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CONTENTS • INHOUD

BOARD NOTICE

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THE SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

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

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 sections of Annexure A of the *Rules relating to Good Pharmacy Practice* are amended-

    - Section 1.2.13
    - Section 3.5

3. The following minimum standards and criteria as published herewith shall constitute additional standards to be added to Annexure A of the *Rules relating to Good Pharmacy Practice published* in accordance with Section 35A(b)(ii) of the Act.

    - Minimum standards regarding maintenance and disposal of confidential information relating to patients.

    - Information relating to compliance with Good Pharmacy Practice to be submitted in support of an application for a licence for a pharmacy premises issued in terms of the *Regulations relating to the ownership and licensing of pharmacies*

TA MASANGO
REGISTRAR

Amendment of Section 1.2.13.1

The following sub-sections is substituted as follows –

Three types of areas for the furnishing of information and advice should be considered for the pharmacy, depending on the services offered by the pharmacy and the degree of privacy required. These models are:

(a) semi-private area at each point where dispensing of medicine to the patient or the patient's agent/caregiver occurs;

(b) a private area;

(c) a consultation area for the provision of screening and monitoring services

Every pharmacy must have at least one type of area for the furnishing of information and advice. In cases where a pharmacy only has a semi-private area(s) at each point where dispensing of medicine to the patient or the patient's agent/caregiver occurs, there must in addition be access to another separate private room/area where communication can take place between a pharmacist and a patient or the patient's agent/caregiver in private.

Standards for the different types of areas, including the equipment required, are provided below.

Amendment of Section 1.2.13.2

The following sub-sections is substituted as follows –

Semi-private area(s)

This area(s) is for the provision of information and/or advice that may occur in an area visible to other patients.

(a) The area(s) could be of a modular "bank teller" type, where a counter is utilised, offering the patient or his/her agent/caregiver reasonably private access to the pharmacist. Another option is an aperture, which is surrounded by a "telephone booth" type structure to prevent other persons from crowding around the patient or his/her agent/caregiver who is communicating with the pharmacist. Figure 1 is a schematic representation of an example of a semi-private area.

(b) In such an area(s), patient counselling may take place in a professional manner regarding medicine use and other relevant information, but does not provide the privacy required to advise patients on sensitive issues.

Amendment of Section 1.2.13.3(a)

The following sub-sections is substituted as follows –

The area should be professionally planned, furnished and equipped, so as to allow the pharmacist to consult and counsel patients who may have sensitive emotional or health care problems and advise a patient and/or his/her agent/caregiver on medicines, and other related issues

Amendment of Section 1.2.13.3(c)

The following sub-sections is substituted as follows –

The size of the area should be adequate. It should have a table, comfortable chairs and shelves for reference books. The pharmacist's qualifications could also be displayed. Informative wall posters and charts could be used. Figure 2 is a representation of an example of a private area for the furnishing of advice.

Amendment of Section 1.2.13.4(b)

The following sub-sections is substituted as follows –

The consultation area should have sufficient space (at least 7.5 square meters)

Amendment of Section 3.5

The following sub-sections is substituted as follows –

Any person registered with the South African Pharmacy Council who performs one or more of the functions relating to the scope of practice of the category in which he/she is registered must be covered by his/her own indemnity insurance.

The following minimum standards and criteria as published herewith shall constitute additional standards to be added to Annexure A of the *Rules relating to Good Pharmacy Practice published* in accordance with Section 35A(b)(ii) of the Ac

MINIMUM STANDARDS REGARDING MAINTENANCE AND DISPOSAL OF CONFIDENTIAL INFORMATION RELATING TO PATIENTS

INTRODUCTION

In terms of the National Health Act 61 of 2003 all information concerning patients, including information relating to his/her health status, treatment or stay in a health establishment is confidential.

Patient information is generally held under legal and ethical obligations of confidentiality. Information provided in confidence must not be used or disclosed in a form that might identify a patient without his or her consent. The exception to the above is contained in the rules relating to code of conduct for pharmacists and other persons registered in terms of the Pharmacy Act, 53 of 1974.

1. Confidential information is defined as information accessed or maintained by the pharmacy, which contains personally identifiable information that could be used to identify the patient. This information may relate to but is not limited to:

(a) the patient's name, address, telephone number, identity number and/or any other identifying number;
(b) the name, address and details of a prescriber; and
(c) medicines (i.e. prescription and/or non-prescription medicines) or medical devices, prescribed, dispensed, sold and/or supplied to the patient including information such as therapeutic effect, diagnosis, allergies, disease state, pharmaceutical services rendered, medical information, and drug interactions.

