.3 Medicine dispensing.
4. Quality management in Clinical pharmacy	4.1 Quality assurance. 4.2 Pharmaceutical infrastructure management.
5. Professional and Personal Practice	5.1 Good record keeping. 5.2 Patient-centred care. 5.3 Professional practice. 5.4 Continuing professional development.
6. Education, training, and research	6.1 Provision of education and training. 6.2 Practice embedded education or workplace education. 6.3 Clinical Trials. 6.4 Research.

DOMAIN 1: PUBLIC HEALTH

INTRODUCTION

The domain covers competencies that are required to promote clinical pharmacy services. Participation of pharmacists in the promotion of public health utilising clinical pharmacy entails the following competencies:

1.1 Promotion of clinical pharmacy services.

1.2 Pharmacoeconomics.

DOMAIN 1: PUBLIC HEALTH	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
1.1 Promotion of clinical pharmacy services.	1.1.1 Demonstrating an ability to develop, implement and monitor health systems for the promotion of public health through the safe and effective use of medicine and medical devices. 1.1.2 Develop, monitor, and maintain clinical pharmacy services. 1.1.3 Demonstrate qualities to improve the performance of and manage clinical pharmacy services. 1.1.4 Promote good clinical pharmacy practice.
1.2 Pharmacoeconomics	1.2.1 Monitor and maintain cost-effective utilisation of medicines as part of a healthcare team. 1.2.2 Demonstrate an ability to develop, monitor and maintain health systems to ensure the rational and cost-effective use of medicines in accordance with the burden of disease.

DOMAIN 2: SAFE AND RATIONAL USE OF MEDICINE AND MEDICAL DEVICES

INTRODUCTION

Clinical pharmacists must have the knowledge of procedures and operations relating to safe and rational use of medicine and medical devices to ensure appropriate therapeutic assessments and decisions including medicine therapy. The competencies required in the domain of safe and rational use of medicines are:

2.1 Patient consultation.

2.2 Patient medicines review and comprehensive medicine management.

2.3 Medicines, medical devices and in vitro diagnostics (IVDs) safety.

DOMAIN 2: SAFE AND RATIONAL USE OF MEDICINES AND MEDICAL DEVICES	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
2.1 Patient consultation	2.1.1 Demonstrate the ability to - (a) gather and document patients' medical histories to inform pharmaceutical care decisions. develop, monitor, and review the pharmaceutical care plan; (b) create and update the pharmaceutical care plan based on patients' medical histories and treatment goals; (c) counsel patients to optimise and individualise their treatment outcomes; (d) educate patients on their treatment regimens, ensuring they understand how to use medications effectively and make informed decisions about their care; (e) collaborate with other disciplines to develop a platform for interprofessional pharmaceutical care; and (f) use medical devices and IVDs to evaluate clinical parameters.
2.2 Patient medicines review and comprehensive medicine management	2.2.1 Demonstrate the ability to - (a) develop, implement and monitor pharmaceutical care plans that incorporate the pharmacodynamic, pharmacogenomic and pharmacokinetic properties of medicines; (b) implement health systems that allow for the monitoring of patient treatment plans and assessment of medicine and medical device use; and (c) recommend appropriate diagnostic tests that can improve clinical patient management. 2.2.2 Ensure safe and effective medicine use with optimal therapy outcomes. 2.2.3 Monitor, evaluate and report on therapeutic outcomes.
2.3 Medicines, medical devices and IVD safety	2.3.1 Promote safe handling of medicines, medical devices and IVDs. 2.3.2 Demonstrate and apply safe disposal/destruction of medicines and diagnostic equipment.

DOMAIN 2: SAFE AND RATIONAL USE OF MEDICINES AND MEDICAL DEVICES	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
	2.3.3 Demonstrate the ability to proactively manage or assist with the infection, prevention and control (IPC) programmes in the clinical pharmacy to minimise risks of contamination.

DOMAIN 3: SUPPLY OF MEDICINES, MEDICAL DEVICES AND IVDS

INTRODUCTION

The clinical pharmacist plays an important part in the supply of clinical pharmacy services by ensuring that patients receive individualised doses in accordance with their therapy charts, taking into consideration their disease states, laboratory results and genetics. The competencies required in the domain to supply medicines and medical devices are as follows.

3.1 Medicine compounding.

3.2 Supply chain management.

3.3 Medicine dispensing.

DOMAIN 3: SUPPLY OF MEDICINES AND MEDICAL DEVICES	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
3.1 Medicine compounding	3.1.1 Manage the preparation of individualised patient doses by ensuring accurate dosing calculations. 3.1.2 Ensure safe compounding of medicines to meet individualised patient needs according to GMCP. 3.1.3 Ensure that compounded medicines meet the quality, safety and environmental control requirements. 3.1.4 Monitor the safe and effective use of compounded medicine by patients. 3.1.5 Utilise Therapeutic Drug Monitoring (TDM) techniques to ensure safe and effective dosing alternations for patients, taking into account individual patient factors and treatment goals.
3.2 Supply chain management	3.2.1 Develop, maintain and monitor systems for the provision of patient-centred medicine therapy management. 3.2.2 Manage the storage and transportation of compounded medicine in accordance with GxP.
3.3 Medicine dispensing	3.3.1 Evaluate a patient's prescription and ensure that an appropriate pharmaceutical care plan is developed. 3.3.2 Implement and monitor the implementation of the plan (including the monitoring of personalised medicine treatment plans for patients). 3.3.3 Demonstrate the ability to design the pharmacy area for provision of clinical pharmacy services.

