

DEPARTMENT OF HEALTH

NO. 2820

2 December 2022

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965)

**REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR
MEDICINES AND SCHEDULED SUBSTANCES: (DRAFT DISPENSING FEE FOR
PHARMACISTS FOR 2023)**

I, DR MJ PHAAHLA, the Minister of Health have, on recommendation of the Pricing Committee, in terms of section 22G of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) as amended, made the regulations in the Schedule.

The dispensing fee is derived following a zero-based model which was accepted by the Pricing Committee following consultations with stakeholders.

In Government Gazette number 39046 of 31 July 2015, the Minister of Health, on recommendation of the Pricing Committee, published for comment requesting interested stakeholders to provide proposals on the systematic review of the methodology for the review of the Dispensing Fee for Pharmacists. The review intended to consider Expenditure apportioned to the dispensary within the pharmacy and the revenue apportioned to the dispensary within the pharmacy.

Based on the above publication, interested parties were invited to submit substantiated methodology and data sources for their suggested input. Owing to the very submissions received at the time and subsequent consultations with the stakeholders, the Pricing Committee continues to determine the dispensing fee on an annual basis by adjusting the zero-based with inflation figures as published by Stats SA.

Interested persons are requested to submit comments in writing, both on a compact disc and hard copy, on the proposed regulations within three months of publication of this notice to the

Director-General: National Department of Health (**Attention to the Director: Pharmaceutical Economic Evaluations Directorate, Dr AB Xuma Building, Office C6-18A, 1112 Voortrekker Rd, Pretoria Townlands 351-JR, Pretoria, 0187**)

SCHEDULE

Definitions

1. In these regulations any word or expression to which a meaning has been assigned in the Act shall have such meaning and, unless the context indicates otherwise-

“dispense” means the supply of medicines based on a prescription to a patient or someone on behalf of the patient by a health professional authorized by law to supply medicines and includes-

- (a) the interpretation and evaluation of the prescription;
- (b) the selection, reconstitution, dilution, labelling, recording and the actual supply of the medicine;
- (c) the provision of information and instructions to ensure safe and effective use of a medicine by a patient; or
- (d) the provision of information as contemplated in section 22F (1) (a) of the Act.

“dispensing fee” means a fee determined in terms of these regulations, exclusive of Value Added Tax, that may be charged to dispense a medicine; and

“the Regulations” means the Regulations Relating to the Transparent Pricing System for Medicines and Scheduled Substances published under government Notice No. R1102 of November 2005 as amended.

Amendment of Regulation 10

2. The following regulation is hereby substituted for regulation 10 of the regulations:

- “10. (1) The appropriate dispensing fee, exclusive of VAT, as contemplated in section 22G of the Act to be charged by pharmacists, must:
- (a) Where the single exit price of a medicine or scheduled substance is less than one hundred and twenty-eight rand eighty-four cents (R128.84), the dispensing fee shall not exceed R17.77 plus 46% of the single exit price in respect of that medicine or scheduled substance;
 - (b) where the single exit price of a medicine or scheduled substance is greater than or equal to one hundred and twenty-eight rand and eighty-four cents (R128.84) but less than three hundred and forty-three rand fifty-five cents (R343.55), the dispensing fee shall not exceed R32.97 plus 33% of the single exit price in respect of that medicine or scheduled substance;
 - (c) where the single exit price of a medicine or scheduled substance is greater than or equal to three hundred and forty-three rand fifty-five cents (R343.55) but less than one thousand two hundred and forty rand thirty-two cents (R1240.32), the dispensing fee shall not exceed R94.19 plus 15% of the Single Exit Price in respect of that medicine or scheduled substance;
 - (d) where the single exit price of a medicine or scheduled substance is greater than or equal to one thousand two hundred and forty rand thirty-three cents (R1240.33), the dispensing fee shall not exceed R218.28 plus 5% of the Single Exit Price in respect of that medicine or scheduled substance.
- (2) The provisions of regulation 10 must be reviewed annually by the Minister after taking into account-
- (a) the need to ensure the availability and affordability of quality medicines and scheduled substances in the Republic;

- (b) annual inflation rates published periodically by Statistics South Africa;
 - (c) information supplied by pharmacists in accordance with guidelines determined by the Minister from time to time by Notice in the Gazette; and
 - (d) any other information the Minister may deem necessary to consider.
- (3) A pharmacist dispensing a medicine must-
- (a) by means of a clearly displayed notice in the pharmacy, inform members of the public of the maximum fee structure used by such pharmacist to determine the dispensing fee; and
 - (b) provide an invoice in respect of the sale of each medicine that clearly indicates the-
 - (i) dispensing fee charged; and
 - (ii) the single exit price.



DR MJ PHAAHLA, MP
MINISTER OF HEALTH

DATE: 21/10/2022