2. Confidential documents relating to patient information refers to personally identifiable data about an individual patient and such data is not generally considered to be public knowledge. Confidential documents relating to patient information includes but is not limited to the following documents:

(a) Labels
(b) Prescriptions
(c) Prescription records and registers
(c) Patient medication records
(d) Patient medical records
(e) Records relating to screening tests performed

PURPOSE

3. The purpose of this standard is to ensure patient's records are maintained and disposed of in confidential manner.

GENERAL CONSIDERATIONS

4. In order to protect personal information from improper disclosure and potential misuse, the responsible pharmacist of the pharmacy must take the necessary action to prevent the acquisition and misuse of personal information relating to patients.

5. The responsible pharmacist must ensure that there are policies and procedures in place in the pharmacy to protect documents relating to patient information from any unauthorized disclosure and use, whether or not it results from disposal. At a minimum, this means restricting access to documents relating to patient information to staff whose responsibilities do not require them to have this information i.e. persons who are not registered with council.

Maintenance of the patient's records

6. Any information stored about a patient must be pertinent, accurate and up-to-date.

7. To maintain the integrity and confidentiality of patient information contained in records and prescriptions for medicine, any system or computer utilized must have adequate security including system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records and prescriptions.

Computer records

8. All computer records in the pharmacy must be secure. Any system used must be capable of restricting access. Suitable passwords, Personal Identification Number (PIN) or other restricted access systems must be in place.

9. PIN numbers or passwords should be changed at regular intervals (for example if a member of staff terminates employment at the pharmacy). The level of access that various members of the pharmacy team have to a patient's records should be appropriate to their duties. For example, a member of staff who is responsible only for ordering stock will not need access to patient medication records.

10. Computers must be situated so that data cannot be seen intentionally, or by accident, by those who are not authorised to have access to it.

11. Access to the database must be restricted at all times. In particular, it is important to ensure proper control over computer media such as flash sticks, compact disks, backup copies that may contain copies of medication records that are also maintained in paper files.

12. The responsible pharmacist must ensure that third parties such as software vendors, manufacturers, medical schemes and managed healthcare companies do not have access to the database without their authorisation. Disclosure of any patient's information must be within the legal and ethical obligations of confidentiality.

13. The responsible pharmacist must ensure that information given to software vendors and manufacturers concerning medicine usage does not contain personally identifiable data about an individual patient. Information given to software vendors and manufacturers must be anonymised i.e. the identity of the individual who is the subject of that information cannot be traced back to him/her or ascertained from the information.

Disposal of the patient's records

14. Disposal of patient records is defined as the day-to-day discarding of duplicate, extra or obsolete reports, which contain personally identifiable information that could be used to identify the patient. The records include but are not limited to items such as labels, prescriptions, prescription records and registers, patient medication records, patient medical records and records relating to screening tests performed.

15. Destruction of patient records is defined as the systematic permanent disposal of patient's records that have been maintained for the prescribed retention period. The purpose of disposal or destruction is to permanently remove records from active use, with no possibility of reconstructing the information contained in them, while maintaining the confidentiality of the information they may contain.

16. Disposal of any materials containing or including patient-specific or confidential information must be conducted in such a manner as to preserve patient confidentiality. Disposing may involve shredding documentation, or alternatively placing it in confidential waste or deleting the information by way of a permanent marker.

17. The following steps must be followed prior to disposing of confidential documents

(a) Shred the entire record.
(b) Erase the personal information contained in the record.
(c) Modify the record to make personal information contained in it unreadable.
(d) Take action to ensure that no unauthorized person will have access to the personal information contained in the record from the time it is disposed of until the time it is ultimately destroyed.

