BOARD NOTICE 75 OF 2019

THE SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

The South African Pharmacy Council intends to publish amendments and additional minimum standards to be added 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 amendments to the existing minimum standards and/or the additional minimum standards. Comments must be addressed to The Registrar, South African Pharmacy Council, Private Bag X40040, Arcadia, or fax (012) 326-1496 or email BN@sapc.za.org

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 rules to Annexure A of the *Rules relating to good pharmacy practice* are hereby amended –

    (a) Rule 1.2.4: Minimum standards for pharmacy premises, facilities and equipment - Control of access to pharmacy premises;

    (b) Rule 3.6: Minimum standards for locum tenens pharmacists and pharmacy support personnel; and

    (c) Rule 4.2.3.3: Minimum standards for pharmacy administration and management - Standard Operating Procedures.

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REGISTRAR

1.2.   **MINIMUM STANDARDS OF PHARMACY PREMISES, FACILITIES AND EQUIPMENT**

Rule 1.2.4 Control of access to pharmacy premises

Rule 1.2.4(a) which reads, "The responsible pharmacist of a pharmacy must ensure that every key, key card or other device, or the combination of any device, which allows access to a pharmacy when it is locked, is kept only on his/her person or the person of another pharmacist at all times",

be replaced with

"The Responsible Pharmacist of a pharmacy must ensure that every key, key card or other device, or the combination of any device, which allows access to a pharmacy when it is locked, is kept only on his/her person, the person of another pharmacist and/or the person of the owner/delegated person.'"

3.6   **MINIMUM STANDARDS FOR LOCUM TENENS PHARMACISTS AND PHARMACY SUPPORT PERSONNEL**

Rule 3.6: Minimum standards for locum tenens pharmacist and pharmacy support personnel is replaced as follows:

(a)   The qualifications and current registration status of locum tenens (locum) pharmacists and/or pharmacy support personnel (PSP) must be verified.

(b)   Locum pharmacists and PSP must have the necessary information to ensure the compliant operation of the pharmacy.

(c)   Operational information including Standard Operating Procedures (SoP), must be accessible to locum pharmacists and PSP. This information must include at least the following:
   (i)   computer instructions (as applicable);
   (ii)   names and contact details of key staff;
   (iii)   contact details of key medical practitioners;
   (iv)   instructions on use of alarm system (as applicable);
   (v)   emergency contact numbers; (include plumber, electrician, IT, etc.);
   (vi)   information pertaining to outstanding work;
   (vii)   opening and closing procedure of the pharmacy.

(d)   The responsible pharmacist must be able to demonstrate which registered persons were in the pharmacy at any particular time on any day in terms of the requirement for record keeping.

4.2   **MINIMUM STANDARDS FOR PHARMACY ADMINISTRATION AND MANAGEMENT**

The intent of this standard is to have the pharmacy organised in such a way that its services and processes contribute to the highest quality of pharmaceutical care. The pharmacy management plans the development and implementation of its goals and evaluates its effectiveness in achieving them.

Rule 4.2.3.3: Standard Operating Procedures is replaced as follows:

4.2.3.3 Standard Operating Procedures

A Standard Operating Procedure (SOP) is that set of instructions or steps which must be followed in order to complete a specific job or task safely, with no adverse impact on the environment, and in a way that maximises operational and production requirements. SOPs can be written for virtually any task undertaken in a pharmacy that has to be performed regularly and in a pre-determined way.

The responsible pharmacist is responsible for the existence of and adherence to SOPs in a pharmacy and must be involved in the compilation, regular review and dissemination of SOPs to all staff members.

SOP must-

(a) provide personnel with all the safety, health, environmental and operational information necessary to perform a job properly;
(b) ensure that operations are performed consistently to maintain quality control of processes and products;
(c) ensure that processes continue uninterrupted and are completed timeously;
(d) ensure that no failures occur that could harm anyone;
(e) ensure that approved procedures are followed in compliance with legislation;
(f) serve as a training document, e.g. pharmacist interns or pharmacist's assistants;
(g) serve as a historical record of the how, why, when of steps in an existing process;
(h) serve as an explanation of steps in a process so they can be reviewed in incident investigation.

The SOP must be reviewed annually and/or as required. SOPs are adapted to the operations of the specific pharmacy and staff is suitably trained on the SOPs.

