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GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 476

13 June 2014

MEDICINES AND RELATED SUBSTANCES ACT, 1965

REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR MEDICINES AND SCHEDULED SUBSTANCES: AMENDMENT

(DRAFT DISPENSING FEE FOR PHARMACISTS)

The Minister of Health, on recommendation of the Pricing Committee, in terms of section 22G (2) (b) of the Medicine and Related Substances Act, 1965 (Act No. 101 of 1965), intends to amend the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances, 2013.

Interested persons are requested to submit comments on the proposed regulations within 3 months of publication of this notice to the Director-General: Health (**Attention to the Director: Pharmaceutical Economic Evaluations**): Room S 2610, South Tower, Civitas Building, Corner Andries and Bloed Streets, Pretoria

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, labeling, 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 as contemplated in section 22G (2) (b) of the Act to be charged by pharmacist must be calculated as follows:

- (a) where the single exit price of a medicine or scheduled substance is less than eighty five rand and seventy cents, the dispensing fee shall not exceed R6.95 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 eighty five rand and seventy cents but less than two hundred and twenty eight rands and fifty three cents, the dispensing fee shall not exceed R18.55 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 two hundred and twenty eight rand fifty three cents but less than seven hundred and ninety nine rands and eighty five cents, the dispensing fee shall not exceed R59 plus 15 % of the Single Exit Price in respect of that medicine or scheduled substance; and
- (d) where the single exit price of a medicine or scheduled substance is greater than or equal to seven hundred and ninety nine rands and eighty five cents, the dispensing fee shall not exceed R140.00 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 to be added to the SEP of a medicine or scheduled substance thus resulting in a final price to be paid by the consumer. It does not preclude pharmacists from charging a lower dispensing fee.


(2) The provisions 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; 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 using the pharmacy of the maximum fee structure used by such pharmacist to determine the dispensing fee; and
- (b) provide an invoice that in respect of each medicine clearly indicates the-
- (i) dispensing fee charged; and
 - (ii) the single exit price;



DR A MOTSOLEDI, MP
MINISTER OF HEALTH

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