

BOARD NOTICE 480 OF 2023**SOUTH AFRICAN PHARMACY COUNCIL****RULES RELATING TO GOOD PHARMACY PRACTICE**

The South African Pharmacy Council intends to publish amendments to Annexure A of the *Rules relating to good pharmacy practice* which was published on 17 December 2004, Government Gazette No: 27112, Board Notice 129 of 2004, in terms of Section 35A(b)(ii) of the Pharmacy Act, 53 of 1974.

Interested parties are invited to submit, within **60 days** of publication of this notice, substantiated comments on or representation regarding the additional minimum standards. Comments must be addressed to The Registrar, South African Pharmacy Council, by email BN@sapc.za.org (for the attention of the Company Secretary and Legal Services).

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 included –
 - (a) Minimum standards relating to pharmacies that only provide oncology services



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MINIMUM STANDARDS RELATING TO PHARMACIES THAT ONLY PROVIDE ONCOLOGY SERVICES

1. PURPOSE

The purpose of these minimum standards is to regulate pharmacies that only provide oncology services.

2. GENERAL CONSIDERATIONS

Pharmacies that only offer oncology services must apply to the Director-General: National Department of Health (DG) for a pharmacy licence with the condition to only offer oncology services. Nothing in these minimum standards precludes a community or institutional pharmacy from offering oncology services over and above the pharmaceutical services as prescribed in the *Regulations relating to the practice of pharmacy (GNR. 1158, published on 20 November 2000)*. Therefore, Rule 2.17.3: *Cytotoxic preparation and reconstitution service*, still applies to all pharmacies that offer oncology services.

3. TRAINING

Pharmacists who provide any of the services identified in these minimum standards should:

- (a) ensure that they have adequate training, knowledge and skills to provide the services which they offer; and
- (b) ascertain themselves of the instructions and requirements of all the products that are used in the provision of the respective services they offer.

4. PHYSICAL FACILITIES AND EQUIPMENT

Notwithstanding the provisions of the *Minimum standards for pharmacy premises, facilities and equipment* as contained in 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.

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) proof that 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.

6. REFERENCE SOURCES

- (a) 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.

7. STANDARD OPERATING PROCEDURES (SOPs)

- (a) 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.

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

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.

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