GENERAL NOTICES • ALGEMENE KENNISGEWINGS

DEPARTMENT OF HEALTH

NOTICE 431 OF 2017

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

   (a) Rule 2.7.5

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REGISTRAR

AMENDMENT TO RULE 2.7.5

The title of Rule 2.7.5 is hereby amended to read:

MINIMUM STANDARDS SPECIFICALLY RELATING TO THE COLLECTION AND THE DELIVERY OF MEDICINES TO PATIENTS FROM A COMMUNITY OR INSTITUTIONAL PHARMACY

Rule 2.7.5 is hereby withdrawn and substituted as follow:

2.7.5.1 Purpose

The purpose of this standard is to regulate activities relating to the collection by and the delivery of medicines to patients from a community or institutional pharmacy.

2.7.5.2 General considerations

(a) All efforts must be made to enable access to counselling of the patient by a pharmacist relevant to their healthcare needs;

(b) When a person other than a pharmacist delivers medicines to a patient or a patient's caregiver, the pharmacist must furnish written instructions, that shall include the patient's details and information regarding the correct use of medicine, and a patient information leaflet (where applicable);

(c) All medicines should, whenever possible, be delivered to patients at an agreed time or date; and

(d) In the absence of an adult (i.e. a person above 14 years old as defined by the Medicines Act) or another person entitled by law to receive the medicine, it must be retained and stored under appropriate conditions until delivery can be affected or be returned to the pharmacy.

2.7.5.3 Collection of medicines from the pharmacy

Definition: **Agent** – a person nominated, either formally or informally, by the patient

Caregiver: a person who has accepted responsibility for looking after a patient

The caregiver or agent may not practice the scope of practice of a pharmacist

(a) A patient's agent or caregiver may collect medicines and accept information pertaining to a particular patient provided that the pharmacist is satisfied that patient safety, confidentiality and

medicine quality is maintained and the patient has~~,~~ provided written consent;

(b) The patient's caregiver may only collect medicines for a patient or patients who are under their direct care, a patient's agent may only collect medicines for a patient or patients who have given written consent for such collection, and in the case of multiple patients the pharmacist must satisfy themselves that the patient's agent or caregiver is the appropriate person to give the medicines to.

2.7.5.4 Transportation for the delivery of medicines

(a) Transportation of medicines must be in such a way that it is secure and limits access to medicines by persons allowed to have access to medicine in law only, prevents any contamination and ensures integrity to the manufacturers product specifications;

(b) The vehicle should allow orderly storage to ensure safety, quality and efficacy of pharmaceutical products during transportation;

(c) Where relevant and to the extent that it is applicable, cold chain management must be observed, and delivery must prove compliance with the minimum standards for thermolabile pharmaceutical products;

(d) Personnel transporting pharmaceutical products must be appropriately trained and shall provide the suitable documentation as proof, for this function and they must ensure that the correct procedures are followed to maintain the cold chain within the manufacturer's specification;

(e) At any stage of transportation, a delivery document must show evidence that the transport requirements, inter alia temperature control have been met;

(f) Damage to containers or any other event or problem which occurs during transit must be reported to and recorded by the responsible pharmacist of the pharmacy from which the pharmaceutical products were sent;

(g) Upon arrival the person responsible for the transportation of the pharmaceutical products must inform the patient or patient's caregiver, that the package contains pharmaceutical products and provide information about specific storage requirements (as applicable); and

(h) Proof of delivery (signed by the patient or the patient's caregiver) must be presented to the pharmacy to ensure that the medicines have been received.