

DEPARTMENT OF HEALTH

NO. 1618

17 December 2021

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)**

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.

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.

Interested persons were invited to submit substantiated proposed methodology and data sources for their suggested input. Few submissions were received and the Pricing Committee continued with inflating the Zero Based Model.

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, Room 2611, South Tower Civitas Building, Corner: Thabo Sehume & Bloed Streets Pretoria, 0001**) ; e-mail: sepupdates@health.gov.za or Ntobeko.Mpanza@health.gov.za

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.

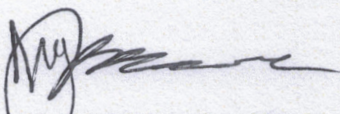
Amendment of Regulation 10

- 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-one rand and fifty-five cents (R121.55), the dispensing fee shall not exceed R16.76 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-one rand and fifty-six cents (R121.56) but less than three hundred and twenty-two rand and eighty-six cents (R322.86), the dispensing fee shall not exceed R31.10 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 twenty-two rand and eighty-seven cents (R322.87) but less than one thousand one hundred and thirty-four rand and forty-seven cents (R1134.47), the dispensing fee shall not exceed R88.86 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 one hundred and thirty-four rand and forty-eight cents (R1134.48), the dispensing fee shall not exceed R206.82 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) Not less than three months before the review contemplated in regulation 10, the Minister must publish a notice in the Gazette declaring his or her intention to make that review and inviting interested persons to furnish him or her in writing with any comments thereon or any representation they may wish to make in regard thereto.
- (4) A pharmacist's 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.
 - iii VAT component



DR MJ PHAAHLA MP

MINISTER OF HEALTH

DATE: 19/10/2021