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.

Services

(a) SOP for professional services and procedures provided not included in the *Rules related to the services for which a pharmacist may levy a fee* in the pharmacy and clinic;
(b) informed consent;
(c) confidentiality;
(d) infection control;
(e) disposal of sharps & hazardous materials;
(f) needle stick injury & blood spill procedures (where applicable).

Management

(a)　ADR & Quality reporting combined with handling of product complaints;
(b)　storage, retrieval and disposal of records and patient information;
(c)　receiving of medicines;
(d)　storage of medicine;
(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 parenterals (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.

4.2.3.3.2　Institutional pharmacy:

Premises

(a)　good housekeeping (cleaning procedures, etc. as well as pest elimination);
(b)　Access control – keys, who can be in dispensary & stockrooms, etc.

Services

(a)　SOP for professional services and procedures provided that are not included in the *Rules related to the services for which a pharmacist may levy a fee* in the pharmacy and clinic (where applicable);
(b)　informed consent (where applicable);
(c)　confidentiality;
(d)　infection control;
(e)　disposal of sharps & hazardous materials;
(f)　needle stick injury & blood spill procedures.

Management

(a)　ADR & Quality reporting combined with handling of product complaints;
(b)　storage, retrieval and disposal of records and patient information;
(c)　receiving of medicines;
(d)　storage of medicine;
(e)　cold chain management;

(f)   handling of S6 medicines;

(g)   pre-packing and quality assurance procedures) (where applicable);

(h)   effective stock rotation;

(i)   stock-taking;

(j)   disposal or removal of expired, damaged and/or contaminated stock as required;

(k)   recall of medicine;

(l)   Compounding of extemporaneous preparations, (where applicable);

(m)   enquiry or complaint procedure;

(n)   preparation of TPN/large volume parenterals (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)   control over medicine kept in hospital or health facility, e.g. wards, theatres, etc. (including controls over issuing ward stock and medicine per patient to the wards);

(r)   staff training.

4.2.3.3.3   Wholesale pharmacy:

<u>Premises</u>

(a)   good housekeeping (cleaning procedures, etc. as well as pest elimination);

(b)   Access control.

<u>Management</u>

(a)   handling of product complaints;

(b)   procurement of medicine;

(c)   receiving of medicines;

(d)   storage of medicine;

(e)   cold chain management (including procedures to be followed in the event of a refrigerator power failure);

(f)   handling of Specified S5 and S6 medicines;

(g)   pre-packing and quality assurance procedures (where applicable);

(h)   delivery of medicines;

(i)   effective stock rotation;

(j)   stock-taking;

(k)   disposal or removal of expired, damaged and/or contaminated stock as required in regulation 44 published in terms of the Medicines Act;

(l)   recall of medicine;

(m)   verification that the person/organisation to whom medicines are supplied, are duly registered to be supplied with medicines;

(n)   handling of section 21 medicines.

4.2.3.3.4   Consultant pharmacy:

(a)   good housekeeping (cleaning procedures and pest elimination);

(b)   SOP for professional services and procedures provided not included in the rules related to the services for which a pharmacist may levy a fee in the pharmacy and clinic (where applicable);

(c)   storage, retrieval and disposal of records and patient information;

(d)   Enquiry or complaint procedure.

4.2.3.3.4   Primary health facility:

Premises

(a)   good housekeeping (cleaning procedures, etc. as well as pest elimination;

(b)   Access control – keys, who can be in dispensary & stockrooms, etc.

Services

(a)   SOP for professional services and procedures provided in the dispensary;

(b)   informed consent;

(c)   confidentiality and record keeping.

Management

(a)   ADR & Quality reporting combined with handling of product complaints;

(b)   storage, retrieval and disposal of records and patient information

(c)   procurement of medicine;

(d)   receiving of medicines;

(e)   storage of medicine;

(f)   cold chain management;

(g)   handling of S6 medicines (where applicable);

(h)   effective stock rotation;

(i)   stock-taking;

(j)   disposal or removal of expired, damaged and/or contaminated stock;

(k)   recall of medicine;

(l)   enquiry or complaint procedure;

(m)   control over medicine kept in places other than the dispensary.

The following policies must be available in all pharmacies:

(a)   Hygiene or infection control policy;

(b)   Occupational health and safety policy.