BOARD NOTICE 674 OF 2024

SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

The South African Pharmacy Council herewith publishes amendments for implementation to the Minimum Standards as contained in Annexure A of the *Rules relating to Good Pharmacy Practice,* which was published on 17 December 2004, Government Gazette No: 27112, in Board Notice 129 of 2004 (as amended), in terms of Section 35A(b)(ii) of the Pharmacy Act, 53 of 1974.

SCHEDULE

Rules relating to what constitutes good pharmacy practice.

1. In these rules "the Act" shall mean the Pharmacy Act, 53 of 1974, as amended, and any expression to which a meaning has been assigned in the Act shall bear such meaning.

2. The following rule to Annexure A of the *Rules relating to Good Pharmacy Practice* is hereby added:

   (a) Rule 1.12: Minimum Standards relating to Pharmacies that only provide Oncology Services.

3. The following rule to Annexure A of the *Rules relating to Good Pharmacy Practice* is hereby amended:

   (a) Rule 4.2.3.3.1: Standard operating procedures: Community Pharmacy.

VM TLALA

REGISTRAR/CEO

Address: 591 Belvedere Street, Arcadia, Pretoria, 0083,

Private Bag X40040, Arcadia, 0007. Telephone: 0861 7272 00

CHAPTER 1

PROFESSIONAL STANDARDS FOR PREMISES

1.12 MINIMUM STANDARDS RELATING TO PHARMACIES THAT ONLY PROVIDE ONCOLOGY SERVICES

1.12.1 PURPOSE

The purpose of this Minimum Standard is to regulate pharmacies that provide oncology services only.

1.12.2 GENERAL CONSIDERATIONS

Pharmacies that only offer oncology services must apply to the Director-General (DG): National Department of Health, for a pharmacy licence with the condition to provide oncology services only. Nothing in this Minimum Standard precludes a community or institutional pharmacy from offering oncology services over and above the pharmaceutical services as prescribed in the Regulations. Therefore, Rule 2.17.3: *Cytotoxic preparation and reconstitution service,* still applies to all pharmacies that offer oncology services.

1.12.3 TRAINING

Pharmacists who provide any of the services identified in this standard should:

(a) ensure that they have adequate training, knowledge and skills to provide the services they offer; and

(b) ascertain the instructions and requirements of all the products that are used in the provision of the respective services they offer.

1.12.4 PHYSICAL FACILITIES AND EQUIPMENT

Notwithstanding the provisions of the minimum standards for pharmacy premises, facilities and equipment of the *Rules relating to Good Pharmacy Practice*, the pharmacy may share the waiting area and the private area with the healthcare facility where the oncology service is being provided. In the case where the waiting area is shared with the healthcare facility, the following will apply:

(a) proof that patients have access to a waiting area, and/or private area (compliant with GPP) if the service is offered within a healthcare practice; and
(b) documentary evidence that the waiting area and/or private area may be used for this purpose.

1.12.5 COUNSELLING AND CONFIDENTIALITY

(a) Complete and uninterrupted privacy must be maintained during the provision of these services.

(b) Patient information must only be disclosed to another duly authorised pharmacist, healthcare professional or to a person authorised by law to request it with the consent of the patient or the caregiver, when applicable.

(c) During counselling, the pharmacist must act in an ethical and professional manner that takes into consideration the fundamental personal constitutional rights of patients.

(d) In terms of counselling areas, the following will apply:

(i) patients have access to a counselling room (compliant with GPP) if the service is offered within a healthcare practice; and

(ii) that the private area for counselling may be used for this purpose.

1.12.6 REFERENCE SOURCES

The pharmacy providing oncology services must ensure that in addition to the requirements in terms of Rule 1.2.11.5, reference sources that are relevant to oncology services are in place.

1.12.7 STANDARD OPERATING PROCEDURES (SOPs)

The Responsible Pharmacist of the pharmacy providing oncology services must ensure that in addition to the requirements in terms of Rule 4.2.3.3, written policies and SOPs relevant to oncology services are in place.

1.12.8 SPECIFIC CONSIDERATIONS WHERE THE SERVICE IS DELIVERED FROM A PHARMACY IN ANOTHER HEALTHCARE FACILITY

1.12.8.1 Designation and condition of the pharmacy:

(a) a pharmacist must be present when medicines are prepared and dispensed;

(b) there must be a suitable room designated as a dispensary with adequate equipment to offer such service; and

(c) the pharmacy must comply with the minimum standards relevant to dispensaries.

1.12.8.2 Control of access to the pharmacy:

(a) the pharmacist must ensure that every key, key card, or other device, or the combination of any device, which allows access to the dispensary when it is locked, is kept only on his/her person; and

(b) a procedure must be in place to ensure access to the pharmacy in an emergency.

CHAPTER 4

PROFESSIONAL STANDARDS FOR PHARMACY MANAGEMENT

4.2 MINIMUM STANDARDS FOR PHARMACY ADMINISTRATION AND MANAGEMENT

Rule 4.2.3.3.1, Standard operating procedures: Community Pharmacy is hereby deleted and replaced with Rule 4.2.3.3.1 as follows:

4.2.3.3.1 Community Pharmacy

Premises

(a) good housekeeping (cleaning procedures, etc. as well as pest elimination);
(b) access control – keys, who can be in dispensary & stockrooms etc; and
(c) procedures for specialised services (dependent on what specialised services the pharmacy offers).

Pharmaceutical Services:

(a) all professional services and procedures provided as per the scope of practice of a pharmacist;
(b) informed consent;
(c) confidentiality;
(d) infection control;
(e) elimination;
(f) disposal of sharp-edged & hazardous materials;
(g) needle stick injury & blood spill procedures (where applicable); and

Management and Administrative Procedures:

(a) ADR & Quality reporting combined with the handling of product complaints;
(b) storage, retrieval and disposal of records and patient information;
(c) receiving of medicines;
(d) storage of medicines;
(e) cold chain management;
(f) handling of S6 medicines;
(g) pre-packing and quality assurance procedures (where applicable);
(h) collection and delivery of medicines;
(i) effective stock rotation;
(j) stock-taking;
(k) disposal or removal of expired, damaged and/or contaminated stock as required;
(l) recall of medicine;
(m) compounding of extemporaneous preparations, where applicable);
(n) preparation of TPN/large volume parenteral (including quality assurance procedures) (where applicable);
(o) oncology mixing (including quality assurance procedures) (where applicable);
(p) preparation of IV admixtures (including quality assurance procedures) (where applicable);
(q) enquiry or complaint procedure;
(r) staff training.