No. 53729 37

DEPARTMENT OF HEALTH

NO. 6879 28 November 2025

MEDICINES AND RELATED SUBSTANCES ACT, (101 OF 1965 AS AMENDED)

REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR MEDICINES AND SCHEDULED SUBSTANCES: 2026 DRAFT DISPENSING FEE FOR PHARMACISTS

The Minister of Health, on the recommendation of the Pricing Committee and in terms of Section 22G(2)(b) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965, as amended), hereby intends to amend Regulation 10, as set out in the Schedule below, to provide for the timeous publication of the appropriate dispensing fees to be charged by pharmacist.

The Minister intends to recalibrate the timelines for the publication of the dispensing fees to align with actual market determinants of the fees and with stakeholder requests that such fees be published at the beginning of each calendar year. Accordingly, the draft fee for 2026 will be based on the prevailing dispensing fees published by Notice in Government Gazette No. 53426, dated 26 September 2025, as reflected in the Schedule below. In accordance with regulation 10 of the Transparent Pricing Regulations, the period January 2025 to December 2025 will be considered in determining the key inflationary inputs for recalibrating the dispensing fee for 2026.

Interested persons are invited to submit written comments on the proposed regulations within three months of the date of publication of this Notice. Submissions must be made both electronically and in hard copy, and delivered to:

The Director-General: National Department of Health (Attention to the Director: Pharmaceutical Economic Evaluations Directorate, Dr AB Xuma Building, Office D-16A, 1112 Voortrekker Rd, Pretoria Townlands 351-JR, Pretoria, 0187)); e-mail: SEPUpdates@health.gov.za and Ntobeko.Mpanza@health.gov.za.

SCHEDULE

Definitions

- In this schedule, "the Act" means the Medicines and Related Substances Act, 1965 (Act
 No. 101 of 1965) and any word or expression to which a meaning has been assigned in
 the Act shall have such meaning, 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; and
 - (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;
 - "the Regulations" means the Regulations Relating to the Transparent Pricing System for Medicine and Scheduled Substances published in terms of 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 as contemplated in Section 22G (2) (b) of the Act to be charged by a pharmacist, must be calculated as follows:

- (a) where the single exit price of a medicine or scheduled substance is less than or equal to one hundred and fifty-nine rand and one cent (R159.01), the dispensing fee shall not exceed R23.13 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 fifty-nine rand and two cents (R159.02), but less than or equal to four hundred and twenty-three rand and fifty-five cents (R423.55), the dispensing fee shall not exceed R42.91 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 four hundred and twenty-three rand and fifty-six cents (R423.56), but less than or equal to one thousand five hundred and thirty rand and seventy-two cents (R1530.72), the dispensing fee shall not exceed R122.59 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 five hundred and thirty rand and seventy-three cents (R1530.73), the dispensing fee shall not exceed R270.54 plus 5% of the Single Exit Price in respect of that medicine or scheduled substance.

This fee which is exclusive of VAT represents a maximum dispensing fee and doesn't preclude dispensers from charging a lower fee to be added to the SEP of a medicine or scheduled substance thus resulting in a final price to be paid by the consumer.

- (2) The provision of sub-regulation (1) 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.
 - (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 each medicine which clearly indicates the-
 - (i) dispensing fee charged; and
 - (ii) the single exit price.
 - (iii) VAT component

DR FAINOTSOALEDI, MP

MINISTER OF HEALTH

DATE