DOMAIN 4: QUALITY MANAGEMENT IN CLINICAL PHARMACY

INTRODUCTION

The competencies required in this domain implement quality management in clinical pharmacy according to GxP as follows:

4.1 Quality assurance.

4.2 Pharmaceutical infrastructure management.

DOMAIN 4: QUALITY MANAGEMENT IN CLINICAL PHARMACY	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
4.1 Quality assurance	4.1.1 Demonstrate the ability to develop, implement, and maintain a comprehensive clinical pharmacy system that ensures the quality, safety and efficacy of the pharmaceutical services including the creation and review of: (a) SOPs; (b) change control reports; (c) risk assessments; and (d) guidance documents. 4.1.2 Raise and investigate deviations and address deviations through Corrective and Preventative Actions (CAPAs). 4.1.3 Establish a quality assurance governance system.
4.2 Pharmaceutical infrastructure management	4.2.1 Design, implement and manage a clinical pharmacy monitoring system.

DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE

INTRODUCTION

The competencies required in the domain to ensure good personal and professional practice are:

5.1 Good record keeping.

5.2 Patient-centred care.

5.3 Professional practice.

5.4 Continuing professional development.

DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
5.1 Good record keeping	5.1.1 Ensure the maintenance and review of patient records in accordance with relevant legislation. 5.1.2 Develop, implement and maintain records for training and assessment of healthcare teams. 5.1.3 Maintain a portfolio of evidence related to clinical pharmacy services.
5.2 Patient-centred care	5.2.1 Review, appraise and evaluate the pharmaceutical care concept against the patient's medical history. 5.2.2 Perform medication reconciliation and assess treatment in conjunction with patient health status, including pathology laboratory results and vital signs. Make recommendations where treatment can be optimised, adverse effects can be reduced, and outcomes can be improved. 5.2.3 Demonstrate and apply in-depth knowledge of various drug mechanisms of action, indications, adverse reactions, dosing and interactions. 5.2.4 Develop, monitor and evaluate patient care plans in line with the patient's ongoing therapy. 5.2.5 Provide direct patient care including the treatment and monitoring of potential adverse drug-drug, drug-food and drug-complementary medicine reactions within a multi-disciplinary team. 5.2.6 Provide clinical care to patients receiving specialised nutrition support. 5.2.7 Formulate and implement non-pharmaceutical measures including lifestyle modifications.
5.3 Professional practice	5.3.1 Develop and monitor clinical protocols as required and mandated. 5.3.2 Demonstrate knowledge of the legislation, guidelines, and procedures for clinical pharmacy. 5.3.3 Contribute to the review and development of legislation, policies and guidelines relating to clinical pharmacy. 5.3.4 Perform HTAs and apply rational medicine use at PTC level. 5.3.5 Demonstrate the ability to assist patients dealing with trauma, death and bereavement. 5.3.6 Effectively communicate with patients, caregivers and members of the multidisciplinary team.

DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
5.4 Continuing professional development	5.4.1 Develop, implement and maintain continuous professional evidence of training and assessment. 5.4.2 Identify knowledge and skills gaps to advance the role of a clinical pharmacist. 5.4.3 Develop a personal development plan to keep abreast with the provision of pharmaceutical services as a clinical pharmacist. 5.4.4 Keep abreast with the current research findings and current practice guidelines. 5.4.5 Demonstrate the ability to provide and receive peer reviews.

DOMAIN 6: EDUCATION, TRAINING AND RESEARCH

INTRODUCTION

Education is essential for the initial development of clinical pharmacists and is required throughout their careers to maintain currency on knowledge, skills, attitudes, and values.

Clinical pharmacists should participate in the education and training of patients and other healthcare practitioners. Clinical pharmacists should also critically evaluate information sources, literature and research on medicines and practice in terms of evidence for decision-making and implementation in practice. The domain includes behavioural statements relating to education, training, and research in a clinical pharmacy setting. The competencies required in the domain are:

6.1 Practice embedded education or workplace education.

6.2 Provision of education and training.

6.3 Clinical Trials.

6.4 Research.

DOMAIN 6: EDUCATION, TRAINING AND RESEARCH	
COMPETENCIES	**BEHAVIOURAL STATEMENTS**
6.1 Practice embedded education or workplace education	6.1.1 Develop, implement and monitor training policies on clinical pharmacy. 6.1.2 Demonstrate the ability to supervise the training of clinical pharmacists in accordance with approved treatment or clinical guidelines. 6.1.3 Provide training on the role of a clinical pharmacist in patient care to the healthcare team, patients, and caregivers.
6.2 Provision and oversight of education and training	6.2.1 Develop, implement and maintain training systems for the clinical pharmacy team. 6.2.2 Assess the performance and learning needs of the clinical pharmacy team. 6.2.3 Plan a series of effective learning experiences for the clinical care team including other health care professionals. 6.2.4 Provide technical coaching, support, and training to the clinical pharmacy team and other health care professionals. 6.2.5 Provide specialist clinical advice on a broad range of clinical pharmacy services.
6.3 Clinical Trials	6.3.1 Identify, develop, implement and monitor all phases of clinical trials. 6.3.2 Develop a clinical trial plan including the identification, screening and selection of the clinical trial participants. 6.3.3 Participate as a member of the clinical trial team.
6.4 Research	6.4.1 Critically evaluate information sources, literature and research on medicines and practices in terms of evidence for decision-making and implementation in practice. 6.4.2 Apply the principles of research methodology in the development of a research protocol. Obtain ethical clearance if necessary. 6.4.3 Conduct research in accordance with established research methodology and ethics, as well as GCP where necessary. 6.4.4 Analyse data, interpret findings and/or results and formulate conclusions and recommendations. 6.4.5 Write and submit a technical report, manuscript for publication or minor dissertation based on the research outcomes with the necessary approvals.