DEPARTMENT OF HEALTH

NOTICE 591 OF 2017

THE SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

The South African Pharmacy Council intends to publish an additional minimum standards to be added to Annexure A of the *Rules relating to good pharmacy practice* which was published on the 17 December 2004 Government Gazette No: 27112 in 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, the South African Pharmacy Council, Private Bag X40040, Arcadia or fax (012)326-1496 c/o Senior Manager – Legal Services and Professional Conduct 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 minimum standard as published herewith shall constitute an additional standard to be added to Annexure A of the *Rules relating to good pharmacy practice* in accordance with section 35A(b)(ii) of the Act –

   (a) Minimum standards specifically relating to the approval of facilities (other than primary healthcare clinics) where a pharmacist's assistant (post-basic) may practice under indirect supervision – pharmacy linked distribution points.

TA MASANGO
REGISTRAR

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South African Pharmacy Council

MINIMUM STANDARDS SPECIFICALLY RELATING TO THE APPROVAL OF FACILITIES (OTHER THAN PRIMARY HEALTHCARE CLINICS) WHERE A PHARMACIST'S ASSISTANT (POST-BASIC) MAY PRACTICE UNDER INDIRECT SUPERVISION - PHARMACY LINKED DISTRIBUTION POINTS

PREAMBLE

Regulation 12 of the *Regulations relating to the practice of pharmacy*, GNR 1158, published on 20 November 2000 ("the Practice Regulations") published in terms of the Pharmacy Act, 53 of 1974, ("the Act) provides for the following, namely:

"… a pharmacist's assistant (post-basic) may perform the acts or provide services as prescribed in sub-regulations 11(5), 11(6), 11(8) and 11(9), as well as the reading and preparation of a prescription, the selection, manipulation or compounding of medicine and the labelling and supply of medicine in an appropriate container under the **indirect personal supervision of a pharmacist**: provided that such indirect personal supervision will take place only under the following circumstances:

(1) The services are provided or acts are performed at a primary healthcare clinic **or any other facility as approved by Council**;

(2) Only **re-packaged medicines** or **patient ready packs** are provided;

(3) Written and updated protocols and standard operating procedures are available describing clearly the responsibilities of the pharmacist's assistant and pharmacist under whose indirect supervision the pharmacist's assistant performs the acts and provides the services; and

(4) The pharmacist under whose indirect personal supervision the pharmacist's assistant performs the acts and provides the services visits the pharmacist's assistant at the primary health care clinic **or other facility as approved by council** for purposes of supervision and support, which visits must be documented and take place at least once a month".

The following *Minimum standard specifically relating to the approval of facilities (other than primary healthcare clinics) where a pharmacist's assistant (post-basic) may practice under indirect supervision*, enables community or institutional pharmacies to apply to Council for the approval and recording of other facilities, such as a "pharmacy linked distribution point", subject to compliance with the minimum standards as indicated hereunder.

1. DEFINITIONS

"**Pharmacy linked distribution points**" are 'other facilities' as referred to within Regulation 12 of the *Regulations relating to the practice of pharmacy* (GNR. 1158, published on 20 November 2000) in terms of the Pharmacy Act, 53 of 1974, where a pharmacist's assistant (post-basic) may practice under indirect supervision of a pharmacist (the supervising pharmacist); provided that such indirect supervision takes place from an existing pharmacy (the principal pharmacy), which has been duly approved and recorded as such by the Council.

"**Principal pharmacy"** means the pharmacy to which the Pharmacy Linked Distribution Point (or "PLDP") is directly connected and under which supervision any approved acts are performed or services provided, in accordance with these minimum standards.

"Supervising pharmacist" means the pharmacist, at the principal pharmacy, under whose indirect supervision the pharmacist's assistant (post-basic), at the PLDP, performs the acts or provides the services as prescribed in Regulation 12 of the *Regulations relating to the practice of pharmacy* (Practice Regulations).

2. APPLICATION FOR APPROVAL BY COUNCIL

2.1 A pharmacy owner must apply and pay the prescribed recording and annual fees for the approval and recording of the other facility (**hereafter referred to as a PLDP**) as referred to in Regulation 12 of the Practice Regulations.

2.2 A pharmacy owner may only apply for one (1) PLDP per community or institutional pharmacy.

2.3 The PLDP applied for may not be established within a radius of 5 km by road from any other existing community pharmacy. If and when a new community pharmacy is approved and properly licensed at a site within the 5 km radius concerned, the owner of the PLDP concerned will receive notice from Council to close the doors of the PLDP within 6 (six) month of receiving such notice.