INFORMATION RELATING TO COMPLIANCE WITH GOOD PHARMACY PRACTICE TO BE SUBMITTED IN SUPPORT OF AN APPLICATION FOR A LICENCE FOR A PHARMACY PREMISES TO BE ISSUED IN TERMS OF THE *REGULATIONS RELATING TO THE OWNERSHIP AND LICENSING OF PHARMACIES* PUBLISHED IN TERMS OF THE PHARMACY ACT 53 OF 1974 AS AMENDED

The following information must be submitted to Council as proof of compliance with Good Pharmacy Practice for purposes of recommendations made by Council to the National Department of Health for the issuing of a licence by the Director-General for a premises wherein or from which the business of a pharmacy shall be carried out in terms of the Pharmacy Act 53 of 1974 as amended:

SUPPORTING DOCUMENTATION

	CRITERIA	Yes	No
1.	A letter of appointment for the responsible pharmacist; **NB: No pharmacist may be the responsible pharmacist for more than one pharmacy**		
2.	A letter of acceptance of the above appointment;		
3.	Copy of the site plan of the building indicating the location of the pharmacy premises in relation to adjoining or surrounding businesses and access to and from the premises;		
4.	Copy of the professionally drawn floor plan indicating the actual layout of the pharmacy premises drawn to scale with exact measurements;		
5.	Signed affidavit regarding eligibility, ownership and compliance with standards (must be signed by sole proprietor, all partners of the partnership, all members of the Close Corporation, all shareholders of a Private Company and all Directors of a Public Company;		
6.	In case of a Close Corporation the latest CK2 (as approved);		
7.	In case of a company a copy of the Certificate of Incorporation (Change of name if applicable) and the latest CM29;		
8.	If applicable, schedules from the auditors certifying the names of the directors and shareholders;		
9.	A bank guaranteed cheque or proof of payment of the licence application fee made payable to the SAPC.		

FLOOR PLAN

The following information must be clearly indicated in the submitted copy of the professionally drawn floor plan indicating the actual layout of the pharmacy premises drawn to scale with exact measurements:

	CRITERIA	Yes	No
1.	The size of the premises;		
2.	The size of the dispensary		
3.	All entrances and exits of the pharmacy;		
4.	All entrances to the enclosed areas in the pharmacy e.g. admin office, manager's office, dispensary, kitchen, private area and consultation area		

5.	A separate facility for washing hands;		
6.	A separate facility for compounding of extemporaneous preparations and cleaning of equipment;		
7.	Sufficient and adequate lighting;		
8.	A suitable waiting area;		
9.	A fridge for heat sensitive pharmaceuticals and vaccines;		
10.	A suitable separate private room for private consultation of patients;		
11.	A suitable consultation area for the provision of screening and monitoring tests, where applicable;		
12.	All Scheduled medicines to be stored/displayed inaccessible to the public;		
13.	A dispensing counter for prescriptions and pharmacist initiated prescriptions (OTC), with a suitable semi private area for each point *where dispensing of medicine to the patient or the patient's agent/caregiver occurs* ; the dimensions of the dispensing counter and semi private area are to be indicated on the floor plan and are to comply with the following requirements: (i) Height of partitioning of the semi private area from floor – 1800mm (ii) Dispensing point: 900mm deep by 1000mm wide (iii) 400mm from edge of the counter **NB:** If a counter for pharmacist initiated prescriptions (OTC) is separate from the prescription counter, the above criteria apply to both counters.		

Trading Title

The following criteria will be applied by Council in considering applications for the use of a title, trading title, name, description, brand name or logo (referred to as the "name") used with respect to a **community or an institutional pharmacy situated in a private or a public health facility** in terms of Section 35A(c) of the Pharmacy Act 53 of 1974. Council shall regard the use of following names as unacceptable -

	CRITERIA	Yes	No
1.	The use of the same or a similar name, including a name that sounds similar but is spelt differently, as that of another pharmacy if such pharmacies do not have the same owner;		
2.	Any name which is likely to be considered offensive;		
3.	A name that is calculated to suggest that the pharmacy in question is superior to another pharmacy or pharmacies;		
4.	A name which creates the impression that medicines are being sold at discounted prices;		
5.	A name which may be misleading to the public;		
6.	A name that is not associated with or does not belong to the pharmacy concerned;		

7. A name that is calculated to suggest that the professional skills or ability or facilities for the rendering and supply of services which form part of the scope of practice of a pharmacist are superior or better than those of other pharmacies or pharmacists;		
8. A name that is calculated to suggest that a pharmacy is associated with, belongs to or is in any way connected with a body corporate, firm or business, when not owned or part owned by that body corporate, firm or business;		
9. Any name which is in contravention to the Pharmacy Act 53 of 1974.		

GENERAL

The application must be signed and sworn in the presence of a Commissioner of Oaths.