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GOVERNMENT NOTICE

NATIONAL DEPARTMENT OF HEALTH

No. R. 1053 **6 November 2009**

MEDICINES AND RELATED SUBSTANCES ACT, 1965

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

DISPENSING FEE FOR PHARMACISTS: AMENDMENT

The Minister of Health, on recommendation of the Pricing Committee intends, in terms of section 22G(2) (b) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), to make the regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations in writing on the proposed regulations within one month of publication of this notice to the Minister of Health (for the attention of the Chief Director: Financial Planning and Health Economics, Private Bag X828, Pretoria, 0001).

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" in relation to a dispensing fee means:
(a) the application by a health professional, authorised by law to dispense medicines, of his or her mind, in the context of the sale of a particular medicine to an identifiable user, to –

(i) the legality of such sale;
(ii) the evaluation of a written prescription if any;
(iii) the appropriate dosage of that medicine for that user;
(iv) safety issues for that user regarding the use of that medicine;
(v) the pharmaceutical and pharmacological incompatibilities of that medicine with any other medicine being taken by the user;
(vi) possible allergies of the user to that medicine
(vii) possible medicine interactions

(viii) the optimal use and duration of the use of that medicine with regard to a particular health condition of that user; and

(b) the preparation of a particular medicine for an identifiable user including the reconstitution of a medicine in a non-sterile environment, picking, packaging and labelling of the medicine, checking of expiry dates of the medicine, and keeping of appropriate dispensing records as required by law; and

(c) the handing of a particular medicine to an identifiable user or such user's caregiver with advice or instructions as to its safe and effective use or administration, or the provision of a patient information leaflet or other written material on the safety or efficacy of the medicine, but excludes the manufacturing, manipulation or compounding of a medicine;

"dispensing fee" means the maximum fee, exclusive of VAT, 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 11 November 2005.

Amendment of Regulation 10

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

"10. The appropriate dispensing fee as contemplated in section 22G(2)(b) 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 rand, the dispensing fee shall not exceed R6.00 plus 36% 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 rand but less than two hundred and fifty rand, the dispensing fee shall not exceed R32.00 plus 10% 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 fifty rand but less than one thousand rand, the dispensing fee shall not exceed R45.00 plus 5% 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 one thousand rand, the dispensing fee shall not exceed R65.00 plus 3% of the single exit price in respect of that medicine or Scheduled substance.

Insertion of regulation 10A

3. The following regulation is hereby inserted after regulation 10 of the regulations:

"10A Exemption

(1) In the event that the dispensing fee contemplated in regulation 10 would result in a pharmacy becoming financially unviable, the owner of such pharmacy may apply to the Minister for an exemption from such dispensing fee.

(2) The application contemplated in subregulation (1) must be made within six weeks of the publication of the dispensing fee or any time thereafter on justifiable cause shown why the application was not made within six weeks.

(3) The application contemplated in subregulations (1) and (2) must be accompanied by the following information:

(a) audited financial statements (income and expenditure statements and balance sheets);
(b) number medicines dispensed in the pharmacy and the single exit price for such medicines;
(c) structure of the dispensary relative to the pharmacy size;
(d) the turnover of the pharmacy;
(e) the location of the pharmacy in relation to other pharmacies in the area;
(f) the services that are offered by the pharmacy; and
(g) any other information that may be considered necessary by the Minister and such information must be provided within the time frame requested.

(4) During the time when an application is being considered, the pharmacy in respect of which the application is made must continue to charge the dispensing fee contemplated in regulation 10.

(5) The Minister shall, after receipt of a complete application, refer such application to the Pricing Committee for a recommendation. In making a recommendation, the Pricing Committee shall take the following into account:

(a) the financial viability of the pharmacy after taking account of the potential for efficiency gains;

(b) access and affordability to pharmaceutical services for the community being serviced by the pharmacy; and

(c) any other factor that may affect access to pharmaceutical services.

(6) The Minister may, on the recommendation of the Pricing Committee, within three months of the date of receipt of an application for an exemption, grant or refuse such exemption.

(7) In an instance where an exemption is granted, the Minister shall by notice in the Gazette, publish-

(i) the name, registration number and location of the pharmacy; and
(ii) the dispensing fee that such a pharmacy may charge.

(8) An exemption contemplated in subregulation (7) is valid for a period of one year and may be renewed upon application. The renewal application must contain the information referred to in subregulation (3).

(9) A pharmacy that has been granted an exemption must by means of a notice displayed clearly in the dispensary inform patients that the pharmacy charges higher dispensing fees compared to other pharmacies.

(10)The notice contemplated in subregulation (9) must-

(a) be clearly visible to patients that require a dispensing service;
(b) be printed in bold and not less than 20 point font with the following words:

"This pharmacy levies a higher dispensing fee than other pharmacies and has the following fee structure:

R SEP	Dispensing fees
.....	.....
-R	R + %

The above fee structure has been approved by the Department of Health until ....."

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
28/10/2009