2.4 The application(s) must only be for purposes of improving access to medicines, for patients who are clinically stable and on long term therapy (chronic) in underserviced area(s), where there is no community pharmacy within the radius of 5km.

2.5 Only medicine that is already dispensed (phase 1 and 2) for a particular patient by a pharmacy may be dispensed (phase 3) at this PLDP.

3. GUIDELINES FOR PLDP PREMISES, FACILITIES AND EQUIPMENT

3.1 Registration of a PLDP

(a) The PLDP, as referred to in Regulation 12 of the Practice Regulations, is not a pharmacy and is not licenced as a pharmacy in terms of section 22 of the Pharmacy Act. However, such facility must be approved and registered by Council prior to any service being provided from such facility by a pharmacist's assistant (post-basic) under indirect supervision.

(b) The PLDP must be an extension of, owned by and under the direct control of an existing community or institutional pharmacy, called the **principal pharmacy** for purposes of these minimum standards.

3.2 Condition / structure / appearance of a PLDP

3.2.1 General requirements

(a) The design and layout of a PLDP must reflect the volume of medicines, dispensed as in point 2.5 above, (forecast workload); permit a logical flow of work, effective communication and supervision and ensure effective cleaning and maintenance and must minimise the risk of errors and cross-contamination, which would have an adverse effect on the quality of the products received and issued.

(b) The PLDP, its fittings and equipment must be adequate and suitable for the purpose of supplying medicines.

(c) All parts of the PLDP premises must be maintained in an orderly and tidy condition.

(d) Entrances and doorways must be wide enough to allow access to disabled persons to enter should it be necessary.

(e) The temperature inside the PLDP must be below 25^{o} C.

(f) The PLDP must be located in an area easily accessible and convenient to patients and staff. The name of the pharmacist's assistant (post-basic) on duty must be visibly displayed in the PLDP for purposes of identification of such person(s) by the public.

(g) The pharmacist's assistant (post-basic) on duty must wear a name tag or badge indicating his/her name and designation for the purposes of identification of such person by the public.

3.2.2 Safety in the PLDP premises

(a) Working conditions must be so arranged as to protect the safety of the public and people working in the PLDP premises.

(b) Proper provision for electrical connections must be made with an adequate number of electrical sockets. Care should be taken to avoid trailing wires across floors, work surfaces or sinks.

3.2.3 Condition of a PLDP premises

(a) The walls, floors, windows, ceiling, woodwork and all other parts of the dispensary or medicine room must:

(i) be kept clean; and

(ii) be kept in such good order, repair and condition as to enable them to be effectively cleaned and to prevent, as far as is reasonably practicable, any risk of infestation by insects, birds or rodents.

(b) Countertops, shelves and walls must be finished in a smooth, washable and impermeable material which is easy to maintain in a hygienic condition.

(c) Light conditions, temperature and humidity within the dispensary or medicine room must comply with the requirements for the storage of medicine, other pharmaceutical products, and packaging materials.

(d) The PLDP must have the following fixtures/fittings:

(i) an air-conditioner in good working order;

(ii) a refrigerator in good working order;

(iii) a wash hand basin with hot and cold water.

(e) The PLDP must have a suitable area for the furnishing of advice and a waiting area for patients must be provided which comply with the GPP standards.

3.2.4 Construction of a PLDP premises

(a) The construction of the premises must prevent unauthorised access to medicines.

3.2.5 Hygiene in the PLDP premises

(a) There must be an area where equipment and other utensils can be washed which has a source of at least cold tap water, a suitable, clean washbasin made of impervious material and a closed drainage system.

(b) Adequate toilet and hand-washing facilities must be available nearby.

3.3 Storage areas inside PLDP premises

(a) The receiving area must be separated from the storage area as per GPP.

(b) Storage areas must have sufficient shelving constructed from an impervious, washable material for the keeping of medicines off the floor.

(c) Storage areas for pharmaceuticals must be self-contained and secure.

(d) Storage areas must be large enough to allow orderly arrangement of stock and proper stock rotation.

(e) Storage of thermolabile pharmaceutical products must be in accordance with the storage instructions of the manufacturer and in accordance with GPP.

(f) Products must be protected from the adverse effects of light, freezing or other temperature extremes and dampness.

(g) Levels of heat, light, noise, ventilation, etc., must exert no adverse effects on personnel or products.

(h) All parts of the PLDP premises must have suitable and effective means of heating, lighting and ventilation. If windows are capable of being opened, they must be securely locked when the PLDP is closed.

(i) Background music or other broadcasts in the PLDP must not be played at such a volume so as to cause distraction.

3.4 Security

(a) Careful consideration needs to be given to the overall security of the PLDP. It must be lockable and as far as possible exclude any unauthorised entry.

(b) The Supervising Pharmacist must ensure that there is no unauthorised access to the PLDP outside of normal working hours.

(c) A security policy must be implemented which is designed to ensure as far as is reasonably practicable the safety of both staff and medicines, and must take account of local crime prevention advice.

(d) A health and safety procedure must be read and signed by all staff.

(e) Fire extinguishers must be available and checked regularly and all staff must know the fire safety procedures.

(f) Electrical equipment must be regularly maintained.

3.5 Control of access to PLDP

(a) The Supervising Pharmacist must ensure that every key, key card or other device, or the combination of any device, which allows access to a PLDP when it is locked, is kept only on his/her person and the person of the pharmacist's assistant (post basic).

(b) Control of access to the PLDP must be of such a nature that only pharmacists and pharmacist's assistants (post basic) under the indirect personal supervision of a pharmacist, may handle medicines in the PLDP.

(c) Every PLDP must, except in such circumstances and subject to such conditions as may be prescribed, be conducted under the indirect personal supervision of a supervising pharmacist (by definition).

3.6 Waste disposal

(a) A suitable and adequate means of waste disposal must be available and in use.

(b) Waste material must not be allowed to accumulate and must be collected in suitable, covered receptacles for removal to collection points.

(c) Written sanitation procedures must be available detailing schedules, methods, materials and equipment available. Responsibility must be assigned in writing.

(d) Under no circumstances must substances be disposed of, down surface water drains, i.e. storm water drains.

3.7 Returned and uncollected medicines

(a) All uncollected or returned medicines must be dealt with in accordance with the Service Level Agreement / Standard Operating Procedure (SOP).

3.8 Reference sources

The following reference sources must be accessible in a PLDP where the dispensing of medicine takes place:

(a) Standard Treatment Guidelines and Essential Medicine List for Primary Health Care;

(b) the latest edition of SAMF;

(c) Good Pharmacy Practice in South Africa;

3.9 Equipment for PLDP

There must be adequate, suitable equipment for the supply of medicines in each PLDP. Each item must be clean, in good repair and of suitable material. The list given below provides a standard -

(a) A refrigerator equipped with a suitable thermometer and capable of storing medicines at temperatures between 2°C and 8°C. The refrigerator must be cleaned, defrosted and checked periodically to ensure efficient running. This refrigerator must be used only for storing pharmaceutical products. Where applicable, a freezer for the storage of ice packs must be available.

(b) A suitable range of dispensing containers for medicine. The use of child-resistant closures is encouraged.

(c) Labels for the dispensing of medicines. Labels and labelling must comply with the requirements of Regulation 8 of the General Regulations published in terms of the Medicines Act.

(d) Suitable refuse receptacles.

4. SUPPLY OF MEDICINE TO PATIENTS FROM THE PLDP

The Supervising Pharmacist must ensure that:

(a) all acts performed or services provided at the PLDP are within the scope of practice of a pharmacist's assistant (post-basic);

(b) only medicine that is already dispensed (phase 1 and 2) for a particular patient by the principle pharmacy may be dispensed (phase 3) at this PLDP

(c) a system is in place to ensure the correct identification of patients, including proper recordkeeping of all medicines received, stored and issued;

(d) a system is in place to effectively deal with medicines not collected or returned by patients.

5. SAFE SYSTEMS OF WORK

The Supervising Pharmacist must take all reasonable steps to ensure that working conditions are so arranged at the PLDP as to protect the safety of the public and people working in the PLDP. In adhering to this principle, the following must be taken into consideration:

(a) Safe systems of work must be established and maintained by the Supervising Pharmacist to eliminate, as far as possible, errors in any component of the service provided at the PLDP;

(b) Secure storage for medicines must be provided in the PLDP premises and approved store-keeping procedures and adequate stock control systems must be maintained;

(c) A policy for the receiving, storage and supply of medicines must be defined, regularly updated and in accordance with the GPP; and

(d) The correct and safe use of any medicine supplied at the PLDP.